European Communities – Measures Affecting the Approval and Marketing of Biotech Products

(DS291, DS292, DS293)

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ACRE	UK Government's Advisory Committee on Releases to the Environment
ACT	Australian Capital Territory
AIA procedure	Advance Informed Agreement procedure
ASEAN	Association of South East Asian Nations
BINAS	Biosafety Information Network and Advisory Service
Bt	Bacillus thuringiensis
CA	Competent authority
CTFBT	Codex Alimentarius Commission established an Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology
Directive 2001/18	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
Directive 90/220	Council Directive 90/220/EEC of 23 April 1990 on the deliberate release of genetically modified organisms
DNA	Deoxyribonucleic Acid
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EPA	United States Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSE	Crops and Farm Scale Evaluations
GATT 1994	General Agreement on Tariffs and Trade 1994
GEF	Global Environment Facility
GILSP	Good industrial large-scale practice
GM foods	Food products containing, consisting or produced from GMOs
GM products	Genetically modified products
GMHT	Genetically Modified Herbicide Tolerant
GMOs	Genetically modified organisms
IANB	UN Inter-Agency Network for Safety in Biotechnology
ICPM	Interim Commission on Phytosanitary Measures
IOE	The International Office of Epizootics
IPPC	International Plant Protection Convention
LMOs	Living modified organisms
LMO-FFPs	Living modified organism intended for direct use as food or feed, or for processing
NAS	United States National Academy of Science
OECD	Organisation for Economic Cooperation and Development
Regulation 258/97	Regulation (EC) N° 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods

	and novel food ingredients
SCP	Scientific Committee on Plants
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
UNEP	United Nations Environmental Programme
UNIDO	The United Nations Industrial Development Organisation
WHO	World Health Organisation

TABLE OF CASES CITED IN THIS SUBMISSION

Short Title	Full Case Title and Citation
Australia – Salmon	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
Argentina - Poultry	Panel Report, *Argentina - Definitive Anti-Dumping Duties on Poultry from Brazil*, WT/DS241/R, adopted 22.04.2003
Brazil – Desiccated Coconut	Appellate Body Report, *Brazil – Measures Affecting Desiccated Coconut*, WT/DS22/AB/R, adopted 20 March 1997, DSR 1997:I, 167
Canada – Periodicals	Panel Report, *Canada – Certain Measures Concerning Periodicals*, WT/DS31/R and Corr.1, adopted 30 July 1997, as modified by the Appellate Body Report, WT/DS31/AB/R, DSR 1997:I, 481
Canada – Periodicals	Appellate Body Report, *Canada – Certain Measures Concerning Periodicals*, WT/DS31/AB/R, adopted 30 July 1997, DSR 1997:I, 449
Canada - Wheat and Grain	Panel Report, *Canada - Measures Relating to Exports of Wheat and Treatment of Imported Grain*, adopted 06.04.2004
Chile – Price Band System	Appellate Body Report, *Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products*, WT/DS207/AB/R, adopted 23 October 2002
EC – Asbestos	Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001
EC – Bananas III	Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591
EC – Hormones	Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
EC – Sardines	Appellate Body Report, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, adopted 23 October 2002
Japan – Apples	Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003
Japan – Film	Panel Report, *Japan – Measures Affecting Consumer Photographic Film and Paper*, WT/DS44/R, adopted 22 April 1998, DSR 1998:IV, 1179
Japan – Semi-Conductors	Panel Report, *Japan – Trade in Semi-Conductors*, adopted 4 May 1988, BISD 35S/116
Korea – Alcoholic Beverages	Panel Report, *Korea – Taxes on Alcoholic Beverages*, WT/DS75/R, WT/DS84/R, adopted 17 February 1999, as modified by the Appellate Body Report, WT/DS75/AB/R, WT/DS84/AB/R, DSR 1999:I, 44
Korea – Dairy	Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R, adopted 12 January 2000, DSR 2000:I, 3
Korea – Various Measures on Beef	Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R, adopted 10 January 2001

Short Title	Full Case Title and Citation
Mexico – Corn Syrup (Article 21.5 – US)	Panel Report, *Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States – Recourse to Article 21.5 of the DSU by the United States*, WT/DS132/RW, adopted 21 November 2001, as upheld by the Appellate Body Report, WT/DS132/AB/RW
US – Corrosion-Resistant Steel Sunset Review	Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/AB/R, adopted 9 January 2004.
US – Export Restraints	Panel Report, *United States – Measures Treating Exports Restraints as Subsidies*, WT/DS194/R and Corr.2, adopted 23 August 2001
US – Gasoline	Panel Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R, adopted 20 May 1996, as modified by the Appellate Body Report, WT/DS2/AB/R, DSR 1996:I, 29
US – Gasoline	Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, DSR 1996:I, 3
US – Section 301 Trade Act	Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, adopted 27 January 2000, DSR 2000:II, 815
US – Shrimp	Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
US – Softwood Lumber III	Panel Report, *United States – Preliminary Determinations with Respect to Certain Softwood Lumber from Canada*, WT/DS236/R, adopted 1 November 2002
US – Steel Plate	Panel Report, *United States – Anti-Dumping and Countervailing Measures on Steel Plate from India*, WT/DS206/R and Corr.1, adopted 29 July 2002
US – Wool Shirts and Blouses	Appellate Body Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R and Corr.1, adopted 23 May 1997, DSR 1997:I, 323

I. INTRODUCTION

1. Argentina, Canada and the United States ("the Complainants") have initiated these proceedings to challenge what they allege to be a general "moratorium" in the European Communities concerning the approval of genetically modified organisms ("GMOs") and products derived therefrom ("GM products"), the alleged failure to approve a number of specific applications for the placing on the market of certain GMOs, and certain derogations that exist in the European Communities from the authorisations for GMOs that have already been granted in the European Communities.

2. The European Communities would like to make clear at the outset that it has not adopted any general position either in favour or against GMOs. It recognises the very real potential benefits which such products may bring. It is equally conscious, however, that the technologies which produce GMOs are new and their long-term consequences relatively unknown. The European Communities' regulatory framework has therefore sought to adopt a prudent approach. The European Communities has not sought to impose its approach to GMOs on the Complainants; they are free to form their own view on the balance of benefits and risks. Equally, however, it cannot be right that the Complainants should be allowed to impose their approach on the European Communities, or indeed on any other countries, and to do so through the WTO. Even less so at a time when countries around the world are still trying to clarify the balance between risks and benefits.

3. The cases brought by the United States, Canada and Argentina undeniably raise a number of very complex issues which the Complainants seek to evade or ignore. First of all, the question of GMOs and GM products is politically and socially controversial. The Panel needs no reminding that in many countries both at the political level and in society at large extensive debates have been going on about the advantages and risks of these products. Secondly, the matter is scientifically complex. The effects of GMOs and GM products on human, animal and plant life and health are only beginning to be better known, as is the environmental impact of these products. Thirdly, the matter is factually complex. The European

Communities' legislation has been applied to a large number of applications relating to different GMOs and GM products. Fourthly, the matter is legally complex: it raises difficult questions of interpretation of the different WTO agreements and of the relationship between them. On nearly all these points the Complainants, quite naturally, try to simplify matters. It is the European Communities' contention that they have gone too far in this and that the Panel will have see the matter in its full complexity, before its true simplicity can be properly recognized.

4. As far as the political and social controversies are concerned, it is against that backdrop that the European Communities has reviewed, amended and completed its legislation on GMO and GM products in the period 1998-2001. By 1998 it was apparent that its original regulatory framework did not adequately address all the health and environmental risks which scientists, the authorities of the European Communities and the international Community had come to recognise. In the Spring of that year it proposed amendments to its existing regulatory framework. The European Communities' new regulatory framework was finally put in place in 2001 and became operational at the end of 2002. It represents a very finely calibrated equilibrium between all interests involved. In this connection the European Communities welcomes the fact that the Complainants are not attacking the European Communities' regulatory framework for GMOs but only individual decisions adopted (or not adopted) thereunder. Moreover, there is no claim by the Complainants that the European Communities is discriminating in favour of GM products produced within the European Communities.

5. As far as scientific complexity is concerned, the arguments put forward by the Complainants are simplistic and largely ignore the scientific and regulatory issues which have dominated debate on GMOs over the past five years. They argue, for example, that there is no difference between GMOs and their conventional counterparts, in terms of risks to human health and the environment. The international Community has clearly rejected that view: between 1996 and 2000 a specialised international convention – the Cartagena Protocol on Biosafety ("Biosafety Protocol") - was negotiated, which is premised on a clear understanding that the inherent characteristics of GMOs require them to be subject

to rigorous scrutiny so as to ensure that they do not cause harm to the environment or human health, or cause socio-economic disruptions.

6. Moreover, the Complainants ignore entirely the extensive evidence which demonstrates that some GM crops, in particular herbicide tolerant crops in combination with the herbicides to which they have been made resistant may cause damage to biodiversity. In this respect, they make no mention of the initial results of the world's longest farm-scale trials which were concluded in the Autumn of 2003 (five years after they were initiated).

7. In respect of factual complexity, the Complainants seek to simplify matters beyond recognition by qualifying a large number of individual regulatory steps taken during the application procedures for specific GMOs and GM products as "a moratorium". In this submission the European Communities will provide full factual transparency on all the different procedures that have been applied to individual products under its legislation. In this way it will become clear to the Panel that each GM product has to be considered individually, and that the process of assessment of the risks is complex and legitimately time-consuming, especially at a time when the legislation that is being applied is subject to overhaul.

8. Where legal complexity is concerned, the Complainants prefer that the matter be treated under the *SPS Agreement*, but measures in respect of GMOs and GM food are much too complex to be covered by that WTO agreement alone. These measures seek to protect against risks, in particular environmental risks that are not covered by the *SPS Agreement*. And even with respect to health risks, the European Communities will demonstrate that some risks against which the EC legislation seeks to protect, may not come under the SPS notion of "disease." It will, therefore be necessary to arrive at a much more sophisticated legal analysis than the Complainants have set out.

9. Against this background the claim of a "moratorium" or of undue regulatory delay that seems to be at the heart of the Complainants' case is unacceptable and must be rejected. The underlying science and the evolution of acceptable regulatory solutions – both national and international – were and are still in a state of great

flux. The European Communities' actions in taking all necessary steps demanded by its citizens to protect against risks to human health and the environment were prudent and they were reasonable. The European Communities did not go as far as certain other states (or parts of states) which actually adopted outright bans (albeit sometimes of a temporary nature) on trade in, and cultivation of, GMOs and/or GM products.

10. The Complainants in these proceedings are seeking to use the *WTO Agreement* to short circuit the responsible actions of the European Communities. The European Communities considers that the approach is entirely misconceived: it is not the function of the *WTO Agreement* to allow one group of countries to impose its values on another group. Nor is it the purpose of the *WTO Agreement* to trump the other relevant rules of international law which permit – or even require – a prudent and precautionary approach. There is a serious question as to whether the WTO is the appropriate international forum for resolving all the GMO issues that the Complainants have raised in these cases. The European Communities can only regret that the Complainants have chosen to start a dispute settlement procedure based on flawed premises, rather than to promote international co-operation as a means to build a sound international framework for addressing the GMO issue.

11. For the convenience of the Panel the European Communities is submitting a single and composite first written submission in response to the three complaints, even though the claims of the Complainants differ. In the short time which has been available since the filing of the Complainants' first written submissions, it has not been possible to deal with all the factual, and especially not all the legal issues, that arise. The European Communities has therefore concentrated on trying to correct the most serious of the distortions inherent in the Complainants' presentation of the facts and to highlight the fundamental legal errors on which their cases are constructed. A full refutation of the Complainants' first written submission will have to remain reserved for the rebuttal submission, by which time the European Communities hopes that the Complainants will have clarified the nature of their complaints and the claims that they are making. For the avoidance of doubt the European Communities should not be considered to have accepted any factual or

legal submissions by the Complainants which are not here specifically addressed. Nor should the fact that the European Communities responds to the submissions of the Complainants globally be taken as an acceptance that anyone of them may make or develop claims that it has not itself made or developed in its panel request and first written submission.

12. As already mentioned, these cases raise complex issues, which cannot easily be summarised. However, it may be useful to indicate that the European Communities' overall approach in its first written submission is based upon the following principles:

- the GMOs which are the subject of these proceedings each have characteristics which are recognised by the international Community to pose potential threats to human health and the environment, and they cannot be treated as "like" or "equivalent to" their non-GMO counterparts ;

- in addressing the potential risks for each of these GMOs the Community regulatory framework has operated on a case-by-case basis, and there has been no formal (*de jure*) or informal (*de facto*) moratorium in respect of the authorisation process or any part of it;

- the approach of the European Communities to the identification, assessment and prevention of risks to human health and the environment from each of these GMOs has been fully consistent with evolving and applicable international standards, and any finding to the contrary would seriously undermine the effectiveness of those standards, which are premised on the application of a prudent and precautionary approach;

- it is of fundamental importance that the nature of the action or alleged inaction of the European Communities in respect of each of the GMOs be correctly understood. The WTO agreements contain different provisions relating to different kinds of measures and it is not admissible to re-designate them artificially to allow for the application of provisions that the Complainants find more convenient but which are not in reality applicable;

- in particular, in respect of each of the GMOs the steps which have been taken to protect the environment and to conserve biodiversity are reasonable and legitimate, are not necessarily sanitary or phytosanitary in character, and fall in whole or in part outside the scope of the *SPS Agreement*;

- to the extent that any steps taken to protect against risks to human, animal or plant life or health in respect of each of the GMOs could be

said to be subject to the *SPS Agreement*, there has been no undue delay or breach of any part of that Agreement on the part of the European Communities or any Member States, and in any event such steps are provisionally justified on the basis of the insufficiency of scientific evidence;

- all steps taken by the European Communities and its Member States in respect of each of the GMOs are consistent with the *TBT Agreement* and GATT 1994, and in any event are justified in accordance with Article XX of GATT 1994.

II. FACTUAL PART

13. This Chapter describes the factual background and context to these proceedings. The facts are complex but of great importance, since GMOs are the product of new technologies whose effects are, for the most part, not fully understood, and which have been the subject of intense debate between governments and amongst members of the public. The European Communities notes that the Complainants have downplayed these aspects, and present the issues raised in these proceedings in a narrow and simplistic fashion. The proper treatment of the legal issues concerning the authorisation of GMOs requires a complete understanding of the facts. This Chapter addresses the facts in four parts. It begins by addressing the scientific background on GMOs, including the health and environmental concerns which have been identified to date in relation to the production and consumption of GMOs (Section A). It then moves on to look at the international regulatory context, including international instruments adopted at the regional and global levels and measures adopted by other states restricting or prohibiting the production and consumption of GMOs (Section B), and to describe the regulatory approach adopted by the European Community (Section C). Against this background it then concludes by giving a detailed description of each of the forty-three individual product applications as well as of the national safeguard measures called into question by the Complainants (Section D).

14. The Chapter demonstrates in general terms that certain GMOs may present potential threats to human health and the environment. In some cases actual harm to the environment through the use of certain GMOs has already been established

(for example in the case of the United Kingdom Field Trials, which were concluded in September 2003). In all other cases the existence of a potential threat justifies the assessment of risks on a case-by-case basis and, eventually, a precautionary approach.

15. The Chapter also establishes that the international Community accepts that GMOs are not to be treated as being the same as their non-GMO, conventional equivalents, and that special measures of protection, based on the precautionary principle, are justified. This is reflected in a number of international conventions and other instruments, most notably the 1992 Convention on Biological Diversity and its Biosafety Protocol. It is also reflected in measures adopted by many countries around the globe, which indicate that a large number of countries have gone beyond the European Communities by adopting a total and indefinite ban on the import of GMOs, and that other countries have adopted bans for the period to which these proceedings relate. These international and national measures are important because they demonstrate the inherent reasonableness of the approach taken by the European Communities' legal and regulatory framework, as well as its application on a case-by-case basis.

16. Finally, this Chapter also indicates that national and international measures recognise the novelty of the risks posed by GMOs and the extent of the uncertainty, as well as the fact that the timetables for preparing and acting upon assessment, and the constant need to re-assess the science, necessarily mean that decision-making is likely to take place over extended periods of time. The history of the individual cases of applications under the EC GMO legislation, which this Chapter describes, proves the point. For a reasonable and prudent government there can be no quick-fixes on the issues associated with the protection of human health and the environment arising from GMOs.

A. Scientific Background

1. Definition

17. A genetically modified organism (GMO) is an organism[1] in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.[2] GMOs are also referred to as "living modified organisms" (LMOs),[3] "genetically engineered organisms,"[4] or "transgenic organisms." In substance, however, all these terms refer to the same or similar processes. For the purposes of this case the Complainants have chosen the expression "biotech products." The European Communities considers that this term is misleading since biotechnology covers techniques and practices other than genetic modification.[5] The European Communities will use the term GMOs.

18. The alteration to genetic material which leads to the production of a GMO usually consists of the insertion of foreign genes into the cells of the receiving organism. Genes are pieces or lengths of DNA (*Deoxyribonucleic Acid*) in the cell containing genetic information that encodes proteins. DNA consists of two complementary strands of nucleotides arranged in a double helix structure. The sequence of the nucleotides (of which there are four)[6] and their sequential combination in the double helix structure determines the proteins that the cell will produce. Proteins are the basic "building blocks" of any organism, and they determine the organism's physical characteristics and development. A particular sequence of nucleotides leading to the creation of a particular protein is the piece of DNA that constitutes a gene. The whole of an organism's genetic material is called a "genome."

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1 Organism means any biological entity capable of replication or of transferring genetic material. A tomato plant, for example, is an organism, but so is the tomato itself. Also bacteria are organisms.

2 See also Article 2(2) of Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220, JO L 106, p. 1, (Exhibit US-24)

3 See also Article 3 (g) of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity done in Montreal 29 January 2000, available at: http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf (visited 12 May 2004) (Exhibit EC-1).

4 See also 7 CFR 340.1 (Exhibit EC-2)

5 See the definition in the *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 231: "Orig., the branch of technology that dealt with the actions and requirements of human beings. Now, the industrial application of biological processes."

6 DNA is a polymer made up of repeated units, *nucleotides*, comprising three components: a *sugar* (2'-deoxyribose), *phosphate* and one of four nitrogen-containing purine or pyrimidine heretocyclic *bases*; adenine (A), thymine (T), guanine (G), cytosine (C). Together, the nucleotides form triplets (codons), which eventually give rise to amino acids, the component molecules of proteins.

19. When foreign genes are inserted (or certain genes from the DNA are deleted or silenced) the cell may produce a different set of proteins. This may lead to changed characteristics in the plant or fruit. In plants, for example, a flower may be given a different colour; a potato may have a different starch content; and other parts of a plant may be endowed with the ability to generate a new toxin that kills only certain insects.

20. Certain changes in physical characteristics (phenotypes) can also be obtained through conventional breeding methods where desired traits, or agronomic characteristics (natural or induced mutations), are selected and used intensively in traditional intra-specific crossing programmes. The difference between genetic modification and conventional breeding practices is that the latter do not allow for the crossing of natural species barriers, or for the transfer of single or few genes instead of whole genomes. This is a qualitative difference, which is recognised in the Biosafety Protocol (see above). Canada is therefore wrong to assert, as it does in these proceedings, that "the nature of the risks associated with biotech products is similar to the nature of the risks associated with conventionally bred plants",[7] or that the GM products which are the subject of its complaint are, apart from minor genetic differences, "otherwise physically indistinguishable from domestically-grown non-biotech" products.[8] The approach taken by Canada in this case is inconsistent with the reality of science and with the Biosafety Protocol, which it has signed.

2. Techniques of genetic modification

21. There are a number of different methods and technologies for the introduction of foreign DNA into plants, a process commonly referred to as plant genetic transformation (foreign DNA may also be introduced into animals and fish, such as salmon, but the technologies are not here addressed as no such GMO is at issue in these proceedings). In practice three techniques are typically used to insert foreign DNA into a plant genome.

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7 First Written Submission of Canada, para. 25.

8 Ibid, para. 306.

22. The first technique is to use a bacterium, *Agrobacterium tumefaciens*, as an intermediate delivery mechanism. In nature, *Agrobacterium tumefaciens* colonises a wide range of plant hosts, transferring a piece of its own DNA (its "tumour inducing plasmid", or "Ti plasmid")[9] into the host plant cells. This piece of DNA is then incorporated into the host's genome and, using the host's molecular and wider cellular processes, causes the plant to produce sugars of nutritional value for the bacterium. The consequences of these events are commonly observed in nature as swellings, or galls, on host plants. Scientists have harnessed this naturally occurring system for the purpose of plant genetic modification. The foreign DNA of interest is first inserted into the bacterium's Ti plasmid DNA, using established DNA recombinant techniques.[10] As a consequence, the foreign DNA becomes part of the bacterium's Ti plasmid DNA. While transferring a piece of its own DNA into the host organism, the bacterium also transfers the (formerly) foreign DNA of interest. This process is commonly referred to as "Ti plasmid-mediated gene transfer".[11]

23. The second technique is to insert DNA into a plant protoplast through micro-injection, or with the help of electroporation or chemical treatment. A protoplast is a plant cell without a cell wall. The cell wall has been chemically removed, exposing the cell membrane. The foreign gene to be inserted into the target cell (protoplast) is located on a plasmid vector, which serves as a delivery vehicle. The plasmid vector carrying the foreign DNA of interest is also produced using accepted DNA recombinant techniques. The resultant circular molecule, consisting of the plasmid and inserted DNA of interest is sometimes referred to as a recombinant vector. The recombinant vector containing the foreign DNA is

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9 Plasmids are autonomously replicating extra-chromosomal circular DNA molecules, distinct from the normal bacterial genome and nonessential for cell survival under non-selective conditions. A number of bacterially derived and artificially constructed plasmids are used as cloning vectors and, as many are capable of integrating into the host genome, are employed as transformation vectors in the genetic modification of organisms.

10 DNA recombinant technology allows for the *in vitro* construction, or recombination, of biologically active DNA molecules from different taxonomic sources by enzymatically joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.

11 This method only applies to so-called dicotyledon (or dicot), but not to monocotyledon (or monocot) plants. The kingdom of plants is divided into two classes: dicots and monocots. A dicot is a plant with two primary seed leaves. Monocots are plants with one single primary seed leaf. For example, maize, wheat, barley, and oat are monocots; rape, potato, beet, and soy are dicots.

inserted into the protoplast. This is done by micro-injection, electroporation or chemical treatment.

24. The third technique to insert DNA into a plant's cell is achieved by mechanical means, by high velocity ballistic delivery, or microprojectile bombardment, directed to the plant cells. Recombinant plasmid molecules containing the foreign gene of interest are coated onto the surface of paramagnetic or gold micro-beads. The coated beads are subsequently shot, at high velocity, into the target cells. As the beads pass through the cells the recombinant vector molecules coating the beads are dislodged and pass to the nucleus where the cell's genome resides.

25. There is a further technique which is relatively novel and not yet widely used. This involves the use of a modified plant virus to transfer the DNA of interest. Deleterious viral genes are removed and the gene of interest inserted. The growing plant is inoculated with the recombinant virus, which then starts to express the novel gene product throughout the plant.

26. It is essentially important to note that none of these methods are actually able to precisely control where the foreign gene will insert into the recipient cell's genome, or whether that insertion will be stable. This is one reason why some consider the process of genetic modification may have potentially adverse consequences for human health and the environment.

27. Once single plant cells are modified they are grown in *in vitro* tissue culture, until such time as the entire plants can be regenerated carrying the modified genetic information. The surviving transformants from a single transformation experiment must be screened for the desired trait (i.e. the desired phenotypic characteristic) according to a number of selection criteria, including copy number, phenotypic expression, and genomic stability. The transferred piece of foreign DNA at the specific location where it has successfully been inserted into the host genome, is commonly referred to as a "transformation event."

28. The recombinant genome remains intact in the living organism as natural unmodified genomes would. Although subject to different levels of degradation, DNA (modified or not) may also continue to exist once the organism has been

processed, for example, into food. A genetically modified tomato and the ketchup made from these tomatoes may contain modified DNA or novel proteins (i.e. proteins which are not present in conventional tomatoes). Oil made of rapeseed, on the other hand, normally does not contain DNA or proteins because of the way it has been processed.

3. Types of GMOs and potential benefits

29. Research on GMOs began in the 1970s.[12] The technology indicated the possibility of providing significant benefits, such as increased agricultural output, added nutritional value to foods, and certain environmental benefits such as reductions in the use of pesticides. The European Communities recognises these potential benefits, and subscribes to the approach taken in the preamble to the Biosafety Protocol, which states that "modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health".

30. The first GMO was created in 1973, but the first GMO plant was not produced until 1983.[13] Since then research on GMOs has progressed in distinct generational steps. Genetic modification initially focused on the creation of insect-pest resistant crops for the minimisation of crop losses and maximisation of yield. To date, all insect-pest resistant plants express genes derived from the common soil bacterium *Bacillus thuringiensis* (Bt). Bt produces an insecticidal protein which becomes toxic to the target insect when it ingests the protein. The Bt gene, which produces the insecticidal protein, is inserted into the plant's DNA. In this way the plant itself is able to produce the protein.

31. Another example of a 'first generation' GMO is herbicide-tolerant crops. Herbicide tolerant crops were developed to resist non-selective broad-spectrum herbicides,

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12 Cohen, S. N., A. C. Y. Chang, H. W. Boyer, and R. B. Helling, "Construction of Biologically Functional Bacterial Plasmids in Vitro.", 70 Proceedings of the National Academy of Sciences, 3240 (1973) (Exhibit EC-3).

13 Framond, A.J., M.W. Bevan, K.A. Barton, F. Flavell, and M.D. Chilton, "Mini-Ti plasmid and a chimeric gene construct: new approaches to plant gene vector construction" in "Advances in Gene

including glyphosate and glufosinate. These herbicides work by inhibiting amino acid synthesis in plants. The resistance against these herbicides comes from genes which were also isolated from soil micro-organisms.

32. Research now extends to the development of stacked gene events where two or more genes of interest are introduced into the same genome. This is achieved through co-transformation[14] or the hybridization (i.e. crossing) of two GM varieties each expressing one of the particular GM characteristics. To date such stacked events have been created mainly by combining herbicide tolerant and insecticidal traits.

33. Following the initial yield-focused aim of genetic modification, refined genetic modification techniques subsequently focused on providing new value-enhancing traits. Genetic modification has developed beyond on-farm benefits (offering the potential ability to change the agronomic characteristics of a product) to the improvement of nutrient content, flavour, processing and post-harvest storage characteristics. Examples include high oleic acid soybeans that contain less saturated fat than conventional soybean oil; high sucrose soybeans that improve food quality (taste and digestibility); and potatoes resistant to browning. These are "second generation" GM crops.

34. GM development may also permit the transformation of production systems. A new generation of GMOs may be used for industrial or medical purposes (phytofarming) to replace or enhance existing production systems. Examples include biologically based plasticisers and lubricants, pharmaceuticals (e.g. the production of vaccines in crops), and so-called 'functional foods' (where food crops contain micronutrients capable of reducing some of the risk factors for diseases). An example of such a development is a strain of rice modified to

Technology: Molecular Genetics of Plants and Animals. Miami Winter Symposia" Vol. 20:159-170 (1983) (Exhibit EC-4).

[14] Co-transformation: where two or more pieces of exogenous DNA recombinant constructs are used in one single transformation experiment.

produce pro-vitamin A, which might assist in reducing the incidence of blindness in developing countries[15], and canola oil with high beta carotene content.

35. In terms of volume, the first generation GMOs remain the most common. Herbicide tolerant crops account for some 73% of commercially planted area worldwide, followed by insect resistance (18%), and stacked genes (i.e. both herbicide tolerant and insect resistant) 8%. Virus resistant and quality traits amount to less than 1% of GM crops grown worldwide.[16]

4. Possible harmful effects on human health and the environment

36. GMO research and development is an ever evolving science. To begin with, the very process of creating GMOs is still surrounded by uncertainties. Despite advances, it has already been mentioned that the various techniques of inserting foreign DNA do not control where the insertion takes place, the number of copies inserted or their level of expression, nor do they guarantee that the foreign gene is stably integrated by the host genome.

37. As mentioned above, DNA contains sequences of nucleotides that are responsible for the production of individual proteins. The insertion of foreign DNA in an undesirable genomic location may alter (lead to over expression) or silence certain protein production processes. Further undesirable, or unintended, effects may occur in the process of creating a GMO: there may be too much foreign or unwanted extraneous DNA [17] unintentionally inserted, multiple rearranged integration events may occur, or the foreign DNA may have been contaminated

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15 Burkhardt P.K., P. Beyer, J. Wünn, A. Klöti, G. Armstrong, M. Schledz, J. von Lintig and I. Potrykus, "Transgenic rice (*Oryza sativa*) endosperm expressing daffodil (*Narcissus pseudonarcissus*) phytoene synthase accumulates phytoene, a key intermediate of provitamin A biosynthesis", 11 The Plant Journal 1071 (1997) (Exhibit EC-5).

16 International Service for the Acquisition of Agri-Biotech Applications "Global status of commercialised transgenic crops: 2003", 30 ISAAA briefs (2003) (Exhibit EC-6).

17 The number and location of copies of the inserted foreign DNA introduced into the genome generally cannot be controlled during the insertion process. In addition, when DNA is shot into the plant cells, *via* the ballistic projectile delivery system, extra-cellular DNA components, such as mitochondrial or chloroplast DNA, may be picked up *en route* to the plant nucleus and be co-transferred into the host genome. Further, re-arrangement(s) of the transforming vector plasmid, and gene of interest (including partial sequences), may also occur and be randomly dispersed across the host genome with this approach.

during laboratory manipulations. Such situations may lead to metabolic disruptions of existing pathways or over expression of inserted genes which may have a harmful effect.

38. Such harmful effects, that can result from these unwanted alterations, are part of the list of potential harmful effects that scientific research has identified and is still in the process of identifying as possible effects. These effects can be described as effects on human health, on the one hand, and as effects on the environment, on the other.

(a) Effects on human health

39. As regards harmful effects on human health a number of potential hazards have been identified as arising from GMOs.

i) Toxicity

40. Many plants contain toxins. Some toxins are self-defence substances to protect the plant against disease or stress, or against grazing, while the function of others is unknown. The level of toxins in a particular food can vary widely depending on the environmental stresses, and treatment conditions throughout the plant's life.

41. Through genetic manipulation, plants which do not naturally contain toxins may become toxic or capable of inherent toxin production (and hence toxicity). This can be dangerously enhanced in many ways. For example, inserted genes may produce toxic proteins in intolerable amounts or can silence other genes which produce counter-toxin agents which balance the toxicity of the organism for human consumption. Furthermore, substances which are acknowledged to be non-toxic, such as vitamins or trace minerals, may be safely consumed within a relatively narrow range. Beyond that range the consumption of such substances may develop toxic effects.[18]

[18] Russell, R.M., "The vitamin A spectrum: from deficiency to toxicity", 71 American Journal of Clinical Nutrition 878 (2000) (Exhibit EC-7).

42. The state of scientific knowledge and understanding on the assessment of toxicity is limited and subject to considerable debate. For example, a feeding study on rats testing genetically modified potatoes (published in 1999) caused major concerns, as the rats were shown to suffer harmful effects to their immune systems. The basic parameters of that study, however, were subsequently put into question and, as a consequence, the results of the study were not recognised as valid by most scientists.[19] The debate triggered a review of current risk assessment techniques regarding toxicology.

ii) Allergenicity

43. Food and food ingredients can cause allergic reactions. This fact is known for some 160 different substances.[20] The vast majority of known food allergens are proteins, and in particular those that have a larger molecular structure or a slower rate of digestibility.

44. Where an organism is genetically modified to contain DNA derived from a species that has known allergenic effects, there is a risk for the recipient organism to acquire allergenicity. One prominent example is the case of the "Brazil nut": Brazil nuts are known to cause severe allergic reactions in a relatively small proportion of the population. A soybean variety had been genetically modified to contain a certain storage protein from the Brazil nut in order to increase the nutritional value of the soybean. Further checks established that the modified soybean had acquired the same allergenic qualities as the parental crop because of the expressed exogenous protein.[21]

45. Allergenicity may also be caused by novel proteins derived from a species that has no known history of allergenic effects. This may come about through novel proteins that the organism produces as a result of the genetic modification, or

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19 Ewen, S.W.B. and A. Pusztai, "Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine", 354 The Lancet 1353 (1999) (Exhibit EC-8).

20 Hefle, S. L., J.A. Nordlee and S.L. Taylor, "Allergenic foods", 36 Crit. Rev. Food Sci. Nutr S69 (1996) (Exhibit EC-9).

through known proteins that are produced in increased quantities, again, as a consequence of the genetic modification. Proteins that are allergens do not necessarily have properties that completely differentiate them from other proteins.

46. One example of these concerns is the "StarLink" case.[22] "StarLink" (a trade name) is a genetically modified corn variety containing a plant pesticide protein which kills certain insects (Bt Cry9C protein). Because of its molecular properties, this novel protein was believed to be potentially allergenic. This was the reason why the competent U.S. authority (Environmental Protection Agency – EPA) limited the registration of the product to animal feed and industrial purposes only. That limited registration was withdrawn when it turned out that corn for human consumption had been contaminated. The scientific understanding and processes of assessing potential allergenicity of novel proteins is continuously developing.[23]

iii) Horizontal gene transfer

47. Horizontal gene transfer takes place where an organism transfers genetic material to another cell that is not its offspring.[24] Horizontal gene transfer may occur through the transfer of insertion events between ingested GM food products and resident gut microflora and the subsequent integration of the DNA in the receiving microflora. Foreign and transgenic DNA has been shown to persist in the stomach and intestine of animals after ingestion of GM products and can be taken up into the cells and nuclei of the receiving organism.[25] Such a scenario would represent a

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21 Nordlee, J..A., S.L. Taylor, J.A. Townsend, L.A. Thomas and R.K. Bush, "Identification of a Brazil-nut allergen in transgenic Soybeans", 334 The New England Journal of Medicine 688 (1996) (Exhibit EC-10).

22 Bucchini, L. and L. R. Goldman, "Starlink Corn: A Risk Analysis", 110 Environmental Health Perspectives" 5 (2002) (Exhibit EC-11).

23 See, for example, the Report of the 2nd Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, on "Evaluation of Allergenicity of Genetically Modified Foods", Rome, Italy, 22-25 January 2001, available at <http://www.fao.org/es/ESN/food/pdf/allergygm.pdf (visited 12 May 2004), (Exhibit EC-12).

24 By contrast, vertical gene transfer occurs in normal reproduction, when an organism receives genetic material directly from its ancestor, i.e. from parent to offspring.

25 Schubbert, R., U. Hohlweb, D. Renz, and W. Doerfler, „On the fate of food ingested foreign DNA in mice: chromosomal associations and placental transmission to the fetus", 259 Molecular and General Genetics 569 (1998) (Exhibit EC-13); Schubbert, R., D. Renz, B. Schmitz, and W. Doerfler, "Foreign (M13) DNA ingested by mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA", 94 Proceedings of the National

particular risk to human health if antibiotic resistance genes were to be horizontally transferred (see below).[26]

iv) Antibiotic resistance

48. The most conceptually problematic case of horizontal gene transfer is the transfer of antibiotic resistance genes to gastrointestinal bacteria.[27] Antibiotic resistance genes are inserted into plasmid vectors (harbouring the inserted gene of interest) as "markers". They permit, in preliminary selection, determination of whether the gene of interest has been successfully inserted into the genome of a plant cell: the cells are treated with the antibiotic in question, and only those with the correct inserted antibiotic resistance gene survive.

49. Even though they are only used as markers, the selectable antibiotic resistance gene often remains in the genetically modified organism.[28] When ingested, fragments of that DNA could be taken up by gastrointestinal bacteria. The uptake of antibiotic resistance genes could potentially result in the development of antibiotic resistance of human bacteria against known antibiotic medication. Thus, important and existing medical treatments may become ineffective in the fight against severe diseases. In its first written submission Canada fails to mention this important aspect, notwithstanding its evident importance.

50. More recently, antibiotic markers are being replaced by other marker technologies, or replaced by mutated native genes which confer a selectable advantage, or

Academy of Sciences 961 (1997) (Exhibit EC-14); Phipps, R.H., E.R. Deaville, B.C. Maddison, "Detection of transgenic and endogenous plant DNA in rumen fluid, duodenal digesta, milk, blood, and feces of lactating dairy cows" 86 Journal of Dairy Science 4070 (2003) (Exhibit EC-15); E. H. Chowdhury, H. Kuribara, A. Hino, P. Sultana, O. Mikami, N. Shimada, N. S. Guruge, M. Saito & Y. Nakajima, "Detection of corn intrinsic and recombinant DNA fragments and Cry1Ab protein in the gastrointestinal contents of pigs fed genetically modified corn Bt11", 81 *Journal of Animal Science* 2546 (2003) (Exhibit EC-16).

[26] Report of the Joint FAO/WHO Expert Consultation on the safety assessment of foods derived from genetically modified animals, Rome, November 2003, point 5.2.2.4 (Exhibit EC-17).

[27] Hohlweg, U. and W. Doerfler, „On the fate of plant or other foreign genes upon the uptake in food or after intramuscular injection in mice", 265 Molecular Genetic Genomics 225 (2001) (Exhibit EC-18).

[28] Although certain techniques do allow for their specific excision, or if a co-transformation approach has been employed in the GMO construction, with the foreign gene of interest on one plasmid vector and the selectable marker on another, subsequent meiotic segregation can remove the marker gene.

avoided entirely with high frequency transformation techniques such as microprojectile bombardment or electroporation.

(b) Effects on the environment

51. With regard to the environment, the potential harmful effects may arise for the same reasons as relate to human health. Toxicity may endanger biodiversity as well as wildlife and livestock in the same way that it might affect humans. Similarly, antibiotic resistance is a concern with farm animals. In addition, potential negative effects specifically for the environment include the following:

i) Non target effects

52. GMO crops that are insect pest resistant have been described above[29]. They are designed to produce proteins which are toxic for specific groups of insects. For the moment, these proteins are all derived from the soil bacterium ***Bacillus thuringiensis*** (Bt). Thus, for instance, Bt Cry1Ab is a protein that acts against Lepidoptera (i.e. mainly the European corn borer, which is a major maize pest) while the Bt toxin Cry-3Bb1 protein is specific to Coleopteran species (i.e. beetles).

53. Nevertheless specific Bt toxins are thought to have adverse effects on non-target organisms, namely insects which are not pests of crops, birds (that would feed on Bt plants), or microflora/microfauna (e.g. soil micro-organisms which would be affected by toxin exudates from the roots of Bt crops).[30]

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29 See, above, Section II.A.3.

30 As for effects of Bt toxins on non-target organisms: Hilbeck, A. et al., "Effects of transgenic Bacillus thuringiensis corn-fed prey on mortality and development time of immature Chrysoperla Carnea (Neuroptera: Chrysopidae)", 27 Environ. Entomol. 480 (1998) (Exhibit EC-19); Hilbeck, A. et al., "Toxicity of Bacillus thuringiensis Cry 1 Ab Toxin to the Predator Chrysoperla carnea (Neuroptera:Chrysopidae)", 27 Environ. Entomol. 1255 (1998) (Exhibit EC-20); Losey, JE., Raynor, LS., and Carter ME., "Transgenic Pollen Harms Monarch Larvae", 399 Nature 214 (1999) (Exhibit EC-21); Losey, J.E., Obrycki, J.J., Hufbauer R.A., "Biosafety Considerations for Transgenic Insecticidal Plants: Non-Target Predators and Parasitoids", Encyclopedia of Plant and Crop Science 156 (2004), <http://lamar.colostate.edu/~hufbauer/Articles/LoseyObrykHufbauer2004a.pdf> (Visited 12 May 2004) (Exhibit EC-22). As for effects of Bt toxins on soil organisms: Koskella J. and G. Stotzky, "Microbial Utilization of Free and Clay-Bound Insecticidal Toxins from Bt and Their Retention of Insecticidal Activity after Incubation with Microbes", Applied and Env. Microbiology 3561 (1997) (Exhibit EC-23); Tapp H. and G. Stotzky, "Persistence of the Insecticidal Toxin from Bt

54. An example is recent research focusing on the impact of pollen from Bt-corn plants on non-target Lepidoptera and other organisms. This found that larvae of the monarch butterfly on milkweed leaves dusted with transgenic Bt-corn pollen ate less, grew more slowly, and suffered higher mortality than those fed leaves dusted with untransformed corn pollen or leaves without pollen.[31] Subsequent field studies later have shown that under field conditions this was not a concern.[32]

ii) Invasiveness and development of resistance

55. GM plants with inserted genes such as herbicidal or insecticidal genes might cause a problem of invasiveness and persistence in the environment. The "resistance-gene" may outcross into other plants (an example of vertical gene transfer) surrounding the crop such as wild relatives, neighbouring non-GM crops of the same species or volunteers (i.e. re-growth of a previous crop in a subsequent crop).[33] Further,

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subsp. Kurstaki in Soil", 30 Soil Biology and Biochemistry 471 (1998) (Exhibit EC-24); Saxena D., S. Flores, G. Stotzky, "Bt toxin is released in root exudates from 12 transgenic corn hybrids representing three transformation events", 34 Soil Biology & Biochemistry 133 (2002) (Exhibit EC-25); Zwahlen C., A. Hilbeck, P. Gugerli, W. Nentwig, "Degradation of the Cry1Ab protein within transgenic Bacillus thuringiensis corn tissue in the field", 12 Molecular Ecology 765(2003) (Exhibit EC-26); Zwahlen C., A. Hilbeck, R. Howald, W. Nentwig, "Effects of transgenic Bt corn litter on the earthworm Lumbricus terrestris", 12 Molecular Ecology 1077 (2003) (Exhibit EC-27); Saxena, S. Flores & G. Stotzky, "Insecticidal toxin in root exudates from Bt corn" 408 Nature 402 (1999) (Exhibit EC-28).

31 Losey, J.E., L.S. Rayor and M.E. Carter "Transgenic Pollen Harms Monarch Larvae", 214 Nature 399 (1999) (Exhibit EC-21).

32 Diane E. et al. "Assessing the impact of Cry1Ab-expressing corn pollen on monarch butterfly larvae in field studies", 98(21) Proceedings of the National Academy of Sciences 11931 (2001) (Exhibit EC-21bis); Zangerl AR et al. "Effects of exposure to event 176 Bacillus thuringiensis corn pollen on monarch and black swallowtail caterpillars under field conditions", 98(21) Proceedings of the National Academy of Sciences 11908 (2001) (EC-21ter); Karen S. Oberhauser et al. "Temporal and spatial overlap between monarch larvae and corn pollen", 98(21) Proceedings of the National Academy of Sciences 11913 (2001) (EC-21quater); Mark K. Sears et al. "Impact of *Bt* corn pollen on monarch butterfly populations: A risk assessment", 98(21) Proceedings of the National Academy of Sciences 11937 (2001) (EC-21quinques).

33 FDA Talk Paper, "FDA Action on Corn Bioengineered to Produce Pharmaceutical Material", U.S. Food and Drug Administration, T02-46, 19 November, 2002, available at : <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01174.html> (Visited 12 May 2004) (Exhibit EC-29); Stewart AN, All JN, Raymer PL, Ramachandran S., "Increased fitness of transgenic insecticidal rapeseed under insect selection pressure" 6 Mol Ecol 773 (1997) (Exhibit EC-30); Ramachandran S, Buntin D, All JN, Raymer PL, Stewart CN, "Intraspecific competition of an insect resistance transgenic canola in seed mixtures", 92 Agron J, 368 (2000) (Exhibit EC-31); Jørgensen R.B., Andersen B., Snow A, Hauser T.P., "Ecological risks of growing genetically modified crops" 16 Plant Biotechnology 69 (1999) (Exhibit EC-32); Jørgensen R.B. and Andersen B., "Spontaneous hybridization between oilseed rape (Brassica napus) and weedy Brassica campestris: A risk of growing genetically engineered modified oilseed rape", 81 American Journal of Botany 1620 (1995) (Exhibit EC-33); Mikkelsen, T.R., B. Andersen and R.B. Jørgensen, "Spread of transgenes", 31

cross-pollination of previously out-crossed events or volunteers with another GM pollen may lead to stacked events.

56. This transfer of genetic material may then confer the selectable advantage, such as insecticidal properties, to the wild relatives, giving them a competitive edge over other members of the same species and other plant species in the same community. The plant could become invasive of and persistent in natural habitats. This phenomenon may negatively impact local and regional biodiversity.

57. One example occurred in Canada in 2000: cross pollination between three distinct varieties of oilseed rape (or "canola") led to the emergence of volunteers expressing resistance to three distinct herbicides (two of the resistant traits were acquired from inadvertent cross-breeding involving two GMO varieties and one was from a conventionally bred resistant line).[34] The expeditious rise of such unintended stacked events poses distinct challenges to traditional agricultural management practices which would have to be adapted accordingly.

iii) Unintended effects arising through GMO related management practices

58. The use of GM crops as opposed to conventional crops may lead to a change in agricultural and management practices. Such changes, based on the specific GM crop in question, may have adverse effects on the agro-ecological environment and on biodiversity. Of particular significance are the results from a recent long-term study in the United Kingdom (referred to as the Farm Scale Evaluation). The GM crop farm-scale evaluations were a three-year programme of research by independent researchers aimed at studying the effect, if any, that the management practices associated with Genetically Modified Herbicide Tolerant (GMHT) crops might have on farmland wildlife, when compared with weed control used with non-

Nature 380 (1996) (Exhibit EC-34); Lefol, E., Danielou, V. and Darmency, H., "Predicting hybridization between transgenic oilseed rape and wild mustard", 45 Field Crops Res. 153 (1996) (Exhibit EC-35); MacArthur, M. "Triple-resistant canola weeds found in Alta", The Western Producer, Feb. (2000) (Exhibit EC-36).

[34] Hall, L., K. Topinka, J. Huffman, L Davis and A. Good "Pollen flow between herbicide-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers", 48 Weed Science 688 (2000) (Exhibit EC-37).

GM crops. A summary of the rationale and results for this important study - the largest ever field trials of GM crops in the world - is set out in Exhibit EC-38.[35]

59. The UK farm-scale evaluations were commissioned by the British Government in 1999, to investigate how growing GM crops might affect the abundance and diversity of farmland wildlife compared with growing conventional varieties of the same crops. The UK Government indicated that it would use the results to help it decide whether to allow such crops to be grown commercially in the UK. The study looked at three GM and conventional crops: sugar and fodder beet (a single crop), spring-sown oilseed rape, and maize. These crops had been genetically modified to make them resistant to specific herbicides. The study found that "there *were* differences in the abundance of wildlife between the GM crop fields and conventional crop fields". It found that

> growing conventional beet and spring rape was better for many groups of wildlife than growing GMHT beet and spring rape. There were more insects, such as butterflies and bees, in and around the conventional crops because there were more weeds to provide food and cover. There were also more weed seeds in conventional beet and spring rape crops than in their GM counterparts. Such seeds are important in the diets of some animals, particularly some birds.[36]

60. By contrast, the study found that GMHT maize was better for many groups of wildlife than conventional maize.

61. Advice on the implications of the farm-scale evaluations was provided to the UK Government by British statutory nature conservation agencies (The Countryside Council for Wales, English Nature, JNCC and Scottish Natural Heritage). Their advice was that they were "convinced by the evidence … that commercial use of GMHT spring oilseed rape and beet would have adverse impacts on biodiversity in farmland landscapes" and that "scientifically defensible decisions on commercial release of these crops can be made on the base of the FSE results. GMHT spring oilseed rape and beet should not be commercialised. GMHT maize may be

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35 Department for Environment Food and Rural Affairs *"*GM crops: Effects on farmland wildlife*"*, October (2003), available at <http://www.defra.gov.uk/environment/gm/fse/results/fse-summary.pdf> (Visited 12 May 2004) (Exhibit EC-38).

36 See ibid, p.1 ("Rationale and Results in Brief").

commercialized, subject to further considerations of future conventional herbicide systems that could be used to replace atrazine".[37] The UK Government's Advisory Committee on Releases to the Environment (ACRE) gave similar advice.[38] On 9 March 2004 the UK Government announced that it would not proceed to authorise the commercial growing of GM spring oilseed rape and GM beet, and would only allow commercial cultivation of the GM maize in the FSE trials if restrictions were imposed on its EC marketing consent to limit herbicide use. The entire process has taken around 5 years, and demonstrated the existence of verifiable adverse impacts on biodiversity caused by certain GM crops. Against this background it is plain that precaution has been fully justified.

iv) Biodiversity - Preservation of centre of origin

62. Genetically modified crops may pose a particular threat to their particular species' centre of origin. The centre of origin of a species is an invaluable and irreplaceable source of genetic material for plant breeding. It is usually characterized by the highest observable levels of genetic variability. A given centre of origin of natural biodiversity for a particular species could be placed at particular risk by cross pollination from genetically modified varieties of the same species to wild relatives.

63. One example relates to the recent reports of genetically modified corn growing in Mexico which has then out-crossed with wild relatives, even over very great distances. Mexico is accepted as the centre of origin of maize.[39] Against a background of growing concern, on 13 April 2004 the relevant advisory committee established under the North American Free Trade Agreement (NAFTA) recommended to the Environment Ministers of Canada, Mexico and the United States that a moratorium on imports of transgenic corn to Mexico should be put in

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37 Department for Environment Food and Rural Affairs "Advice on the implications of the Farm Scale Evaluations for biodiversity in the UK" available at: <http://www.defra.gov.uk/environment/gm/fse/results/en_advice.pdf> (Visited 12 May 2004) (Exhibit EC-39). Atrazine is the conventional method of weed control which is to be phased out in the UK.

38 Department for Environment Food and Rural Affairs, News release "ACRE's advice on the implications of the farm-scale evaluations of genetically modified herbicide-tolerant crops", available at: <http://www.defra.gov.uk/news/2004/040113c.htm> (Visited 12 May 2004) (Exhibit EC-40)

place until the risks to human health, cultural integrity of maize producers in Mexico, and the environment generally are better understood and appropriate long-term decisions can be made. They added: "There is a very strong case to be made here for governments to apply the precautionary principle in their decision-making processes, to require that industry be comprehensive when submitting rationale and to create space for public debate"[40].

5. Conclusion

64. Over the past two decades there has been considerable experience in developing scientific knowledge and understanding of the effects on human health and the environment of GMOs. In some cases clear adverse effects have already been identified; in other cases further studies are being undertaken to assess impacts on human health and the environment over the long-term; and in yet other cases uncertainties exist in the face of differing views as to the effects of specific GMOs on human health and the environment. Many issues concerning possible risks are demonstrable. There remains significant scientific uncertainty, and prudent governments have put in place and funded long-term farm-scale trials to assess these impacts before authorising commercial growing of GM crops as well as requirements for continuous monitoring of the effects (so-called "monitoring plans").

B. International and comparative regulatory arrangements

65. The development of genetic modification techniques is recognised to offer significant potential benefits. However, it is also recognised that this new technology produces risks for human health and the environment that differ from their conventional counterparts. From the earliest days of the development of GMOs, policymakers around the world have focused on how to use and develop

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39 Quist, D. and I. Chapela, "Transgenic DNA Introgressed into Traditional Maize Landraces in Oaxaca, Mexico", 414 Nature 541 (2001) (Exhibit EC-41).

40 See letter of 13 April 2004 from the Joint Public Advisory Committee of the North American Commission for Environmental Cooperation, available at

this potential while adequately addressing all the issues that the new technology raises. This Section describes how regulators have approached the question of containing the potential risks of GMOs for human health and the environment which were outlined in Section A of this Chapter. As will be seen, the reflection process on regulatory approaches has been going in parallel at national and international level, and has been accompanied by an intense public debate. The first section provides examples of national regulatory approaches around the world. The second section describes multilateral initiatives taken to address these issues.

66. This part of the factual background is of central importance to the case. It explains the context against which the European Communities addressed the authorisations which are the subject of these proceedings. From 1998 onwards the international Community was engaged in a major effort to adopt an agreed approach setting minimum standards for the approval of imports of GMOs. Those negotiations led to the adoption of the Biosafety Protocol, in January 2000, and like any prudent government the European Communities adopted its new legislation only after international efforts had been successfully concluded, in order to be sure that its own legislation was consistent with the international approach. Simultaneously other countries, such as New Zealand, were suspending their own authorisation processes whilst regulatory and scientific changes were underway. This part of the factual background indicates that there was nothing unusual in the European Communities' approach and that there were no undue delays in the adoption of its new legislation or any individual instances of decision-making.

1. Regulatory approaches around the world[41]

67. As seen in Section II.A above, the development of GMOs can be associated with possible harmful effect. So far regulators have developed a significant experience in risk evaluation to deal with new man-made risks related to products such as

<http://www.cec.org/pubs_docs/documents/index.cfm?varlan=english&ID=1456> (visited on 14 May 2004) (Exhibit EC-41bis).

[41] The European Communities has preferred not to annex to this submission all the laws, regulations and other national measures that it quotes in this Section in order not to overburden the Panel with an even greater amount of Exhibits. However, the European Communities stands ready to provide any of these documents, should the Panel so wish.

chemicals or pharmaceuticals. However, risk assessment strategies have been far from perfect in predicting risks. There have been numerous cases where unforeseen health or environmental damages were detected only after marketing approval; the use of DDT and other organo-chlorine compounds in agriculture is often quoted as an example of failure of risk evaluation to anticipate certain risks. In all those cases, regulators have been able to remedy the problem by withdrawing authorisations. In the specific case of GMOs, regulators have to deal with new types of *living* organisms which once released into the environment can *self-replicate* and spread without further human intervention. Therefore, product withdrawal after environmental release becomes a lot more complicated in the case of GMOs than in the case of products like chemicals. As a result, the development of GMOs has been raising all new challenges for regulators.

68. The first GMO crop was produced as recently as 1983. These crops were tested in field trials throughout the 1980s. It was only in the early 1990s that the first GM crops were ready for commercialisation.

69. Regulatory approaches reflect this evolution. Early regulation focused on safety standards to be respected in laboratory research and on conditions for field trials. It was only in the 1990s that regulators began to address the question of how to deal with the marketing of GM products, and in particular the conditions under which authorisations could be granted for the commercial cultivation of GM crops and the production and marketing of genetically modified food or other products.

70. Some countries reacted swiftly and immediately put legislation in place. In these cases it often became necessary, soon afterwards, to review the new legislation in the light of further assessment and new scientific developments and understanding. Thus, a review of existing domestic regulatory approaches reflects a situation of evolution: the nature and content of regulations have developed over time, as states have recognised the need to review their regulatory approach in the light of experience, new developments and new concerns. Other countries have only now started to establish their legislative framework, often as a reaction to the outcome of the negotiations of the Biosafety Protocol, which will be described in the following part of this Section. Some 123 countries are in the process of reviewing

or developing their national biosafety frameworks in the context of a United Nations Environment Programme-Global Environment Facility capacity-building initiative for the implementation of the Biosafety Protocol. In many countries the legislative process was (or is) marked by an intense public debate.

2. Differences in regulatory approaches

71. Regulatory approaches vary greatly amongst countries. Sometimes, differences exist even within one and the same country, where some or all relevant decision-making powers have been delegated to sub-entities of the state. Generally, regulators tend to differentiate their regulation on GM crops (release into the environment) from that on GM food. Often, also, regulatory approaches differ over time, as perceptions evolve with the evolving science.

(a) Ban versus laissez-faire

72. Across the spectrum of decision-making there are two "extreme" positions: outright bans on GM products, on the one hand, and proceeding on the basis that there is no need to foresee any kind of specific regulation for products derived from genetic modification techniques, on the other.

73. A general ban on GM plant material, has, for example, been established under the Algerian legislation.[42] The Thai Plant Quarantine legislation bans 49 different GM plants, although it leaves open the possibility of exemptions.[43] Other countries or sub-entities of countries have put in place temporary bans. New Zealand is one example. In 2000, following public debate, the government of New Zealand commissioned an expert committee, the Royal Commission on Genetic

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42 Ministère de l´agriculture et du developpement rural, Arrêté ministériel no 910 due 24 décembre 2000 (Ministerial order by the Minister of agriculture and development of 24 december 2000), quoted from Greenpeace-Briefing, Juli 2003, "Gesetzliche Regelungen GMOs", document available at <http://info.greenpeace.ch/de/gentech/pressreleases/pr210703wto> (visited 13 May 2004).

43 Plant Quarantine Act, B.E. 2507 (1964), B.E. 2546 (2003), document available at <http://www.thaifloriade.thaigov.net/hort_cd/html/PLANT%20_QUARANTINE%20%20ACT%20%201.htm> (visited 13 May 2004). Section 6 of this Act gives the minister in charge the power to declare any plant, pest or medium prohibited; section 8 prohibits import of prohibited items without

Modification, to review the legislation it had put in place in 1996 to address the issue of GMOs. A voluntary moratorium was negotiated between the government, the relevant industry and research groups that same year. In 2002, in reaction to the Commission's report, the government put in place a statutory moratorium on commercial releases for GMOs with an expiry date of 29 October 2003. The decision to ban commercial releases of GMOs was introduced to give the government time to research socio-economic, ethical and environmental concerns.[44] In the meantime the moratorium which lasted several years has expired and revised GMO legislation has been put in place. Also Peru, which is a third party in these proceedings, appears to have banned the import, production or sale of transgenic food and genetically modified organisms for animal or human consumption or for sowing.[45] Another example is El Salvador, which is also a third party in these proceedings. In 2001, El Salvador banned the import, production and marketing of genetically modified seeds.[46] The prohibition was supposed to be temporary, but the European Communities is not aware of it having been lifted.

74. At the level of sub-entities of a state, there have also been moratoria or legislation banning the commercial cultivation of all or certain GM crops (GM free zones), for example, in all Australian States and Territories, except Queensland and the Northern Territory[47] (which are generally considered unsuitable growing areas for

permission by the Department of Agriculture. There was an actual ban on 37 GM crops as at 31 January 2002.

44 The moratorium, i.e. the "restriction" as reads Article 4 lit. b of the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002), lasted from 29 October 2001 to the close of 29 October 2003 and was imposed by the Hazardous Substances and New Organisms (Genetically Modified Organisms) Amendment Act 2002 (part 5A) which came into force by Royal assent on 27 May 2002; document available at <http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes&clientid=2310743439&viewtype=contents> (visited 13 May 2004).

45 Letter of 30 September 2002 from Mr. Juan Carlos Gamarra (Acting Minister for Trade) to Mr. Robert Coleman (Director General for Health and Consumer Protection, European Commission): "*Es importante tener en cuenta que de acuerdo a la "Ley de Alimentos Transgénicos u Organismos Genéticamente Manipulados", esta absolutamente prohibido en el Perú la importación, bajo cualquier modalidad, la producción, venta y/o comercialización de alimentos transgénicos u organismos genéticamente manipulados (OGM's.), para consumo humano, animal o siembra*". See also document WT/DS291/21.

46 Ley de Semillas (Decreto N°530 of 20 September 2001) Article 30 (transitional provision): "*Se prohibe la importación, investigación, producción y comercialización de semillas transgénicas*".

47 The Australian government recognised GM crop free areas as they were designated by several Australian states and territories, in the policy principle *Gene Technology (Recognition of Designated Areas) Principle 2003* (Commonwealth of Australia Special Gazette No. 340, 5 September 2003),

the main GM food crops approved so far by the Office of the Gene Technology Regulator). These moratoria have been implemented in a variety of ways. For example, New South Wales enacted legislation designating the entire State as an area in which specified GM crops cannot be grown for a three-year period. Tasmania declared GMOs to be quarantine pests and the whole of Tasmania to be a protected area under its *Plant Quarantine Act*. In South Australia, on 31 March 2004, the South Australian Genetically Modified Crops Management Bill passed through both the Upper and Lower Houses of State Parliament. The Act allows designation of areas (or the whole of South Australia) as GM-free for marketing purposes.[48] A regulation has been promulgated designating the entire State as an area in which no genetically modified food crops may be cultivated. In the Australian Capital Territory (ACT), a 3 year moratorium is in place. The ACT government recently (11 March 2004) introduced a Gene Technology (GM Crop Moratorium) Bill 2004. This Bill is designed to allow the ACT to be designated as a GM-free zone for certain GM plants in accordance with the Gene Technology Act policy principle. State governments that have initiated moratoria in Australia have argued, in particular, that the moratoria have been implemented as part of a "cautious" or "precautionary" approach to preserving the identity of non-GM crops grown in conventional or organic production systems, for marketing purposes. The moratoria received some legal basis with the issue of the Gene Technology (Recognition of Designated Areas) Principle on 31 July 2003, under which States and Territories are enabled to designate non-GM cropping areas "for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes, if the area is so designated under a State law".[49]

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document avaiable at <http://www.tga.gov.au/gene/policy/gtrdap03.htm#pdf>. For example: In *Western Australia*, the State Ministry of Agriculture, Forestry and Fisheries announced a five-year moratorium on the production of GM crops in May 2001 which has now its legal basis in the *Genetically Modified Crops Free Areas Act 2003*; and in *New South Wales*, the Ministry of Agriculture declared a moratorium on GM food plants on 25.7.2003 (Gazettes No 119, p. 7513) and on 24.12.2003 (Gazette No 198, p 11686) on the basis of the *Gene Technology (GM Crop Moratorium) Act 2003 No 12*.

[48] Genetically Modified Crop Management Act 2004, document available at <http://www.parliament.sa.gov.au/Catalog/legislation/Acts/G/2004.8.un.htm> (visited 13 May 2004).

[49] Gene Technology (Recognition of Designated Areas) Principle 2003, Section 5; document avaiable at http://www.tga.gov.au/gene/policy/gtrdap03.htm#pdf (visited 13 May 2004).

75. The United States, on the other hand, is an example of a country that has adopted, at least in part, an approach that comes closest to a regulatory model of "*laissez faire*". With regard to food derived from GM crops, the competent national authority, the Food and Drug Administration (FDA) issued a policy statement in 1992, in which it established that such food was generally considered to be as safe as conventional food and that pre-market approval was only necessary under certain conditions.[50] At the same time, the FDA set up a voluntary consultation process to help the product developer resolve whether there are any safety or regulatory issues prior to bringing the product on the market. However, in 2001, following public debate, the FDA proposed to make this consultation/review process mandatory.[51]

(b) Authorisation systems – elements

76. The great majority of regulatory systems so far adopted require some form of authorisation before a specific product, be it a GM crop or GM food, is marketed and make the granting of that authorisation dependent on a case by case risk assessment of the individual product in question.[52]

i) Risk assessment

77. Usually these authorization systems have procedures in place under which the submission of specific information/data is requested from the applicant for an authorisation, and on the basis of which certain risks are assessed. These can be health risks and/or environmental risks. The Chinese legislation, for example, as regards the use of GMOs for agricultural production or processing requires evaluations to assess potential risks caused by such GMOs to humans, animals,

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50 Food and Drug Administration, Statement of Policy: Foods Derived From New Plant Varieties, May 29, 1992, see US Fed. Reg. 22984, 29 May 1992; document available at <http://vm.cfsan.fda.gov/~lrd/fr92529b.html> (visited 13 May 2004).

51 Food and Drug Administration, Proposed Rule: Premarket Notice Concerning Bioengineered Foods, January 18, 2001, see US Fed. Reg. 4706, 18 January 2001, document available at <http://www.cfsan.fda.gov/~lrd/fr010118.html> (visited 13 May 2004).

52 Examples include Switzerland, Brazil, Australia, New Zealand, India, Norway, and South Africa. Usually this authorisation requirement is specific to GM products. In Canada, however, there is no legal difference made between novel GM and non-GM traits.

plants, micro-organisms and the environment.[53] The Regulations made under the South African Genetically Modified Organisms Act 1997 establish a permit requirement for activities relating to GMOs, and provide that no person shall undertake any activity involving genetic modification unless a suitable and sufficient assessment of the risks created thereby to the environment and human health has been made. In Australia, the Gene Technology Regulator must prepare a risk assessment and risk management plan for every application for a licence for dealings involving intentional release of a GMO into the environment. The Gene Technology Act specifies matters to be taken into account by the regulator in the preparing the risk assessment, and guidelines have also been issued on the risk analysis framework.[54] In India, risk assessment and regulatory approval for releases of GMOs and GM products are mandatory.[55] Norway requires all applications for approval of deliberate release to contain an impact assessment, and may require further information and investigations in addition to the impact assessment before any decision is made on the application.[56] In Japan, since April 2001, almost all activities (including the import, production, processing or marketing) using GMOs are subject to mandatory risk assessment and mandatory standards for manufacturing. This includes prior notification and approval[57].

78. In many countries the details of the specific risk assessments are being reviewed continuously. Canada, for example, launched a review process in 2000 requesting a scientific committee, the Royal Society of Canada, "to provide advice to ensure the

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53 See 2002 Ag GMO Implementation Measures, Article 4; document available at <http://www.fas.usda.gov/gainfiles/200201/135683205.pdf> (visited 13 May 2004).

54 Australia, Office of the Gene Technology Regulator, *Risk Analysis Framework for Licence Applications to the Office of the Gene Technology Regulator*, January 2002 The Risk Analysis Framework incorporates the formulation of the precautionary principle in Principle 15 of the 1992 Rio Declaration.

55 See 1989 Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, and 1998 Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts).

56 Norway, Gene Technology Act (Act No. 38 of 2 April 1993), Article 11; document available at < http://www.bdt.fat.org.br/binas/Regulations/full_regs/norway/norway1.html#file.3.11> (visited 13 May 2004).

57 MAFF Announcement No. 517 of 2000, NTA Announcement No. 7 of 2000 and MHLW Announcement No. 23 of 2001 introduced mandatory labelling for GM agricultural products (See Section 3.2.1.2(1)~(3)). MHLW Announcement No. 232 of 2000 and MHLW Ordinance No. 95 of 2000 introduced mandatory risk assessment and standards for production process (See Section 3.2.1.1.1(2)).

safety of new food products being developed through biotechnology."[58] The Royal Society, in its report of 2001, *inter alia*, criticized the use of the so-called principle of substantial equivalence[59] as a "decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities because such a regulatory procedure is not a precautionary assignment of the burden of proof."[60] Through its comprehensive action plan following the report of the Royal Society, the government also committed to reviewing its Guidelines for the Safety Assessment of Novel Foods, which is currently being undertaken.[61]

ii) Precautionary approach

79. Often, such authorisation systems are based on the need to take precautionary action. The Australian Gene Technology Act (2000), for example, adopts the definition of the precautionary principle as contained in Principle 15 of the Rio Declaration on Environment and Development (1992).[62] The intention was to

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58 The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biology in Canada, An Expert Panel Report on the Future of Food Biotechnology* (January 2001), Prefatory Note; document available at <http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf> (visited 13 May 2004).

59 The concept of substantial equivalence is used as a risk assessment tool in many regulatory systems on GMOs. It is based on the principle that genetically modified plants can be compared to their conventional counterparts that have an established history of safe use. Thus, substantial equivalence is used to identify similarities and differences between the new food and its conventional counterpart. The use of substantial equivalence as a basis for regulatory shortcuts in the authorization procedure has been criticized both in Canada and in the EC.

60 The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biology in Canada, An Expert Panel Report on the Future of Food Biotechnology* (January 2001), Recommendation Concerning Underlying Policies and Principles Guiding the Regulation of Agricultural Biotechnology No. 8.1, p. 15; document available at <http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf> (visited 13 May 2004).

61 In parallel, there is a review of the specific risk assessment guidelines to GM feed and GM plants, namely the Guidelines for the "Safety Assessment of Livestock Feed from Plants with Novel Traits," and "Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits"; see Health Canada, *Revision of Health Canada's Guidelines for the Safety Assessment of Novel Foods*; document available at <http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/pdf/e_consultation_main.pdf> (visited 13 May 2004).

62 Gene Technology Act 2000, No. 169, 2000, Part 1, Section 4 aa reads: "The object of this Act is to be achieved through a regulatory framework which:
(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and …" (document available at <http://scaleplus.law.gov.au/html/comact/10/6283/pdf/169of2000.pdf>, visited 13 May 2004);
Principle 15 of the Rio Declaration reads: "… Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

underpin the necessity for a precautionary approach to the assessment of environmental risk posed by GMOs.[63] The Swiss GMO legislation, for its part, states that, "by way of precaution, the dangers and harmful effects linked to genetically modified organisms are to be limited as early as possible."[64] The precautionary approach is also a mandatory consideration for the Environmental Risk Management Authority and others functioning under the regulatory framework of the Hazardous Substances and New Organisms Act in New Zealand. Section 7 of that Act provides that all persons excising functions, powers and duties under the Act must take into account the precautionary need for caution in managing adverse effects where there is a scientific and technical uncertainty about those effects.

80. The precautionary principle is also one of the "salutary principles which govern the law of the environment"[65] in India. Though not expressly set out in the relevant legislation on GMOs, it has been applied by the Indian Supreme Court.[66]

iii) Further considerations

81. A number of countries have opted to take into account, in authorisation processes or in the regulatory system more generally, considerations other than risks for

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63 Senate Committee on Community Affairs, Parliament of the Commonwealth of Australia, *A Cautionary Tale: Fish Don´t Lay Tomatoes. A Report on the Gene Technology Act Bill 2000*, November 2000, no. 3.57-3.61; document available at http://www.aph.gov.au/Senate/committee/clac_ctte/gene/report/index.htm (visited 13 May 2004).

64 "Par mesure de précaution, les dangers et les atteintes liés aux organismes génétiquement modifiés sont limités le plus tôt possible." Federal Law Relating to Non-Human Gene Technology, 21 march 2003, Art. 2 ; document available at <http://www.environnement-suisse.ch/imperia/md/content/stobobio/biotech/17.pdf> (visited 13 May 2004).

65 *T.N. Godavarman Thirumalpad v. Union of India* (2002) 10 SCC 606; document available at <http://www.ebc-india.com/lawyer/digest/vol10.htm> (visited 8 April 2004).

66 *T.N. Godavarman Thirumalpad v. Union of India* (2002) 10 SCC 606; Vellore Citizens´ Welfare Forum vs Union of *India* and others, (1995) 5 SCC 647; document available at <http://www.ebc-india.com/lawyer/digest/vol5.htm> (visited 8 April 2004).
In Brazil, the extent to which precautionary principle applies in the authorisation of GMOs is currently subject of an action signed by the Federal Public Ministry, Greenpeace and the Consumer Defense Institute against the Federal Government. The basis for the complaint was that the Federal Government had not required any studies on the possible environmental impact of the commercial release of the transgenic soybean, in the context of an application for release by Monsanto. In August, 2003, a federal judge finally authorized the commercialization of genetically modified soya. There has not yet been a final ruling on the matter and on August 21, 2003, the Federal Public Ministry demanded the referral of the matter to the Superior Federal Court.

human life and health or the environment in order to decide on approvals of GMOs. First, there is a growing recognition that the authorisation of GM crops can have significant socio-economic effects, for example on the production of organic crops. Coexistence between GM crops and conventional crops has become a subject of increasing attention in that context, with research focusing on the potential impacts of GM crops on non-GM crops and on the economic and other consequences of inter-mingling.

82. Many regulatory approaches reflect such concerns. In South Africa, for example, in considering applications for release and distribution, the regulatory body may consider the socio-economic impact that the introduction of a GMO may have on a community living in the vicinity of the introduction.[67] In Argentina, the legislation allows for an assessment of the economic impact the authorisation would have on the country's international trade.[68]

83. Second, beyond socio-economic considerations, some countries also take into account religious and ethical considerations.[69]

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67 *South Africa*, Genetically Modified Organisms Act 1997 (Act no 15 of 1997) – Regulations – Section 5 (9) provides that the Executive Council for Genetically Modified Organisms "may in performing its function consider the socio-economic impact that the introduction of the genetically modified organism may have on a community living in the vicinity of such introduction" (document available at <http://www.pmg.org.za/docs/2003/appendices/030414department.htm>, visited 13 May 2004). See also *India*, Revised Guidelines for Research in Transgenic Plants Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, Department of Biotechnology Ministry of Science and Technology Government of India (August 1998), Guideline no. 6 (Monitoring and Evaluation Mechanism for Green House/Net House Experiments and Limited Field Trials in the Open Environment); document available at <http://binas.unido.org/binas/regulations/indiaguide.pdf.> (visited 13 May 2004).

68 Introduction to Resolución N° 39/2003, of 11 July 2003, of the Ministry of Economy: "La autorización para la liberación comercial de un OVGM es otorgada por el Secretario en base a TRES (3) dictámenes independientes elaborados por sendos entes asesores que pertenecen al ámbito de la Secretaría de Agricultura, Ganadería, Pesca y Alimentos (SAGPyA). Estos TRES (3) dictámenes son: […] c) *la determinación de que no se producirá un impacto no deseado sobre nuestro comercio internacional*, producida por la Dirección Nacional de Mercados Agroalimentarios, que pertenece también a la SAGPyA." Document available at <http://www.infoleg.gov.ar/txtnorma/86871.htm> (visited 13 May 2004).

69 *Australia*, Gene Technology Act 2000, section 112, establishing the Gene Technology Ethics Committee; and section 21 on policy principles which constrain the decision-making of the Gene Technology Regulator and may concern ethical issues (document available at <http://scaleplus.law.gov.au/html/comact/10/6283/pdf/169of2000.pdf>, visited 13 May 2004). In *Switzerland*, the Federal Ethics Committee for Non-Human Gene Technology advises the Federal Council in the enactment of relevant regulations, and issues Statements on licence applications. See Article 23, Federal Gene Technology Law (document available at <http://www.environnement-suisse.ch/imperia/md/content/stobobio/biotech/17.pdf> (visited 13 May 2004)). Under *New Zealand*'s

iv) Post-approval surveillance

84. Finally, given the scientific uncertainty surrounding GMOs many systems provide for labelling and post-marketing surveillance, thus allowing for the monitoring of long-term environmental and health effects of GM products. [70]

85. Australia and New Zealand, for example, jointly put in place rules requiring all genetically modified food and ingredients to be labelled where they contain novel DNA and/or novel protein in the final food, or have altered characteristics.[71] In Japan, there are four different mandatory labelling mechanisms, covering GM agricultural products[72], GM liquors[73] and GM food and food additives[74].

86. The introduction of appropriate monitoring policies is also currently being discussed in the United States following the publication, in 2002, of a report of the United States National Academy of Science (NAS), entitled "The Environmental Effects of Transgenic Plants: the Scope and Adequacy of Regulation."[75] The NAS recommended that post-commercialization validation testing should be used to verify the effectiveness of pre-commercialization risk assessment and that it may be designed to test specific hypotheses regarding major categories of risk which

Hazardous Substances and New Organisms Act, those responsible for implementing the Act must recognise and provide for the need to ensure the maintenance and enhancement of the capacity of people and communities to provide for their economic, social and cultural well-being and for the reasonable, foreseeable needs of future generations (Section 5). They must also take into account other matters, including the intrinsic value of ecosystems, and the relationship of the Maori and their culture and traditions (Section 6); document available at <http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_statutes&clientid=2310743439&viewtype=contents> (visited 13 May 2004).

70 Labelling requirements exist for example in Brazil, Japan, China, Indonesia, Korea, Saudi Arabia, Taiwan, Switzerland, Australia and New Zealand.

71 Standard A18 'Food Produced Using Gene Technology' in the Australian *Food Standards Code*. This standard also appears as Standard 1.5.2 in the joint Australia New Zealand *Food Standards Code*. It entered into force on 7 December 2001.

72 MAFF Announcement No.517 of 2000.

73 National Tax Agency Announcement No. 7 of 2000.

74 MHLW Ordinance No. 23 of 2001.

75 Department of Agriculture, Animal and Plant Health Inspection Service, Notice of intent to prepare an environmental impact statement and proposed scope of study, see US Fed. Reg. 3271, 23 January 2004, document available at <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-1411.pdf> (visited 13 May 2004).

include movement of transgenes, impacts of the whole plant through escape or impact on agricultural practices, non target effects, and resistance evolution.[76]

3. International conventions – Biosafety Protocol

87. These measures at the national level are illustrative of a global trend, which has led to the adoption of several international instruments to address the risks of GMOs. The potential of biotechnology to contribute to the alleviation of some problems of development and environment was recognised by the 1992 UN Conference on Environment and Development (the "Earth Summit"), which devoted chapter 16 of Agenda 21 to "Environmentally sound management of biotechnology".[77]

88. It was at the Earth Summit that countries initiated a multilateral reflection process on "the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."[78] The decision to reflect on multilateral rules on trade in GMOs, thus, was taken at a time where most countries were just beginning to address the issue of GMOs under their own domestic systems.

89. In addition to providing the basis for future negotiation of a specific protocol on biosafety, the Convention on Biological Diversity requires Contracting Parties to establish or maintain specific means to regulate risks associated with GMOs. Article 8(g) of the Convention thus required Parties, as far as possible and as appropriate, to

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76 United States National Academy of Science, *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation (2002)*; document available at <http://www.nap.edu/books/0309082633/html> (visited 13 May 2004).

77 Available at <http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21chapter16.htm> (visited on 14 May 2004).

78 See Article 19(3) of the Convention on Biological Diversity (CBD) done in Rio de Janeiro in June 1992, which was opened for signature at the Earth Summit, available at: <http://www.biodiv.org/doc/legal/cbd-en.pdf > (Visited 12 May 2004) (Exhibit EC-42).

> Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

90. This provision is binding on all 188 Contracting Parties to the Convention, regardless of whether or not they also become parties to the Biosafety Protocol.[79] It reflects a common view that "living modified organisms" are not the same as their non-GM counterparts, and that they have characteristics which inherently require human and environmental risks to be assessed.

91. Multilateral initiatives to address specific issues of risk assessment and management of GMOs, on the other hand, had already been initiated in the early 1980s. Since then, virtually all international organisations and agencies dealing with issues of trade, agriculture, health and/or environment have turned their attention to GMOs and have launched specific activities to deal with questions coming under their respective expertise.

92. Sub-section (a) below provides an overview of the Biosafety Protocol; and sub-section (b) describes the work of a number of international organisations who have been (and are) playing a key role in addressing issues related to risk assessment and management of GMOs.

93. The Biosafety Protocol is the outcome of complex negotiations which began formally in 1996[80] and were successfully concluded in Montreal on 29 January 2000. Over 750 participants, representing 133 governments, NGOs, industry organisations and the scientific community, attended the final meeting in Montreal.

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[79] The United States is, in fact, one of the few counties not yet to have ratified or acceded to the Convention on Biological Diversity, although it participated in its negotiations. Canada and Argentina are Contracting Parties to the Convention. Article 19(4) of the Convention requires Contracting Parties, directly or by requiring any natural or legal person under its jurisdiction, providing living modified organisms to provide any available information about the use and safety regulations required by that Contracting Party in handling such organism, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

[80] The mandate for the negotiations is contained in Decision II/5 of the Conference of the Parties to the Convention on Biological Diversity, adopted in November 1995. Prior to this, the first meeting of

94. The Protocol was opened for signature in May 2000. 102 countries and the European Communities have signed the Protocol. The 103 signatories include four (i.e. Argentina, Canada, Uruguay and Chile) of the six members (the remaining two being Australia and the U.S.) of the so-called Miami Group, which represented grain exporting countries during the negotiations. Following the 50th ratification last year, the Protocol entered into force on the 11 September 2003. As of 6 May 2004, 96 countries and the EC have ratified or acceded to the Protocol.

(a) Overview

95. The Biosafety Protocol is the first international legally binding agreement on the trade of genetically modified organisms, but by no means the only one.[81]

96. The Biosafety Protocol addresses the safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity with a specific focus on transboundary movements. The Protocol establishes an Advance Informed Agreement (AIA) procedure for imports of LMOs intended for deliberate release into the environment; incorporates the precautionary principle; and details information and documentation requirements. The Protocol also contains provisions regarding: confidential information and information-sharing; a compliance mechanism; the consideration of international rules and procedures on liability and redress; and capacity-building and financial resources, with special

Conference of the Parties mandated two meetings of experts, held in Cairo and Madrid in 1995, to consider Article 19(3).

81 Another international convention that explicitly, although not exclusively, addresses the issue of GMOs is the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice on Environmental Matters, adopted in 1998. (Exhibit EC-43). This Convention was adopted under the auspices of the UN-ECE but is open to all states. It entered into force on 30 October 2001, lays down basic rules to promote citizens' involvement in environmental matters and enforcement of environmental law. The issue of GMOs is given emphasis in both the preamble, article 6 and the accompanying Resolution. Although the Convention itself does not set forth an obligation for the Parties to provide for public participation in licensing or permit procedures for GMOs, the Meeting of the Parties has adopted additional non-binding Guidelines on GMOs, and has mandated a Working Group to explore possible legally binding options, including an amendment to the Convention, for the application of the Convention in the field of GMOs.

attention to the situation of developing countries and those without domestic regulatory systems.[82]

97. The relationship between the Protocol and other international agreements, including trade agreements, is addressed by the last three recitals of the Preamble. They recall the concept of mutual supportiveness between trade and environment agreements; they furthermore affirm that the Protocol shall not be interpreted as implying a change in the rights and obligations of Parties under any other existing international agreement, but such statement shall not mean that the Protocol is subordinated to other international agreements.

98. According to Article 1 of the Biosafety Protocol, the objective of the Protocol is to contribute to ensuring, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration, an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. By way of general obligations, Article 2(2) requires that parties "shall *ensure* that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that *prevents or reduces* the risks to biological diversity, taking also into account risks to human health" (emphasis added).

99. According to Article 2(4), Parties retain the right to take action that is more protective of biodiversity than that called for in the Protocol, provided that such action is consistent with the objective of the Protocol and is in accordance with Parties' obligations under international law. The EC legislative framework on GMOs is one example of such stricter measures.

(b) Main provisions of the Protocol

[82] One of the purposes of the Biosafety Protocol is to make sure that those countries, in particular DCs, that do not have in place a regulatory framework for GMOs are at least able to know, through the prior informed consent procedure, that another country intends to export GMOs and thus be given the opportunity to get proper information and eventually decide to accept them or not.

100. The following will describe the main provisions of the Protocol as they may be of interest in the present case.

i) Advance informed agreement

101. Articles 7 to 10 contain the Advance Informed Agreement (hereinafter "AIA") procedure. The procedure shall apply prior to the first intentional transboundary movements of living modified organisms intended to be introduced into the environment of the importing Party. Article 7(2) limits the scope of the AIA procedure providing that "intentional introduction into the environment" in Article 7 (1) does not refer to LMOs intended for direct use as food or feed, or for processing (so-called LMO-FFPs). These include commodities such as genetically modified corn, soya, wheat and tomatoes. LMOs in transit and under 'contained use' conditions are also excluded from the scope of the AIA procedure (Article 6), although the Protocol expressly preserves the right of parties to regulate transport of LMOs in transit through their territory and contained use of LMOs. In addition, LMOs for contained use are subject to specific documentation requirements in accordance with Article 18(2)(b). Specific documentation is also required for LMO-FFPs under Article 18(2(a)

102. Article 8 requires exporting parties to notify, or to require the exporter to notify, the competent national authority of the importing party. Notification must contain the information specified in Annex I of the Protocol, including a risk assessment. Under Article 10 the importing party is required to decide whether it consents to the proposed import unconditionally, consents subject to specified conditions, or prohibits the import. It can also request additional information (in which case the time period for decision-making is extended) or extend the period for decision making.[83] In all cases apart from unconditional import, the importing party must give reasons for its decision.

103. It is particularly noteworthy that the Protocol provides that a failure to respond to the notifying party or exporter and to communicate its decision within the specified

[83] Article 10(3).

time frame of 270 days does not imply the consent of the importing party. This confirms that states are free to take longer to make their decisions, having regard to the need to protect the environment and human health. Decisions taken under Article 10 are to be taken in accordance with Article 15, which provides for risk assessment in accordance with Annex III of the Protocol.

104. A Biosafety Clearing-House is established in order to deal, *inter alia*, with the significant trade in LMO-FFPs (see Articles 11 and 20). It will serve as a multilateral information exchange mechanism. Within 15 days of taking a final decision regarding the domestic use of an LMO, the party taking such a decision is obliged to inform the other parties through the Clearing-House. The information must include, inter alia, details about the producer, the particular LMO and a risk assessment (see Annex II). Pursuant to Article 11(4), other parties may request additional information, and may make their own decision on the import of the LMO-FFP through their domestic regulatory framework. All parties must make available to other parties through the Biosafety Clearing House, copies of their national laws, regulations and guidelines applicable to LMO-FFPs. Article 11 contains special provisions regarding the position of countries that do not have in place a regulatory framework for LMO-FFPs.[84]

ii) Science and Precaution

105. The Protocol places considerable emphasis on the precautionary principle. Article 1 states that the objective of the Protocol is to be pursued "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development." A commitment to the precautionary approach is also expressed in the preamble.

106. This general commitment on the use of the precautionary principle is further specified in Article 10, which governs the procedure by which parties decide on the import of LMOs for deliberate release. Article 10(6) states that "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding

[84] Article 11(6).

the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent a party from taking a decision, as appropriate, with regard to the import of the living modified organism in question (…)." A similar clause is contained in Article 11(8), which covers LMO-FFPs, to which the AIA procedure does not apply.

107. It is notable that after several years of negotiations the Contracting Parties to the Convention on Biological Diversity agreed by consensus that the precautionary principle should be expressly incorporated into the operative provisions of the Protocol dealing with import procedures for LMOs for deliberate release into the environment and LMO-FFPs. This gives the precautionary approach a significant role in the decision to restrict or prohibit import of LMOs in the face of scientific uncertainty. The provisions on precaution are not formulated as obligations but as rights to take precautionary action. They must also be seen in the context of the objective of the Protocol, expressed in Article 1, which is to be achieved "in accordance in the precautionary approach contained in Principle 15 of the Rio Declaration". Annex III of the Protocol, which sets out more detailed guidance on risk assessment under Article 15, specifies that "[l]ack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk".

108. The provisions on decision-making, risk assessment and the precautionary principle are complemented by Article 12(1), according to which parties of import have the right to review and change their decisions on imports, at any time, in the light of new scientific information on potential adverse effects on biodiversity, taking into account also risks to human health. Any new decision needs to be reasoned, and informed to the notifier and the Biosafety Clearing House. This right is counter-balanced by the obligation in Article 12(3) for the importing party to provide a reasoned written response to exporters or notifiers who request a review of an Article 10 decision in the light of additional scientific or technical information or of a change in circumstances that may influence the risk assessment on which the

decision was based. This applies also to decisions taken on the basis of Article 10(6) (precautionary principle).

iii) Identification and documentation requirements

109. Article 18 establishes identification and documentation requirements. LMOs subject to intentional transboundary movement shall be handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

110. There is a distinction in identification and documentation requirements between LMO-FFPs, LMOs destined for contained use and LMOs intended for release into the environment. The latter category of LMOs shall be clearly identified in accompanying documentation, specifying the identity and relevant traits and/or characteristics and other relevant information. For LMO-FFPs, accompanying documentation need only to specify that they "may contain" LMOs and that they are not intended for intentional introduction into the environment. However, the Conference of the Parties serving as the meeting of the Parties to the Protocol is mandated to take a decision on detailed requirements for LMO-FFPs, including on specification of identity and unique identification, within two years from the entry into force of the Protocol.

iv) Socio-economic Considerations

111. Article 26 allows parties to take socio-economic considerations into account in reaching a decision on the import of LMOs, consistent with their international obligations, in so far as these concerns arise from the impact of LMOs on the conservation and sustainable use of biodiversity.

112. In conclusion, as can be seen, the Biosafety Protocol contains most of the elements contained in existing national regulatory approaches described in the first part of this chapter. The process of reflection on and of development of both national and

international rules went on in parallel. As set out below[85], the European Communities considers that the interpretation of the relevant WTO agreements should be consistent with the requirements of the Protocol.

4. Examples of standard setting work in international organisations

113. Standard setting work has been going on in various bodies of international organisations dealing with issue at the interface between trade, agriculture and environment/health issues. Many of them are part of the UN Inter-Agency Network for Safety in Biotechnology (IANB), which was set up in 1999 to enhance the exchange of information and facilitate co-operation.[86]

114. The following is a brief overview of the work of some of the most important international organisations active in this field. It confirms that the potential risks of GMOs for human health and the environment, as well as socio-economic aspects, are recognised by the international Community as legitimate.

(a) Codex Alimentarius

115. In 1999, the Codex Alimentarius Commission established an Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology (CTFBT) to consider the health and nutritional implications of such foods. The objectives for the Task Force's work were to develop standards, guidelines or recommendations, as appropriate, for foods derived from "biotechnology" or traits introduced into foods by "biotechnology", on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices.

116. The Task Force has elaborated three texts, which were adopted at the 26th session of the Codex Alimentarius Commission in Rome in July 2003. These are the

85 See, *infra*, Chapter III.

86 See at <http://www.oecd.org/document/3/0,2340,en_2649_34385_1890691_1_1_1_37437,00.html> (Visited 12 May 2004).

"Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants" and the "Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-organisms".[87] The "Principles" document provides that "A pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis" (paragraph 12); and that "Risk management measures may include, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring" (paragraph 19). It is of paramount importance to note that similar risk assessment and risk management, which are characteristic of a precautionary approach to food safety, are not provided for by *Codex Alimentarius* in respect of conventional food[88]. The Codex Alimentarius Commission has requested Japan to submit a proposal to its next meeting, in June-July 2004, on the establishment of a new Task Force on Foods Derived from Modern Biotechnology, including terms of reference.

117. Work on issues related to the risk assessment and management of GMOs and GM derived products is also ongoing in other Codex committees. Thus, for example, the Codex Committee on Methods of Analysis and Sampling is currently working on methods of analysis for GM foods (CCMAS).[89] The labelling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering is under discussion in the Codex Committee on Food Labelling (CCFL).

(b) WHO

118. The World Health Organisation (WHO) has been addressing a wide range of issues in the field of biotechnology and human health, including safety evaluation of

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87 Report of the Twenty-Sixth Session of the Codex Alimentarius Commission, Rome, Italy, 30 June-7 July 2003, ALINORM 03/41, paras. 51-53 and the appendices referred to: appendices II, III, IV of ALINORM 03/34 and appendix II of ALINORM 03/34A. (Exhibit 44).

88 See "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius", in the Procedural Manual of the Codex Alimentarius Commission, available at <http://www.codexalimentarius.net/procedural_manual.stm> (visited on 14 May 2004).

89 Criteria for the methods for the detection and identification of foods derived from biotechnology – general approach and criteria for the methods, in: report of the twenty-fifth session of the codex

vaccines produced using biotechnology, human cloning and gene therapy. As regards, in particular, the issue of safety assessment of genetically modified food, WHO, from the 1990s onwards, has engaged in a series of Joint Expert Consultations with FAO on safety aspects of GM foods.[90] The outcome of these consultations has been extensively used by the Codex Task Force on Foods Derived from Biotechnology to develop the above-mentioned principles and guidelines. In addition, WHO has organised special workshops, meetings and seminars often in collaboration with other international organisations on specific questions such as substantial equivalence or health aspects of marker genes. Furthermore, the WHO Food Safety Department is currently conducting an evidence-based study of the implications of GM foods on human health and development.[91]

(c) FAO

119. FAO's work on GM issues was taken up by its Commission on Genetic Resources for Food and Agriculture in the early 1990s.[92] An initiative to draft a Code of Conduct on Biotechnology as it relates to genetic resources for food and agriculture was launched. Pending the negotiation of the Biosafety Protocol and the International Undertaking on Plant Genetic Resources for Food and Agriculture, work on the draft code was suspended, but has recently been re-launched.[93]

committee on methods of analysis and sampling**,** para. 107-117, Budapest, Hungary 8 – 12 March 2004. (Exhibit 45)

90 <http://www.who.int/foodsafety/biotech/consult/en/print.html> (Visited 12 May 2004)

91 The initiative goes back to a Resolution adopted, in 2000, by the WHO's governing body, the World Health Assembly, which emphasised the need "to support Member States in providing the scientific basis for health-related decisions regarding genetically modified foods." "WHO study on modern food biotechnology, human health and development", 2003, by the WHO's governing body, the World Health Assembly, which emphasised the need "to support Member States in providing the scientific basis for health-related decisions regarding genetically modified foods.", available at: <http://www.who.int/foodsafety/biotech/who_study/en/index1.html> (Visited 12 May 2004) (Exhibit 46)

92 The Commission was originally established in 1983 as the Commission on Plant Genetic Resources, by the FAO Conference (Resolution 9/83). Its initial mandate to deal with issues related to plant genetic resources was broadened in 1995 to cover all components of agro-biodiversity. It was then renamed the Commission on Genetic Resources for Food and Agriculture.

93 Report of the Ninth Regular Session of the Commission on Plant Genetic Resources for Food and Agriculture, paras. 61-67 (Doc. CGRFA-9/02/REP), and the document referred to in the paragraphs: Commission on Genetic Resources for Food and Agriculture, "The Status of the Draft Code of Conduct On Biotechnology as it Relates to Genetic Resources for Food and Agriculture : Report of

120. FAO is also home to the Interim Commission on Phytosanitary Measures (ICPM), a body established in accordance with the International Plant Protection Convention (IPPC), which was negotiated under the auspices of FAO. The ICPM develops and adopts international standards for phytosanitary measures (see Articles X and XI, IPPC). The ICPM has recently been working on a standard for pest risk analysis for LMOs and, at its sixth meeting in March-April 2004, it considered a Supplement to ICPM No. 11 on pest risk analysis for living modified organisms.[94]

121. With its Statement on Biotechnology in 2000, FAO renewed its commitment to provide policy advice, technical assistance, legal and technical advice on regulatory aspects, promoting dissemination of information and through monitoring new developments and potential impacts of the adoption of biotechnology.[95] In addition to contributing to Codex' work *inter alia* through organising the Joint expert consultations with WHO (see above), FAO regularly organises e-mail conferences, symposia and workshops covering a broad range of biotechnology related issues. It has developed a Glossary of Biotechnology for Food and Agriculture and has set up the web-based database FAO-BioDec.

(d) UNEP

122. The United Nations Environmental Programme (UNEP) has been involved in international regulatory work on GMOs since the mid-1980s on. Chapter 16 of Agenda 21 was prepared under its auspices. In 1995 the International Technical Guidelines on Safety in Biotechnology were adopted under the auspices of UNEP as an interim measure and future complement to the Biosafety Protocol.[96] These Technical Guidelines are intended as a contribution to the implementation of Agenda 21 commitments and aim to assist governments, intergovernmental,

Surveys of FAO Members and Stakeholders" (Doc CGRFA-9/02/18), Ninth Regular Session, Rome, 14-18 October 2002.

94 Sixth Session of the Interim Commission on Phytosanitary Measures, Adoption of International Standards, 29 March – 2 April, - Rome, Italy (2004), ICPM 04/2-Annex III –Supplement to ISPM No. 11 (Pest risk analysis for quarantine pests): "Pest risk analysis for living modified organisms". The final text as adopted has not yet been issued. (Exhibit EC-48).

95 FAO Press Release 00/17, "FAO stresses potential of biotechnology but calls for caution", 15 March, Rome, Italy, available at <http://www.fao.org/biotech/stat.asp> (Visited 12 May 2004) (Exhibit-49).

private-sector and other organizations in the establishment and maintenance of national capacities to provide for safety in GMOs, to assist in developing expert human resources and for international exchange of information.

123. UNEP is currently implementing a GEF project on the development of national biosafety frameworks. 123 countries are participating in this project,[97] which is designed to assist countries to set up a national framework for LMOs so that they can meet the requirements of the Biosafety Protocol.[98] The project also aims to promote appropriate regional and sub regional collaboration.

(e) UNIDO

124. The United Nations Industrial Development Organisation (UNIDO) has been actively involved in developing standards on assessing safety and environmental risks of biotechnology. Together with FAO, WHO and UNEP, in 1990, UNIDO set up an ad hoc working group to draft a Voluntary Code of Conduct for the Release of Organisms into the Environment, which was finalised in 1992.[99] The Code's objective is to outline the general principles governing standards of practice for all parties involved in the introduction of organisms or their products/metabolites to the environment.

125. UNIDO also set up the database BINAS (Biosafety Information Network and Advisory Service) which, in close cooperation with OECD's BioTrack online, monitors global developments in regulatory issues in GMOs.[100]

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96 Document can be found at <http://www.unep.org/unep/program/natres/biodiv/irb/unepgds.htm> (Visited 12 May 2004).

97 GEF Biosafety Projects, UNEP-GEF Project on Development of National Biosafety Frameworks, begun on June 2001, list of 123 Participating Countries, as at 31 January 2004, available at:<http://www.unep.ch/biosafety/devcountries.htm> (Visited 12 May 2004) (Exhibit 50).

98 All of the countries taking part in the project must have either signed or ratified the Cartagena Protocol, or must provide written assurance that the country intends to become a party to the Protocol no later than the date of the completion of the activities foreseen in the project and that concrete steps have been initiated for this purpose, UNEP-GEF, 4 *Biosafety Newsletter* , June (2003) (Exhibit EC-51).

99 *UNIDO / Biosafety Information Network and Advisory Service (BINAS)*, "Voluntary Code of Conduct for the Release of Organisms into the Environment", available at at <http://binas.unido.org/binas/regulations/unido_codes.pdf> (Visited 12 May 2004). (Exhibit 52).

100 <http://binas.unido.org/binas/home.php> (Visited 12 May 2004).

(f) OECD

126. The OECD has provided an international forum for exchange of views and development of expert consensus on modern biotechnology since its first general report in 1982. The work of its Group of National Experts on Safety in Biotechnology led to a "Blue Book" and the Council Recommendation of 16 July 1986. Addressing standards for laboratory research on GMOs (at the time, no field studies had yet commenced, let alone commercial growing) the Blue Book made several recommendations about information sharing, good practice (especially GILSP – good industrial large-scale practice), the importance of public understanding, and the value of continuing research.

127. In the beginning of the 1990s, the Group of National Experts on Safety in Biotechnology worked on developing concepts and principles for the safety evaluation of foods derived by modern biotechnology. With the aim of achieving regulatory harmonisation, work at the OECD has continued, in particular in the production of a series of over 30 "Consensus Documents", under the aegis of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, and (complementing it) the Task Force for the Safety of Novel Foods and Feeds. This continues to review the evolving challenges and needs, arising from continuing technical progress, new products, and safety assessment issues such as the application of "substantial equivalence", feasibility of post-market surveillance, or the ways in which "other relevant factors" (e.g. socio-economic and ethical) are taken into account.

128. In May 2000, reports on their work were prepared by the Working Group and the Task Force for the Okinawa meeting of the G8 summit: these documents were approved (after heavy debate) by the OECD Council for this purpose.[101] In collaboration with UNIDO the OECD has developed valued databanks such as BioTrack Online (for data on products, field trials, regulatory developments,

[101] Report of the Task Force for the Safety of Novel Foods and Feeds, document available at <http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/C(2000)86-ADD1> (Visited 12 May 2004) (Exhibit CDA-7); Report of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology, document available at

documentation) and BINAS and maintains a valued website to ensure availability and diffusion of its work.

(g) Regional intergovernmental organizations

i) Association of South East Asian Nations (ASEAN)

129. In 1999, the 21st Meeting of ASEAN Ministers for Agriculture and Forestry agreed on Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms (GMOs). [102] The Guidelines provide a common framework for assessment of risks of agriculture related GMOs to human health and the environment and scientific basis for decisions relating to the release of agriculture-related GMOs in ASEAN Member Countries. The Guidelines are not legally binding and do not take precedence over national legislation.

ii) *African Union*

130. In 2003 the Executive Council of the African Union adopted a decision on Africa-wide capacity-building in biosafety which, *inter* alia, urges member states of the Union to use the African Law on Biosafety as the basis for drafting their national legal instruments on biosafety, taking into account national circumstances.[103]

<http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/C(2000)86-ADD2> (Visited 12 May 2004). (Exhibit EC-53).

[102] 21st Meeting of the ASEAN Ministers for Agriculture and Forestry, "ASEAN guidelines on risk assessment of agriculture-related genetically modified organisms (GMOs)", 28-29 October, 1999, Bandar Seri Begawan, available at <http://www.aseansec.org/6226.htm> (Visited 12 May 2004) (Exhibit EC-54).

[103] Executive Council of African Union, Decision EX/CL/Dec26(III), Decision on the Report of the Interim Chairperson of the Africa-wide Capacity-building in Biosafety (EX/CL/31(III). The relevant part of the decision states that the Executive Council "urges member states, in abiding by the provisions of the Cartagena protocol, to use the African Model Law in Biosafety prepared by the AU Commission, as a basis for drafting their national legal instruments in Biosafety, taking into account their national peculiarities, in order to create a harmonized Africa-wide space and system in Biosafety for the regulation of Genetically Modified Organisms movement, transportation and importation into Africa", available at www.africa-union.org. The African Model Law provides, *inter alia*, for the evaluation of direct and indirect, short, medium and long-term risk to the environment, biological diversity or human health, including socio-economic conditions or to ethical values arising from GMOs. (Exhibit EC-55)

5. Conclusion

131. As has been seen in this section, national regulatory approaches to GMOs, while varying in a number of aspects, generally have in common that they require pre-market notification, risk assessment and approval. With the adoption of the Biosafety Protocol, the international Community has adopted binding rules on trade in GMOs. At the same time international consensus has been established on certain issues of risk assessment and risk management, and on the role of the precautionary principle in decision-making. Against this background the European Communities submits that it is not plausible to argue that GM products are – or should be treated as – equivalent to non-GM products.

C. EC Regulatory Framework

132. This section describes in overview the regulatory approach adopted by the European Communities on GMOs, in the context of the developing scientific understanding and international regulatory developments as described above. It also describes the administrative and judicial remedies which are available to individual applicants at the national and Community levels, to the extent that they wish to challenge an act or failure to act of the national or Community authorities.

133. As early as the mid-1980's the European Communities established a general policy approach to GMOs, following the recommendations of the OECD[104] to put in place a regulatory regime that would ensure that decisions on GMOs were adopted on a case by case basis.[105] The objectives of the initial regime were to ensure a harmonised approach in the internal market, while guaranteeing a high level of protection of human health and the environment.[106]

134. Alongside the regulatory framework, the European Communities has also provided significant research funding in the field of biotechnology, amounting to 4 billion euros since 1982. Of this amount over 70 million euro has been dedicated to

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104 Reference above Section B.4 (f).

105 See Communication de la Commission au Conseil "Un Cadre Communautaire pour la Reglementation de la Biotechnologie", COM(1986)0573 (Exhibit EC-56).

106 *Ibid.*

research on the potential effects of GMOs on human health and the environment. In the most recent phase of research funding (2002-2006), a project specifically on the safety of GM foods (ENTRANSFOOD)[107] has been funded with 12 million.

135. The Commission presented an initial proposal for a regulatory framework in 1988. This was modified in 1989[108] and followed by the adoption of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release of genetically modified organisms (hereinafter "Directive 90/220").[109] This Directive concerned the release into the environment and the placing on the market of GMOs.[110] As an instrument of so-called "horizontal" legislation it applied to all GMOs across all sectors.

136. As described in greater detail below, it soon became apparent that Directive 90/220 did not address all the issues raised by growing scientific understanding as to the potential effects of GMOs, and the need to accommodate differing approaches to the subject of their regulation which existed amongst the various Member States. The Directive was reviewed and it was concluded that it was necessary to put in place stricter provisions in a number of respects. The revision let to the adoption, in 2001, of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[111] (hereinafter "Directive 2001/18").

137. Early on, the horizontal legislation was complemented by sectoral instruments addressing specific products containing or produced from GMOs. Thus, medicinal products containing or produced from GMOs were addressed by a Regulation on

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107 The final report on this project will come out in June.

108 The proposal are published in the OJ of the EC N° C 198 of 28.07.1988, pp.6 and 19, and N° C 246 of 27.09.1989. (Exhibit EC-57)

109 Published in OJ of the EC N° 117 of 08.05.1990, p.15. (Exhibit US-25).

110 A second Directive adopted on the same day, specifically covers the so-called "contained use" of GMOs, i.e. use of genetically modified micro-organisms for research and industrial purposes under circumstances limiting the contact of these organisms with the public and the environment, see Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms, published in OJ of the EC N° L 117 of 08.05.1990, p.1. (Exhibit EC-58)

111 Published in OJ of the EC N° L 106 of 17.04.2001, p.1. (Exhibit US-24)

pharmaceutical products adopted in 1993.[112] Food containing or derived from GMOs was addressed by Regulation (EC) N° 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (hereinafter "Regulation 258/97").[113]

138. Directive 90/220 and its successor, Directive 2001/18, as well as Regulation 258/97 are described in more detail below, as they provide the legal framework applicable to the individual notifications and safeguard measures which are the subject of the present proceedings. Where reference is made in this submission to all of these legislative instruments taken together, the European Communities will use the expression "EC GMO legislation."

139. Additional legislative instruments have been introduced more recently through new horizontal legislation dealing specifically with labelling and traceability and further sectoral legislation now specifically covering GM food and feed. These new legal instruments are described only very briefly as they are not relevant to the present proceedings.

1. Release into the environment – Directives 90/220 and 2001/18

140. This section describes the system for the authorisation of GMOs as it generally applies, both under the earlier Directive 90/220 and its successor Directive 2001/18. This sub-section will refer to these instruments as the "Directives." The next section will explain in more detail the particular issues that were identified in the application of Directive 90/220 which gave rise to its replacement.

141. It is important to recognise that under Community law once a GM product has been authorised to be placed on the market in one Member State it is free to be used in all 25 Member States. The European Communities therefore has established an authorisation system which permits all Member States to contribute to the authorisation process, and for the system to take into account the markedly

[112] Regulation (EEC) N° 2309/93 of the Council of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, published in OJ of the EC N° 214 of 24.08.1993, p.1. (Exhibit EC-59)

[113] Published in OJ of the EC N° 43 of 14.02.1997, p. 1. (Exhibit US-26)

different ecosystems which pertain in the various Members States, as well as differences in agricultural practices and in public perceptions and attitudes. A harmonised system of decision-making necessarily adds a degree of complexity to the authorisation process.

(a) General description of the approval system

142. The legislation provides for the approximation of the laws of the EU Member States and pursues the objectives of protecting human health and the environment. These are related but distinct objectives. The objective of protecting the environment is a broad one, having regard to the potential impacts of GMOs on biodiversity. The objective of environmental protection is thus not the same as the protection of animal or plant life or health, which is far narrower in scope.

143. To achieve its objectives the Directives require a case by case evaluation of the potential risks to human health and the environment before any GMO or product consisting of or containing GMOs, can be placed on the market or in any other way released into the environment within the Community. On the basis of that risk assessment (which is called "environmental risk assessment" comprising both risks to human health and the environment) a market authorisation is either granted or refused.

144. A distinction is made between release for any purpose other than placing on the market, which is subject of Part B of the Directives, and placing on the market of GMOs as or in products, which is subject of Part C of the Directives. In essence Part B concerns the research and development stage of GMOs in field trials, whereas Part C concerns mainly marketing.

145. As the present dispute concerns issues of the application of the consent procedure under Part C, it is only this procedure which is summarised below.

146. The consent procedure under Part C applies to the placing on the market of GMOs as or in a product. It does not apply to GMOs authorised under the provisions of

certain sectoral legislation, as for example Regulations (EEC) N° 2309/93 and N° 258/97 mentioned above.

147. The consent given in accordance with the Directive is valid for the entire Community and enables the GMO to be marketed afterwards anywhere in the territory of the Community. Therefore the procedure is organised in different stages allowing for the full participation of national authorities and Community bodies.

148. Any person intending to market a GMO must first submit an application (called "notification") to the competent national authority of the Member State where the product is to be first placed on the market. The application must include a risk assessment which has to be carried out by the notifier and must contain other information specified in the legislation.[114]

149. The competent authority which has received the notification must undertake an assessment of the potential adverse effects on human health and the environment. It is required to prepare, in principle within a delay of 90 days, an opinion (now called *"*Assessment report*"*[115]) indicating whether the GMO should or should not be placed on the market. During the preparation of this report the authority may address reasoned requests for additional information to the notifier.

150. If the competent authority concludes that consent cannot be granted, it rejects the application and the procedure is ended (without prejudice to the possibility for administrative or judicial review of such a decision in accordance with the national law applicable to the authority). If it concludes that consent should be granted, the procedure moves on to the Community level: the competent authority submits the notification together with the report to the Commission, which forwards it to the competent authorities of all the other Member States.

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[114] Note that the obligatory content of notifications has been updated by Directive 2001/18 in comparison to Directive 90/220/EEC.

[115] Note that the concept of an "Assessment Report" did not explicitly exist under Directive 90/220/EEC which provided for the establishment of a dossier containing a "favourable opinion" of the competent authority.

151. All competent authorities and the Commission may then within a deadline of normally 60 days, ask for further information, make comments or present reasoned objections to the placing on the market of the GMO in question.

152. If there are no objections from other Member States or the Commission, the competent authority that carried out the original evaluation grants the consent for the placing on the market of the product. The product may then be placed on the market throughout the European Union in conformity with any conditions required in that consent.

153. If objections are raised and maintained, a decision has to be taken at the Community level. The Commission submits a draft decision to a Committee – the so-called "Regulatory Committee" – which is composed of representatives of Member States for opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the decision. If not, the proposal for a decision is submitted to the Council for adoption by qualified majority or rejection, also by qualified majority. If the Council does not act within 3 months, the Commission can adopt the decision. In the case of a favourable decision by the Community the competent authority of the Member State which prepared the Assessment Report shall give the consent and inform the notifier, the other Member States and the Commission.

154. As pointed out above, the consent given is valid throughout the Community. But the legislation contains a safeguard clause which enables Member States, acting under specified conditions, to prohibit provisionally the marketing within their territory of GMOs for which consent had been given.[116] A final decision on whether or not the safeguard measure can be maintained is to be taken at Community level. Thus, the decision by a Member State to adopt a safeguard measure triggers a procedure that brings the case once again up to Community level. The Member State has to inform the Commission and the other Member States giving reasons for its action. The decision is taken by the Commission if the Regulatory Committee composed of representatives of Member States gives a

[116] Note that the conditions and procedures have been spelled out in more detail under Directive 2001/18 as compared to Directive 90/220.

favourable opinion. If not, a proposal for a Decision is submitted to the Council of Ministers for adoption by qualified majority or rejection, also by qualified majority. If the Council does not act within 3 months, the Commission can adopt the decision.

(b) Necessary adaptations – towards stricter rules under Directive 2001/18

155. Under Directive 90/220, altogether 18 products were granted final consent.[117] From the mid-1990s onwards, however, it became apparent that Directive 90/220 did not address all the issues raised by new scientific understandings and the regulatory developments which were taking place at the international level. These developments indicated a pressing need to revise the Community legislation.

156. The experience of the first years of Directive 90/220 revealed that the different competent authorities at Member State level had different conceptions of the risk assessment to be undertaken. These differing conceptions that moved and evolved in parallel with - and with the same degree of controversy as - the scientific debate of these years. To a large extent the debate also focused on the need to put in place mechanisms to ensure monitoring of the long term effects of GMOs, including on biodiversity, on the face of scientific uncertainty. Directive 90/220 did not include common/harmonised criteria on the risk assessment to be performed and did not provide for any post-market surveillance measures.

157. These issues directly affected some of the pending applications as a number of Member States made it clear that they were not in a position to vote in favour of granting market authorisations for individual products without these issues being addressed first. As seen above, the Biosafety Protocol addresses both these issues in some detail, setting out the basic requirements of a risk assessment and providing for "monitoring the living modified organism in the receiving environment". It is therefore clear that the concerns which led the European Communities to replace its legislation were shared by the international Community.

[117] See Exhibit CDA-34.

158. The Commission presented a proposal which was published on 4 May 1998. Given the complexities of the subject its adoption took a further three years, requiring the draft to proceed through the legislative process of the "co-decision" procedure by the Council and the European Parliament. Co-decision involves several rounds of reading in the respective bodies and, as a last resort, a reading in a conciliation committee. The draft Directive went through all these stages before it was finally adopted on the 12 March 2001.

159. The new Directive provides for a number of important changes compared to Directive 90/220. In particular, the new Directive provides for a detailed set of principles (see Annex II of Directive 2001/18) which the competent authorities are to take as a guidance when performing the environmental risk assessment (see also Annex VI which contains guidelines for the assessment reports). In addition, there are a number of provisions ensuring post-marketing surveillance, namely traceability requirements including labelling (see Article 4(6) and Annex IV) and obligations regarding the setting up of a monitoring plan (see Article 20 and Annex VII).

160. Directives under Community law are legislative acts that need to be implemented through national legislation by the EU Member States (by contrast, regulations are directly applicable in national law and do not require any implementation act). Directive 2001/18 provided for an implementation period of 18 months, requiring all the Member States to have adopted implementing national legislation by 17 October 2002.

161. Directive 2001/18 also directly addressed the issue of pending applications, providing that these would be subject to the new requirements. Notifiers had the possibility of complementing their pending dossiers (to conform to the new requirements) before the 17 January 2003.[118] Article 35(1) of Directive 2001/18 provides that

[118] See Article 35 of Directive 2001/18.

> Notifications concerning placing on the market of GMOs as or in products received pursued to Directive 90/222/EEC, and in respect of which the procedures of that Directive have not been completed by 17 October 2002 shall be subject to the provisions of this Directive.

162. Some notifiers availed themselves of this possibility, whereas others chose not to re-submit their applications. These latter applications were, therefore, considered to be withdrawn.

163. Currently, there are 22 pending applications under Directive 2001/18. Section D below provides a detailed overview.

2. Marketing of GM Food – Regulation 258/97

164. Until the adoption of specific sectoral rules, to the extent that GM food consisted of or contained GMOs was covered by Directive 90/220. GM food derived from GMOs but no longer consisting of or containing them could be marketed freely.[119]

165. The initiative to adopt specific legislation on (all) GM foods must be seen in the broader context of the food safety debate within the European Communities, including the issues associated with "mad cow" disease. When, in 1992, the Commission presented its proposal for a regulation covering novel foods in general, it did so in reaction to the massive arrival on the market of new food products produced in all sorts of ways, including genetic modification. These new food products had raised serious public concerns regarding their safety and nutritional value.

166. The Commission's proposal of 1992 was modified in 1994.[120] It then had to go through the above described legislative process of "co-decision" by the Council and the European Parliament. It was only in 1997 that the regulation could finally be adopted.

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119 Genetically modified tomato puree, for example, was put on the market.

120 Published in OJ n° C 190 of 29.07.1992, p.3 and OJ N° C 16, 19.01.1994, p.10. (Exhibit EC-60)

167. There follows a general description of the approval system as established under Regulation 258/97. A second sub-section provides an overview of the application of Regulation 258/97 since its entry into force.

(a) Description of the approval system

168. Regulation 258/97 entered into force on 15 May 1997. By contrast to Directives 90/220 and 2001/18, as a Regulation the legislative instrument did not require implementation through national legislation. It was immediately and directly applicable as law in all of the Member States.

169. According to its preamble, the main objectives of Regulation 258/97 are the functioning of the internal market within the Community and protection of public health.

170. The Regulation sets out rules for the authorisation and labelling of novel foods, including food products containing, consisting or produced from GMOs. As the present dispute concerns issues linked to the authorisation of food products containing, consisting or produced from GMOs (hereafter "GM foods"), it is only the authorisation procedure for GM foods which is summarised below.

171. The authorization procedure is slightly different from the procedure used for the release into the environment of GMOs described above. The basic rule is similar. In general, the authorization of GM foods is either a one-step process, if all Member States agree with the initial assessment carried out by the concerned Member State, or a two-step process if one or more Member States have objections. The procedure begins with an initial assessment, and may proceed to a Community decision in certain circumstances. Certain GM foods may benefit from a simplified procedure.

172. The person responsible for placing a GM food on the Community market for the first time (called "the applicant" in the Regulation), must first submit a request to the Member State where the product is to be first placed on the market and copy this request to the Commission. This request must contain certain information and

include material which demonstrates the compliance of the product with the following criteria: (1) that the food does not present a danger for the consumer; (2) that it does not mislead the consumer and (3) that it does not differ from foods or food ingredients which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous to the consumer.[121] In addition, where the food contains or consists of a GMO, the application must be accompanied with the information requested under Directive 90/220/EEC (now Directive 2001/18/EC).

173. After the Member State has accepted a request it must ensure that an initial assessment is conducted. To that end, following notification from the Member State, the Commission forwards to the other Member States the summary provided by the applicant and the name of the competent food assessment body that will be conducting the initial assessment.

174. The competent food assessment body completes the initial assessment report, within three months of receipt of a request containing the necessary information and in accordance with the Commission's published recommendations.[122] It then decides whether or not the food or food ingredient requires additional assessment. Where necessary the time limit is suspended for the time needed by the applicant to supplement the information as requested by the competent food assessment body.

175. The Member State concerned will then forward the report of the competent food assessment body to the Commission, which in turn forwards it to the Member States. Within a period of sixty days from the date of circulation of the initial assessment report by the Commission, a Member State or the Commission may make comments or present a reasoned objection to the marketing, the presentation or the labelling of the food. Comments or objections[123] must be forwarded to the

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121 See Articles 6(1) and 3(1) of Regulation 258/97.

122 Commission Recommendation of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. (Exhibit US-26)

123 It must be noted that an objection triggers a Community decision in respect of authorization, whereas comments do not.

Commission, which has to circulate them to Member States within the period of sixty days.

176. Where an additional assessment is not required and no reasoned objection has been presented, the concerned Member State informs the applicant that he may place the food on the market.

177. If objections are raised or an additional assessment is necessary, a decision has to be taken at Community level. If the objections raised relate to public health, as well as when an additional assessment is necessary, the Commission requires a scientific opinion from the Scientific Committee for Food (hereinafter "SCF"); since the entry of application of Regulation of Regulation (EC) No 178/2002, the tasks of the SCF have been entrusted to the European Food Safety Authority (hereinafter "EFSA"). The Commission then submits a draft decision to a Regulatory Committee composed of representatives of all Member States for opinion. If the Regulatory Committee delivers a favourable opinion by qualified majority, the Commission adopts the decision. If not, the proposal for a decision is submitted to the Council for adoption by qualified majority or rejection. If the Council does not act within 3 months, the Commission can adopt the decision. The Commission must inform the applicant of the decision taken, which will be published in the Official Journal of the European Communities.

178. Concerning products which are produced from (but do not contain) GMOs and that are considered to be "substantially equivalent" to existing foods or food ingredients, a simplified procedure applies.[124] The applicant notifies the Commission that the competent body of a Member State has established that the product is "substantially equivalent" to an existing food or food ingredient on the market. The Commission forwards a copy of that notification to Member States within 60 days that the product may be placed on the market.

179. The authorization for placing on the market is valid throughout the Community. Article 12 of the Regulation contains a safeguard clause, which enables under certain conditions Member States to temporarily restrict or suspend the marketing

[124] See Article 5 of Regulation 258/97.

within their territory. If that is the case, a Community procedure is triggered just as in the case of the above described Directives. The Member State has to inform the Commission and the other Member States giving reasons for its decision, and a decision is taken after consultation of EFSA.[125] The decision is taken by the Commission in accordance with the "Regulatory Committee" procedure described above. The Member State's restriction or suspension may remain in force only until a Commission's decision has been adopted and entered into force.

(b) Overview of application of Regulation 258/97

180. Since its entry into force, thirteen GM food products have been placed on the market in accordance with Regulation 258/97. All of these have benefited from the application of the simplified procedure (based on "substantial equivalence") described above.[126]

181. A total of nine product applications are still pending under the authorisation procedure. Of these, three are still pending at the level of the competent national authority, requests for additional information having delayed the assessment process. Six applications have reached the Community level and are currently being assessed either by the other competent authorities or by the EFSA committee. One product, NK 603, is currently going through the "Regulatory Committee" procedure described above. Finally, a decision on the authorisation of one product, Bt 11 sweet maize, is expected before the end of May this year.

3. Recent legislative changes

182. For the purposes of completeness it is appropriate to describe the latest legislative developments within the Community.

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125 Given that a safeguard clause can only be invoked in situations of risk to human health or environment, the Commission in light of *Article 11* of the Regulation must consult the EFSA, which succeeded the previous Scientific Committees (including the Scientific Committee for Food).

126 Exhibit CDA-25.

183. Regulation 258/97, as regards its application to GM food, in the meantime, has been replaced by new legislation (it still remains applicable to other novel food).[127] This new legislation was adopted in the summer of 2003. It covers GM food and feed. The authorisation procedure remains essentially the same as described above. The simplified procedure in light of the international debate on the concept of substantial equivalence,[128] has been abandoned.

184. In addition, a new instrument of "horizontal" legislation has been adopted covering labelling and traceability provisions for all products containing or consisting of GMOs irrespective of their use (i.e. food and feed as well as release into the environment) with the exception of medicinal products.[129] As regards the release into the environment, these new rules do not address the substantive requirements which are relevant to the present proceedings under Directive 2001/18.

4. Administrative and judicial remedies under Community and national law

185. To the extent that the applicants for authorisations under Directives 90/220 and 2001/18 and Regulation 258/97 are dissatisfied with any act or failure to act of the national authority of a Member State or of a Community institution they are free to bring proceedings for administrative or judicial review of such acts. In respect of the 43 products which are the subject of these WTO proceedings the European Communities is aware of proceedings brought in respect of national measures (safeguard provisions) only in the case of Italy. No applications have been made to the European Court of Justice challenging any actions or alleged failure to act of the Community institutions in respect of any of the products.

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127 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, published in OJ n° L 268, 18/10/2003, p.1. (Exhibit CDA-20)

128 See above Section B.2 (b)(i) Fn. 59.

129 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, published in OJ n° L 268, 18/10/2003, p. 24. (Exhibit CDA-30)

(a) Legal proceedings before national courts and administrative bodies

186. The law of each Member State provides for administrative and/or judicial review of acts or omissions relating to the application, at the national level, of Directives 90/220 and 2001/18 and Regulation 258/97. The Complainants make no reference to the availability of these national proceedings, or to cases which have been brought and which are pending.[130] Nor do the Complainants make any allegation that the national proceedings are, in some way, inadequate or ineffective.

187. Such national cases as have been brought are taking their course. By way of example, on 13 November 2000 Monsanto Agricoltura Italia SpA and others brought proceedings before the Italian courts challenging the validity of the Italian Decree of 4 August 2000 temporarily suspending trade in and use of certain novel foods within Italy (issued pursuant to Article 12 of Regulation 258/97), and seeking compensation for loss claimed to result from the Decree. The subject matter of that challenge before the national courts, which is still pending, is now addressed in these proceedings by the United States[131]. In its first written submission, the United States fails to mention that the Italian court referred various questions to the European Court of Justice (hereinafter "ECJ") for a preliminary ruling (under Article 234 of the EC Treaty). On 9 September 2003 the ECJ gave its judgment in Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others.*[132] The Court ruled on a number of important points, clarifying the interpretation of Regulations 258/97.

188. First, interpreting regulation 258/97 the ECJ held that "the mere presence in novel foods of residues of transgenic protein at certain levels does not preclude those foods from being considered substantially equivalent to existing foods", but that that was "not the case where the existence of a risk of potentially dangerous effects on human health can be identified on the basis of the scientific knowledge available

130 See e.g. Case C-6/99, *Association Greenpeace France and Others v Ministere de Agriculture et de la Peche and Others*, 2000 ECR I-1651, in which the ECJ provided an authoritative interpretation of parts of Council Directive 90/220 on a preliminary reference from France's Conseil d'Etat.

131 See first written submission of the United States, paras. 62 and 163.

132 Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* 2003 ECR I-0000 [not yet published] (Exhibit EC-61).

at the time of the initial assessment. It is for the national court to determine whether that condition is satisfied". The question of whether such a risk existed was for the national court in Italy to decide, and that matter is now pending before the Italian court.

189. Second, the ECJ ruled that Italy was entitled to adopt safeguards under Article 12 of Regulation No 258/97 even where the simplified procedure was being used, and that such measures "can be adopted only if the Member State has first carried out a risk assessment which is as complete as possible given the particular circumstances of the individual case, from which it is apparent that, in the light of the precautionary principle, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer, in accordance with the first indent of Article 3(1) of Regulation No 258/97". That issue of fact is for the Italian courts to decide, and the matter has now been referred back to the Italian court, where it is pending.

190. Third, the ECJ made it clear (Judgment, para. 112) that "protective measures may be taken pursuant to Article 12 of Regulation No 258/97 interpreted in the light of the precautionary principle even if it proves impossible to carry out as full a risk assessment as possible in the particular circumstances of a given case because of the inadequate nature of the available scientific data (see to that effect *Pfizer Animal Health v Council*, cited above, paragraphs 160 and 162, and *Alpharma v Council*, cited above, paragraphs 173 and 175)."

191. The ECJ has therefore provided important clarifications as to the meaning and effect of Article 12 (safeguards) of Regulation 258/97. These will now be applied by the Italian courts to the particular facts of the case. It will be noted that (a) the ECJ treated the issues on a case-by-case basis, (b) was not presented with any arguments as to the existence of a Community-wide "moratorium", and (c) did not identify the existence of any such moratorium. The approach taken by the ECJ is directly relevant to all the other national measures which are the subject of these proceedings, and sets out the standards to be applied by national courts in reviewing decisions under Regulation 258/97 (and, by analogy) Directives 90/220 and 2001/18).

(b) Direct actions before the ECJ

192. Under Articles 230 and 232 of the EC Treaty the European Court of Justice has jurisdiction to review the legality of acts of certain EC institutions, including the European Commission. Procedures under these provisions may be available to challenge acts and omissions alleged by the Complainants in relation to Directives 90/220 and 2001/18, as well as Regulation 258/97.

193. No legal proceedings have been brought at the ECJ by any of the individual applicants in respect of alleged acts or omissions of the Community institutions which are now the subject of these WTO proceedings. Since the EC regulatory framework is not itself being challenged, the better forum for resolving many of the issues raised by the Complainants is that which is available at the ECJ. It is not the function of the WTO DSU to replace legal remedies which are available within the European Communities in respect of individual acts or omissions concerning the implementation of the Communities' regulatory system where that system is not *per se* the subject of challenge for WTO incompatibility.

194. The question of the available administrative and judicial remedies under Community and national law is raised here as a purely factual matter. It will not be followed up by a claim that Complainants ought to have respected some rule of "exhaustion of local remedies". The fact that recourse may be had by individual operators to the procedures and remedies available to them may be a valid factual element for the Panel to take into account when contemplating its proper role in a dispute such as this, where – as will be demonstrated below – the complaints relate sometimes to small, discrete steps in the approval procedures to be followed by national and Community authorities and where Complainants sometimes seem more intent that the Panel enforce Community law than WTO law.[133].

5. Conclusion

195. The European Communities, like many other regulators around the world, has been faced with the challenge of designing and adjusting its regulatory approach to

GMOs keeping pace with the constant evolution of the scientific and regulatory debate. The European Communities acted prudently by completing (Regulation 258/97), adapting (Regulation 2001/18) and again completing (the recent legislation on traceability and labelling) its legislation. This legislation inevitably took quite some time to be completed in the light of the serious social and political debate on the issues linked to GMO and GM food production, not only in the European Communities, but also elsewhere. Other countries at this time often went through the same adaptation of their GMO legislation or enacted such legislation for the first time. The legislation and its implementation at Member State level is subject to full range of recourses and remedies that is normally applicable at Community and Member State level, thus giving private operators all possible avenues to have their rights respected.

D. Individual Product Applications[134]

196. In the following section the European Communities will provide a detailed account on each of the forty-three applications listed by the Complainants in their requests for the establishment of a panel. To complete the picture it will also provide a brief overview of those applications which were not mentioned by the Complainants.

197. As will be immediately apparent from this account, there has never been a "general suspension" and the individual applications have not been stalled at any moment. The evaluation processes have continued through these years with the competent authorities trying to take account of the changing legislative and regulatory framework as well as the evolving scientific debate in treating the pending applications.

198. Thus, whilst in some cases applications have progressed steadily from Member States level to Community level, in others long, in-depth discussions have taken place between the lead competent authority and the notifier on a number of scientific issues that were not appropriately addressed in the original application,

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133 First submission of Argentina, para. 195.

134 The European Communities will use the term "applications" when referring to both the notifications made under Directives 90/220 and 2001/18 and the requests made under Regulation 258/97.

thus retarding the passage to Community level. In other cases, these discussions have taken place at Community level, before and/or after the opinion of the European Communities' scientific committees, among the competent authorities of the various Member States. Furthermore, an important number of applications have been withdrawn by the respective companies because of various commercial reasons and changes in strategies. No single pattern can, however, be identified and each single product has merited and merits an analysis on its own.

199. Also the production side of this market has evolved substantially over the last decade. Mergers, acquisitions, transfers of production rights have taken place often and at a very fast pace, changing often the protagonists of the applications in the course of the procedure and ending up by concentrating in few large multinationals most of the products at issue. The European Communities will try to give an account of this evolution in relation to the specific applications so as to render the chronologies of the facts more readable.

200. As a matter of convenience, the European Communities presents hereunder just brief summaries of each application process. More detailed chronologies for each application are provided as Exhibits. Each chronology is accompanied by all documents which the European Communities considers most relevant to understanding the issues and problems of each dossier. The European Communities stands ready to supplement these Exhibits, should the Panel wish to receive any further documents mentioned in, but not annexed to, the chronologies.

1. The notifications for release into the environment

201. The following will describe the individual applications for release into the environment, as they have been listed by the Complainants.

(a) Pending notifications

i) Bayer oilseed rape (FALCON GS40/90) – C/DE/96/05[135]

202. Falcon GS40/90pHoe6/AC Oilseed Rape is a winter crop genetically modified to be tolerant for glufosinate-ammonium herbicides.[136] AgrEvo, a company incorporated in Germany[137], submitted a notification for this product for import and cultivation in Germany in May 1996. The notification dossier was incomplete, which led to a number of exchanges of letters between the lead Competent Authority (hereinafter "CA") and the notifier. After having received additional information, the lead CA forwarded the dossier with its positive opinion to the Commission in November 1996.

203. The dossier was circulated to the other Member States in November 1996. Several Member States requested additional information related to molecular characterisation[138] and compositional analysis.[139] Eight Member States raised objections based on grounds of insufficient molecular characterisation, long-term ecological effects of the use of the herbicide, insufficient data on substantial equivalence and labelling.

204. In February 1998 the Commission requested the opinion of the Scientific Committee for Plants (hereinafter "SCP"). The SCP after having requested some

135 See detailed chronology, (Exhibit EC-62).

136 The product consists of inbred lines of the winter oilseed rape (Brassica napus) transformant Falcon GS 40/90 which has been transformed using plasmid pHoe6/Ac containing a synthetic *pat* gene coding for phosphinotricin acetyltransferase under the regulation of 35S promoter and terminator sequences from Cauliflower Mosaic Virus. The product includes any progeny derived from crosses of Falcon GS 40/90 with any traditionally bred oilseed rape. The notifier markets a glufosinate-ammonium herbicide under the trade mark "Liberty Link".

137 AgrEvo was established in 1994 in Germany, when two German producers of chemicals and pharmaceuticals, Hoechst and Schering, merged their crop protection divisions into a new joint venture. In 1996, AgrEvo acquired Plant Genetic Systems (see, infra Section III.D.2.(a) (ii)). In 1999, AgrEvo's majority shareholder, Hoechst, merged with the French pharmaceutical and chemical company Rhône-Poulenc to become Aventis. As a result, AgrEvo and Rhône-Poulenc Agro were combined into Aventis CropScience. Aventis CropScience was bought in 2001 by the German limited liability company Bayer A.G., which created Bayer CropScience. Bayer CropScience is the second largest agrochemical company in the world (it owns the trademark of the herbicide LibertyLink), with an annual turnover of about 30 billion Euro.

138 Molecular Characterisation refers to verifying that the gene inserted corresponds to the real nucleotid sequence foreseen in the gencetic manipulation.Verification involves analysis of the regional borders of the insert, which are called southern and northern blot

additional information from the notifier assessed the dossier on the basis of the criteria set out in Annex II B of Directive 90/220 and issued its opinion in July 1998. It concluded that on the basis of the existing information and of the available knowledge, there was no evidence to indicate that the placing on the market of this product with the purpose to be used as any other oilseed rape was likely to cause adverse effects on human health and the environment. However, the SCP was also of the opinion that it was necessary to develop:

> (i) an agreed code of practice for field management of the particular modified crop involving the active participation of the notifier to promote best practice by farmers.
>
> (ii) a research programme with an agreed design and implementation plan to detect the occurrence and the establishment of herbicide tolerant volunteers and weeds under field conditions in the European Communities.

205. Following the opinion of the SCP, the notifier and the lead CA entered into discussion about a structured stewardship and monitoring programme which went on well into the spring of 1999.

206. In the summer of 1999, in view of the proposed modification of the legislation, and on the basis of the Common Position the Council adopted on it,[140] the notifier voluntarily committed to anticipate in its notification a number of the additional requirements that the proposed modifications were meant to address. Thus, in what was called the "interim approach", the notifier submitted undertakings and commitments on a number of issues including post-market monitoring, traceability and labelling and an updated environmental risk assessment. These commitments and undertakings were extensively discussed by the lead CA, other Member States' CAs and the Commission in a series of meetings. There were several requests for additional information and clarifications on these commitments but also still on issues of molecular characterisation. Exchanges of letters between the lead CA and the notifier went well into late spring of 2002.

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139 Compositional analysis refers to the chemical composition and metabolism properties of the plant.

140 A Common Position is a document adopted by the Council after the first reading of the co-decision procedure if there remains disagreement with amendments proposed by the Parliament in its first reading, see Article 251(2) of the EC Treaty.

207. In view of the impending entry into force of Directive 2001/18, the notifier prepared and up-dated dossier and submitted it in January 2003.

208. The dossier is still pending at the Member State level as the lead CA has requested additional information on molecular characterisation and on the post-marketing monitoring plan. While the former was submitted in October 2003, the lead CA is still awaiting the latter.

ii) Bayer hybrid oilseed rape (MS8/RF3) – C/BE/96/01[141]

209. MS8/RF3 is a spring variety of oilseed rape genetically modified to introduce a pollination control system (hybrid system), linked to an herbicide tolerant trait (to glufosinate-ammonium). Plant Genetic Systems (hereinafter "PGS")[142] submitted to the Belgian authorities a notification for importation, cultivation, and use in food, feed and industrial processing of this product in September 1996. After a positive assessment of the notification, the lead CA transmitted the dossier to the European Commission in January 1997.

210. The dossier was circulated to the Member States in January 1997. Eleven Member States raised objections on grounds related mainly to outcrossing and weed management and monitoring, compositional analysis, molecular characterisation and insufficient labelling. Some Member States requested additional data. In order to address these objections and requests, meetings were held between the CAs of the Member States and the notifier and an intense exchange of correspondence went on until the end of 1997.

211. The Commission requested the opinion of the SCP in January 1998. The SCP, after having addressed a number of questions to the notifier, assessed the dossier on the basis of the criteria set out in Annex II B of Directive 90/220. In its opinion of 19 May 1998, it concluded, on the basis of the existing information and of the

141 See detailed chronology, (Exhibit EC-63).

142 PGS was established in 1982 by a group of researchers from the University of Gent, Belgium. These scientists were among the first in the world in 1983 to develop a genetically modified plant. PGS was the developer and owner of GM products in the area of weed control (LibertyLink), insect control

available knowledge, that there was no evidence to indicate that the placing on the market of this product with the purpose to be used as any other swede rape is likely to cause adverse effects on human health and the environment. However, the SCP was also of the opinion that:

> 2. … the potential transfer of the herbicide resistance gene to wild Brassica relatives is a new issue in Europe in view of the limited scale of release to date. The Committee has examined the available evidence from monitoring and research programmes to date. After evaluating all the information available to the Committee, it was concluded that herbicide-tolerant volunteers that may appear would be canola plants and not wild Brassica relatives. Such herbicide-tolerant volunteers could be controlled in subsequent crops by conventional agricultural methods. The Committee recommends that the introduction of herbicide-tolerant crops should be accompanied by:
>
> i) an agreed code of practice for the particular modified crop involving the active participation of the notifier to promote best practice by farmers.
>
> ii) a monitoring programme with an agreed design and implementation plan to detect the occurrence and the establishment of herbicide-tolerant volunteers and weeds under field conditions in the European Communities.
>
> The Committee should approve the code of practices and the design and implementation plans. The Committee should also be kept informed of the results of monitoring and research studies in Member States. This process will serve to identify and assess the longer term implications of any gene transfer between transgenic oilseed rape and wild relatives under commercial scale conditions.

212. Following the opinion of the SCP, the notifier entered in discussions with the lead CA on proposals to fulfil the SCP recommendations. In particular, discussions on a safety approach and a stewardship plan for post-marketing guidance and monitoring went on until March 1999. In this context, the notifier also submitted additional information. In the meantime, the European Communities' internal procedures for authorisation were proceeding.

213. In the summer of 1999, in view of the proposed modification of the legislation, and on the basis of the Common Position the Council adopted on it, the notifier

(StarLink), and hybrid breeding (SeedLink). PGS was bought by AgrEvo in 1996 (see, above, the company's description in Section III.D.2.(a)(i)).

voluntarily committed to anticipate in its notification a number of the additional requirements that the proposed modifications were meant to address. Thus, in what was called the "interim approach", the notifier submitted undertakings and commitments on a number of issues including post-market monitoring, traceability and labelling. These commitments and undertakings, and in particular the monitoring plans, were extensively discussed by the lead CA, other Member States' CAs and the Commission in a series of meetings with and letters to and from the notifier until well into 2002.

214. By then, Directive 2001/18 had been approved and it was decided to continue the evaluation of the dossier under the old legislative regime, provided the provisions of the new Directive are taken into account by the notifier voluntary and become legally binding. In this context, the lead CA solicited the notifier to complete the dossier with required data on, *inter alia*, reference material concerning the events MS8 and RF3. The request was made in February 2002 and received no reply over the year.

215. In January 2003, the notifier re-submitted an up-dated notification in accordance with the new legislation. After having requested and obtained additional information on, *inter alia*, the conditions for placing on the market and the proposal for packaging, in line with the requirements of Directive 2001/18, the lead CA has submitted the full application to the Commission on 2nd February 2004. At present, the deadline for comments and objections by the CAs of the other Member States is running.

iii) Trifolium/Monsanto/Danisco Roundup Ready fodder beat (A5/15) – C/DK/97/01[143]

216. Roundup Ready fodder beet is a crop genetically modified to be herbicide resistant (glyphosate).[144] A notification for this product for cultivation and animal feed was

143 See detailed chronology, (Exhibit EC-64).

144 The product consists of fodder beet (*Beta vulgaris* L. sp. *vulgaris*) transformed using the *Agrobacterium tumefaciens* vector system based on plasmid pMON17204 to introduce the *cp*4 *epsps* gene (derived from *Agrobacterium* sp. strain CP4) into fodder beet. Transformed line A5/15 tolerant to glyphosate expresses only one new protein CP4 EPSPS (5- enolpyruvylshikimate-3-phosphate

introduced in Denmark in February 1997 jointly by DLF Trifolium, Monsanto and Danisco[145]. The lead CA discussed a number of concerns with the notifier relating mainly to compositional analysis and molecular characterisation. After having received additional information, the lead CA forwarded the dossier with its positive opinion to the Commission in October 1997.

217. The dossier was circulated to the Member States in October 1997. Ten Member States raised objections on grounds relating mainly to molecular characterisation, compositional analysis, weed management and monitoring, with some requesting additional data. Additional information relating to the objections was submitted by the notifier in a series of letters between January 1998 and February 2000.

218. The Commission requested the opinion of the SCP in March 1998, which was issued in June 1998. The SCP after having assessed the dossier on the basis of the criteria set out in Annex II B of Directive 90/220, stated the following:

> The Committee, after examining and considering the existing information and data provided in the dossier against the background of available knowledge in the areas concerned, considers that there is no evidence indicating that the use of the fodder beet tolerant to glyphosate with the purpose to be used as any other fodder beet is likely to cause any adverse effects on human health and the environment.
>
> 2. The Committee was also of the opinion that the notifiers should establish a detailed code of practice and work closely with growers to ensure Good Agricultural Practice which should minimise the spread of herbicide tolerance. The Scientific Committee wishes to be kept informed of progress in this area.

219. Following the opinion of the SCP the notifier entered into discussions with the lead CA on a proposal for a code of practice throughout 1998 and also continued to

synthase) which is tolerant to glyphosate and thereby confers tolerance to Roundup Ready® herbicide on the fodder beet.

145 DLF-Trifolium is a company incorporated in Denmark, leader in plant breeding, and in production and marketing of seeds. Monsanto Company is incorporated in the United States but acts in the European Communities through Monsanto Europe S.A., which is incorporated under the law of Belgium. Monsanto Company is the world leader of biotech crops. In 2003, around 90% of the acres planted with GM crops worldwide contained Monsanto traits. Monsanto is also the third largest agrochemical company in the world and it owns the trademark of the herbicide Roundup Ready. Its net sales in 2003 amounted to about 5 billions dollars. Danisco is a food company incorporated in Denmark.

submit additional information relating to the comments/objections of the Member States (up until February 2000).

220. In the summer of 1999, in view of the proposed modification of the legislation, and on the basis of the Common Position the Council adopted on it, the notifier voluntarily committed to anticipate in its notification a number of additional requirements that meant to address. Thus, in what was called the "interim approach" the notifier submitted undertakings and commitments on a number of issues including public consultation, precautionary approach, specificity of European eco-systems, post-market monitoring and traceability. These commitments and undertakings were extensively discussed in a series of meetings with and letters to and from the notifier until well into 2002. By then, the entry into force of Directive 2001/18 was impending, so that it was decided to await the impending entry into force.

221. In accordance with the new legislation, the notifier re-submitted an up-dated notification in January 2003. In line with the new requirements under Directive 2001/18 the lead CA has requested additional information on detection and validation methods and on certain issues regarding the environmental risk assessment as well as the monitoring plan. This information has not been provided in full as yet. Therefore, the dossier is still pending at the national level.

iv) Monsanto Bt Cotton (531) – C/ES/96/02[146]

222. Bt Cotton (531) is a cotton line genetically modified with an insecticidal activity against lepidopteran insect pests.[147] Monsanto Europe S.A., on behalf of Monsanto, submitted to the Spanish authorities a notification for cultivation and marketing of this product in December 1996. The lead CA requested a number of studies mentioned in the dossier. After having received additional information and after a

146 See detailed chronology, (Exhibit EC-65).

147 The product consists of cotton (*Gossypium hirsutum*) cultivar Coker 312, which has been transformed using plasmid PV-GHBK04. The transgenic line produced is called IPC 531, and expresses the *cry1A(c)* gene (origin: *Bacillus thuringiensis* subsp. *kurstaki*) which encodes a modified *CRYA(c) B.t.k.* protein.

positive assessment by the National Commission on Biosafety, the lead CA forwarded the dossier to the Commission in November 1997.

223. The dossier was circulated to the Member States in December 1997. Nine Member States raised objections or had comments on issues related mainly to toxicity, compositional analysis, molecular characterisation and antibiotic marker gene.

224. The Commission requested the opinion of the SCP in April 1998. The SCP, after having requested additional data from the notifier, assessed the dossier on the basis of the criteria set out in Annex II B of Directive 90/220. In its opinion of 14 July 1998, it concluded, on the basis of the existing information and of the available knowledge, that:

> 1. The Committee, after examining and considering the existing information and data provided in the dossier, against the background of available knowledge in the areas concerned, considers that there is no evidence to indicate that the placing on the market of line IPC 531 (expressing a *B.t.k.* toxin) with the purpose to be used as any other cotton is likely to cause adverse effects on human health and on the environment.
>
> 2. The Committee was also of the opinion that the proposed plan for risk management with regard to *B.t.k.* endotoxin resistance provides an adequate framework to delay the onset of such resistance in the target pests. The Scientific Committee on Plants should be kept informed of monitored progress in the field.

225. Following the opinion of the SCP, the notifier entered in discussions with some CAs on an insect-resistance management plan and on rat feeding. In the meantime, the European Communities' internal procedures for authorisation were proceeding.

226. In the summer of 1999, the Council adopted a Common Position on the proposed modification of the GMOs legislation. This was meant to address a number of concerns arisen since the adoption of the legislation in force, such as post-market monitoring, safety assessment, traceability and labelling. Monsanto submitted information covering some of these new concerns in July 2001 and February 2002.

227. By then, Directive 2001/18 had been approved and in January 2003 the notifier re-submitted an up-dated notification in accordance with the new legislation.

228. At present the dossier is pending at Member State level as the lead CA is still awaiting additional information on the post marketing monitoring plan that it has requested with letters of August and September 2003.

v) Monsanto Roundup Ready cotton (RRC1445) – C/ES/97/01[148]

229. Roundup Ready cotton (RRC1445) is a cotton line genetically modified to be tolerant to glyphosate, the Roundup Ready herbicide.[149] Monsanto Europe S.A., on behalf of Monsanto, submitted to the Spanish authorities a notification for cultivation and marketing of this product in June 1997. After having requested and obtained by Monsanto amendments to the notification regarding labelling, the lead CA forwarded the dossier to the Commission in November 1997.

230. The dossier was circulated to the Member States in December 1997. Eight Member States raised objections or had comments on issues related mainly to compositional analysis, molecular characterisation, antibiotic marker gene, safety and long-term effects on the environment.

231. The Commission requested the opinion of the SCP in April 1998. The SCP, after having requested additional data from the notifier, assessed the dossier on the basis of the criteria set out in Annex II B of Directive 90/220. In its opinion of 14 July 1998, it concluded that:

> The Committee, after examining and considering the existing information and data provided in the dossier, against the background of available knowledge in the areas concerned, considers that there is no evidence to indicate that the placing on the market of line RRC 1445 (expressing the CP4 EPSPS enzyme) with the purpose to be used as any other cotton is likely to cause adverse effects on human health and the environment.

148 See detailed chronology, (Exhibit EC-66).

149 The product consists of cotton (*Gossypium hirsutum*) cultivar Coker 312 , which has been transformed using plasmid PV-GHGT07. The transgenic line produced, called RRC line 1445, expresses the 5-enolpyruvylshikimate-3-phosphate synthase protein (CP4 EPSPS). This protein is encoded by the *cp4 epsps* gene (origin: *Agrobacterium* strain CP4).

232. Following the opinion of the SCP, the notifier entered in discussions with the lead CA on rat feeding. In the meantime, the European Communities' internal procedures for authorisation were proceeding.

233. In the summer of 1999, the Council adopted a Common Position on the proposed modification of the GMOs legislation. This was meant to address a number of concerns arisen since the adoption of the legislation in force, such as post-market monitoring, safety assessment, traceability and labelling.

234. In October 2002, Directive 2001/18 entered into force and in January 2003 the notifier re-submitted an up-dated notification in accordance with the new legislation. At present the dossier is pending at Member State level as the lead CA is still awaiting additional information on the post marketing monitoring plan that it has requested with letters of August and September 2003.

vi) Amylogene Starch potato - C/SE/96/3501[150]

235. The genetically modified potato developed by the company Amylogene[151] has increased starch content.[152] Amylogene filed a notification in 1996 in Sweden for cultivation, industrial use of starch and feeding. The competent authority considered the notification to be incomplete (as did actually Amylogene itself). The constitution of a complete dossier took almost two years. When the dossier was finally in a state to be considered as complete, the lead CA immediately issued its statement and sent it, along with the dossier to the Commission.

236. The dossier was circulated the other Member States in June 1998. Many Member States filed comments and requested additional information. Five Member States raised objections. These were based on the lack of sufficient data on molecular

150 See detailed chronology, (Exhibit EC-67).

151 Amylogene is a Swedish company, owned by two other Swedish companies, starch manufacturer Lyckeby Starkelsen and plant breeders Svalof Weibull AB.

152 Potato line EH92-527-1 is derived from cultivar Prevalent by genetic modification. The genetic modification involves antisense inhibition of the gene encoding granule bound starch synthase protein (gbss) which is responsible for amylose biosynthesis. The starch produced has little or no amylose and consists of branched amylopectin, which modifies the physical properties of the starch.

characterisation and compositional analysis, the possibility of crossing with weedy relatives and concerns about the antibiotic marker genes in the product.

237. The Commission requested the opinion of the SCP in September 1998. The SCP took more than three and a half years to consider this dossier, making altogether nine different requests for additional information. The SCP's concerns were mainly related to an antibiotic resistance marker that encoded a so-called ORF4 protein. The SCP requested additional data on this protein which could provide resistance to a chemotherapeutic used in cancer treatment. Only once it was satisfied with the data provided did the SCP issue its opinion, which was in July 2002. The Committee was of the opinion that the placing on the market of potato clone EH92-527-1, for use in cultivation and starch production was not likely to cause adverse effects on human health and the environment.

238. As the entry into force of Directive 2001/18 was impending by then, it was clear that the dossier had to be re-submitted under the new legislation. The notifier filed its up-dated notification in January 2003. After clarifying a number of issues on the up-dated risk assessment and the proposed monitoring plan, the lead CA completed its assessment and forwarded the dossier to the Commission in April 2004. The notification has been circulated to other competent authorities for comments or objections.

vii) Bayer winter oilseed rape (Liberator pHoe6/AC) – C/D/98/06[153]

239. Liberator pHoe6/AC is a winter oilseed rape genetically modified to be herbicide resistant (glufosinate-ammonium).[154] In January 1998, AgrEvo[155] submitted a notification with the scope of import and cultivation to the German authority. The

153 See detailed chronology, (Exhibit EC-68).

154 The product consists of inbred lines of the winter oilseed rape (*Brassica napus*) transformant Liberator pHoe6/Ac which has been transformed using plasmid pHoe6/Ac containing a synthetic *pat* gene coding for phosphinotricin acetyltransferase, derived from the bacterium *Streptomyces viridochromogenes* strain Tu 494 under the regulation of the 35S promoter and a terminator sequence from Cauliflower Mosaic Virus (CaMV). The transformation event is coded Liberator pHoe 6/Ac. The product will be Liberator pHoe6/Ac and its progeny produced by conventional breeding techniques.

155 See, above, the company's description in Section III.D.2.(a)(i).

lead CA requested additional information and clarifications before considering the dossier to be complete and submitted the dossier along with its statement to the Commission in late October 1998.

240. The full dossier was circulated to the other Member States in December 1998 and January 1999. A number of Member States made comments and requested additional information and eight raised formal objections. These were based mainly on the insufficiency of data on molecular characterisation and compositional analysis and the insufficient evaluation of long term environmental effects.

241. The Commission requested the opinion of the SCP in August 1999. The SCP put several questions to the notifier, the replies to which came in successively over the year 2000. In November 2000, the SCP issued its opinion. It found that there was no evidence to indicate that the placing on the market of the Liberator oilseed rape with the purpose of being used as any other oilseed rape was likely to cause adverse effects on human or animal health and the environment. However, in line with its previous opinions on other herbicide tolerant oilseed rape applications, the SCP recommended:

> (i) an agreed code of practice for field management of the particular modified crop involving the active participation of the notifier to promote best practice by farmers.
>
> ii) a research programme with an agreed design and implementation plan to detect the occurrence and the establishment of herbicide tolerant volunteers and weeds under field conditions in the European Communities.

242. Contrary to what it had done in the parallel dossier on Falcon Oilseed Rape (see above) the notifier did not present any proposal for a code of practice following the opinion of the SCP. Indeed it did not manifest itself at all with the lead CA. Since the dossier remained pending, the lead CA, in November 2002 sent a letter to the notifier reminding it that the dossier would have to be up-dated by January 2003.

243. The notifier submitted an up-dated dossier in January 2003. The lead CA requested additional information on molecular characterisation and on the post marketing monitoring plan. While the former was submitted in October 2003, the lead CA is still awaiting the latter.

viii) Syngenta[156] glufosinate tolerant and Bt resistant (Bt-11) corn (stack) – C/F/96/05-10[157]

244. Maize line "BT11"[158] is genetically modified to confer insect resistance to certain lepidopteran pests. Hilleshög N.K.[159] submitted a notification for this product[160] in France in June 1996. The scope of the notification covered marketing of the product for all types of use, like any other variety of conventional maize, and in particular for its cultivation within the European Communities.[161]

245. The French CA requested further additional information on substantial equivalence analysis, on the absence of use of the herbicide on the plants, on the absence of allergenicity of the truncated synthetic CryIA(b) protein, on the environmental risk assessment, on insect resistance management, on the molecular characterisation of

156 Syngenta is a limited liability company incorporated in Switzerland. Syngenta was founded in the year 2000 as the result of the merger of the two companies, the Swiss Novartis Agribusiness and the British Zeneca Agrichemical. Novartis A.G. had been created just four years earlier from the merger of two other Swiss companies, Ciba (formerly Ciba-Geigy) and Sandoz. Zeneca Agrochemicals was one of the constituent parts of AstraZeneca, which also owned a 50% share of the Dutch/British seed company Advanta and, as 1997, the whole of Mogen, a Dutch plant biotechnology small-to-medium company. Syngenta, with net sales of 6.6 billion dollars in 2003, is the third largest seed company and the third largest biotech company world wide.

157 See detailed chronology, (Exhibit EC-69).

158 "BT11" maize line was obtained through shot gun transformation of one elite line, using plasmid pZO1502 DNA, after restriction enzyme digestion of the plasmid DNA to separate the genes of interest from the ampicillin gene carried by its backbone. The BT11 line contains a synthetic and truncated *cry*IA (b) gene (*Btk*) under the control of the 35S Cauliflower Mosaic Virus (CaMV) promoter, an intron from the alcohol dehydrogenase 1S gene from maize, and the NOS terminator from *Agrobacterium tumefaciens*. It contains also as a selectable marker gene conferring tolerance to the herbicide glufosinate ammonium, the *pat* gene from *Streptomyces viridochromogenes* under the control of the CaMV promoter, an intron from the alcohol dehydrogenase 1S gene from maize, and the NOS terminator from *Agrobacterium tumefaciens*.

159 Hilleshög N.K., Sandoz Seeds, was a company incorporated in Sweden and part of Novartis SA, when it was created in 1996 from the merger of Ciba and Sandoz.

160 The product consists of maize seeds and grains from line BT11 and all progeny (inbred or hybrid) derived from that line and the varieties obtained by traditional varietal selection methods.

161 Separate notifications relating to the same genetically modified maize BT11 line, for different uses, were submitted as follows during the same period. In 1996, the company Northrup King submitted in the United Kingdom a notification (C/UK/96/M4/1) for the placing on the market of that same product, for the purpose of import of grains, and processing. The SCP issued a favourable opinion on this application in February 1998, and the Commission Decision 98/292/EC to authorize the import of BT11 for food uses and for processing was adopted in April 1998, and published in May 1998. In June 1998, the product was authorised to be placed on the market for these uses, by the issuance of the final consent by the UK. (see overview in Exhibit CDA-34) In February 1998, Novartis notified the placing on the market of all processed products derived from this BT11 maize for direct food uses, under Article 5 of Regulation (EC) 258/97 (Exhibit CDA.-25). In May 1998, a second application for the cultivation of the same genetically modified BT11 maize was submitted by Novartis Seeds SA in Spain (notification C/ES/98/02), which was subsequently withdrawn in 1999, see below under (b) (iv).

the BT11 line, on the absence of the antibiotic resistance gene in the genetically modified maize, and on the experimental data used by the notifier to reach its conclusions. This request led to a number of exchanges between the notifier, the lead CA and the French advisory Committee throughout 1996, and 1997 and went on until the end of 1998.

246. In December 1998, after several submissions of additional information and updates of the original application by Hilleshög N.K., the French advisory Committee, the "Commission du Génie Biomoléculaire", issued its favourable opinion on notification C/F/96/05-10, and the notification was submitted to the Commission by the lead CA with its positive recommendation in April 1999.

247. The dossier was circulated to the other Member States in May 1999. Several Member States requested additional information in order to be able to finalise their assessment of this dossier, related to the use of the herbicide, ecological effects on non target organisms, insect resistance management and monitoring, feed safety, and labelling. Eight Member States raised objections on grounds of insufficient information provided by the notifier to appropriately address their request for further information.

248. The Commission then requested the opinion of the SCP. The SCP requested additional information from the notifier, which were submitted until October 2000, and, on the basis of the updated information, assessed the dossier following the criteria set out in Annex II B of Directive 90/220/EEC. It adopted its final opinion in November 2000, concluding that :

> "The Committee is of the opinion that there is no evidence to indicate that the placing on the market for cultivation purposes of maize line *Bt-11* and varieties derived from this line by conventional crossing with maize lines other than genetically modified ones, is likely to cause adverse effects on human health and the environment."

249. The SCP noted also that :

> The development of resistance in injurious target pests will be delayed by the rigorous adoption of a comprehensive resistance management strategy.

> The SCP published an opinion on 4 March 1999 on resistance monitoring (…) as developed by the Expert Group on Monitoring for Insect Resistance to Bt-toxins. Such monitoring should be carried out in Bt-maize and should provide an adequate framework to delay the onset of resistance in the target pest.
>
> The SCP should be kept informed of the results of monitoring and research studies in Member States with particular regard to the development of insect resistance.

250. On the basis of the SCP opinion, further discussions were held between the lead CA, the notifier and the Commission to appropriately implement the post-marketing monitoring, also in light of the new legislation, Directive 2001/18 that had been adopted by then. This issue was extensively discussed by all Member States' CAs and the Commission in a series of meetings with and letters to and from the notifier well into 2002.

251. In this context, the notifier also submitted additional information on this application, including supplementary sequence information on the molecular characterisation of the BT11 line, until may 2002, in order to anticipate the entry into force of Directive 2001/18/EC and to take into account the provisions of the new Directive, *inter alia* on monitoring, traceability and labelling, reference material for detection methods.

252. In January 2003, the notifier submitted to the lead CA a further package of consolidated information to update the notification following article 35 of Directive 2001/18/EC. That new information was assessed from February to May by the lead CA and, on the basis of a favourable opinion of the French competent advisory Committees the lead CA submitted the updated application to the Commission in June 2003, confirming its original positive recommendation to place that product on the market for cultivation in the European Communities. The updated notification was circulated to all Member States CAs in July.

253. Ten Member States requested further information and raised reasoned objections, on *inter alia*, the implementation of the monitoring plan and general surveillance, on the effects on non target organisms, on herbicide use and labelling, on coexistence, on detection and identification. Further information was submitted by

the notifier in January this year, to address these objections, and a meeting between all CAs, the Commission and the notifier was held in February with the aim of arriving at an agreement. Several Member States maintained their reasoned objections at the end of the consultation period, and on that basis, the Commission requested in March the opinion of the EFSA, which is due in June.

ix) Monsanto Roundup Ready oilseed rape (GT73) – C/NL/98/11[162]

254. GT 73 is an oilseed rape genetically modified to be herbicide-resistant (glyphosate).[163] Monsanto submitted a notification for import and feed and industrial processing in 1998 in the Netherlands. The lead CA requested additional information on molecular characterisation and on certain feed safety aspects. Exchanges with Monsanto on this issue went on over the year 2000.

255. After the adoption of Directive 2001/18 the lead CA asked Monsanto to provide information on a detection method as required under the new legislation. Monsanto requested confidentiality status for the information to be provided. The lead CA initially did not accept the reasons provided for requesting that status and several letters exchanged on the issue. The lead CA also so-called requested reference material[164] which, again, triggered a debate on confidentiality. These issues were only settled in the fall of 2002. As Directive 2001/18 had entered into force by then, the lead CA and Monsanto worked on up-dating the notification according to the new legislation.

256. Monsanto submitted the up-dated notification in January 2003 and the lead CA forwarded it together with its assessment report to the Community level almost

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162 See detailed chronology, (Exhibit EC-70).

163 The oilseed rape was genetically modified with two genes encoding proteins conferring glyphosate tolerance. One of the proteins is glyphosate tolerant 5-enolpryuvylshikimate-3-phosphate synthase from *Agrobacterium sp.* Strain CP4 (CP4 EPSPS). The EPSPS activity is needed ofr the biosynthesis of aromatic amino acids in plants and micro-organisms; the plant enzyme is usually sensitive to glyphosate, thereby causing the plant to be killed by the herbicide. The second protein is glyphosate oxioreductase (GOX) which acts by breaking down glyphosate.

164 Reference material (RM) : material or substance, one or more of whose property values are sufficiently homogenous and well established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

immediately. The dossier was circulated to all Member States in January. A few Member States requested additional information and six Member States raised objections. The objections related to issues of molecular characterisation (insufficient data), the monitoring plan, allergenicity as well as traceability and labelling.

257. Meetings were held with Monsanto to settle these issues and Monsanto provided additional information. In October 2003 the Commission requested the opinion of the EFSA Scientific Panel on GMOs. In February 2004, the Scientific Panel issued its opinion in which it concluded:

> Having considered the evidence, the GMO Panel is of the opinion that GT 73 oilseed rape is as safe as conventional oilseed rape for humans and animals, and, in the context of its proposed use, the environment.

258. The Commission is currently preparing a proposal for a decision which it will present to the Regulatory Committee in June.

x) Bayer Liberty Link soybeans (A2704-12 and A5547-127) – C/BE/98/01[165]

259. The genetically modified soybean events A02704-12 and a5547-127 are derived from two different soybean cultivars, A2704 and A5547-127. The genetic modification aims at developing soybean tolerant for glufosinate-ammonium herbicides. This product was notified in Belgium by PGS[166] in September 1998. The notification concerned importation and use by processing industry.

260. The lead CA requested additional information on molecular characterisation, compositional analysis, toxicity, allergenicity, herbicide use, residue behaviour. Exchanges with the notifier on these issues went on well into 1999.

261. In September 1999, a notification for the same product was submitted in Portugal creating procedural problems. The assessment procedure in Belgium was stopped waiting for clarifications from the notifier, which confirmed the intention to

165 See detailed chronology, (Exhibit EC-71).

maintain the Belgian notification in December 2000. The approval process was resumed and the lead CA continued discussions with the notifier on pending issues.

262. The issue arose again in September 2001, as in the meantime the notifier had not withdrawn the notification in Portugal. The lead CA asked again the notifier for clarifications about the status of the double notification and explained to it that maintaining the notification in Portugal would have entailed the suspension of the evaluation process in Belgium. Aventis replied that it intended to maintain both concurrent notifications.

263. In January 2003, the notifier re-submitted an up-dated notification in accordance with Directive 2001/18 and finally withdrew its application in Portugal. The lead CA restarted its evaluation and requested the supply of both the information which was still missing and new information now required under the new legislation. Bayer gave a preliminary informal reply in March 2003. The lead CA is currently awaiting for the completion of the dossier.

xi) Bayer Liberty Link oilseed rape (T45 X Topas 19/2) (stack) - C/GB/99/M5/2[167]

264. "T45 X Topas 19/2" is an oilseed rape genetically modified to be resistant to the herbicide glufosinate ammonium.[168] AgrEvo[169] submitted a notification for import, use in feed and industrial processing in the UK in 1999. The UK CA requested some additional information and after having received that information forwarded the dossier for a preliminary view to its scientific committee, the Advisory Committee on Releases to the Environment (ACRE). The ACRE found that the dossier not only showed inconsistent data on molecular characterisation but was also generally "rather impenetrable." The ACRE, therefore, instructed its

166 See, above, the company's description in Section III.D.2.(a)(ii).

167 See detailed chronology, (Exhibit EC-72).

168 The product consists of spring oilseed rape (*Brassica napus*) transformant T45 which has been transformed using plasmid pHOE4Ac(II) containing a synthetic *pat* gene coding for phosphinotricin acetyltransferase, derived from the bacterium *Streptomyces viridochromogenes* under the regulation of the 35S promoter and a terminator sequence from Cauliflower Mosaic Virus (CaMV). The transformation event is coded T45. The product will be T45 and its progeny derived from traditional crossings with the line containing event T45.

169 See, above, the company's description in Section III.D.2.(a)(i).

secretariat to send the dossier back to AgrEvo for "substantial revision and clarification."

265. After that letter of December 1999, Bayer did not get back to the UK competent authority on this dossier for almost two years. Contact was only re-established towards the end of 2002 when Bayer inquired about what was needed to do to up-date the dossier under the new Directive 2001/18. The company did send some up-dated documents in January 2003, but not the full dossier. The lead CA requested completion of the up-dated notification and the company provided further data, which required further clarifications and led to the lead CA suggesting that the full dossier should be re-submitted. Bayer did so in March 2004 by withdrawing the pending notification and submitting a new notification a few days later. The new dossier is in the course of being assessed by the lead CA.

xii) Stoneville BXN cotton (10215, 10222) – C/ES/99/01[170]

266. Stoneville BXN cotton is derived from lines 10215 and 10222 of the recipient cultivar Coker 315, genetically modified to be tolerant to bromoxynil,[171] the active ingredient of Buctril, an herbicide whose trademark is owned by Bayer CropScience. In April 1999, Rhône Poulenc[172] submitted to the Spanish authorities a notification for production, importation, storage and processing of this product as well as all its derivatives.

267. The lead CA forwarded the dossier to its scientific committee, the National Biosafety Committee, which found that the dossier needed to be improved. A considerable amount of information was missing on issues such as compositional analysis, environmental impact, toxicity, nutritional analysis, and a number of points, such as scope, labelling proposal, etc., had to be clarified. The lead CA forwarded these comments to the notifier in July 1999.

170 See detailed chronology, (Exhibit EC-73).

171 BXN cotton lines 10215 and 10222 have been modified to be tolerant to broxynil by expression of the nitrilase protein isolated from *Klebsiella pneumoniae* Subs. *Ozaenae*.

172 See, above, the company's description in Section III.D.2.(a)(i).

268. After a first exchange of correspondence, the notifier did not get back to the Spanish CA for three years, until January 2003, when Bayer CropScience wrote to the lead CA to inform it that it had assigned this pending application to Stoneville Pedigreed Seed Company.[173] Stoneville Pedigreed Seed Company submitted an up-dated notification in accordance with Directive 2001/18 soon after.

269. The lead CA forwarded the dossier to the National Biosafety Committee, which found that there were deficiencies in the molecular characterisation of the product. The lead CA forwarded these comments to Stoneville Pedigreed Seed Company in October 2003. In November 2003, the lead CA has received a request for clarifications on the additional information requested by the National Biosafety Committee from Emergent Genetics Inc. The lead CA has provided these clarifications and has asked an explanation on the identity of the notifier. A response is still awaited.

xiii) Pioneer/Dow AgroSciences Bt corn Cry1F (1507) – C/NL/00/10[174]

270. Bt corn Cry1F (1507) consists of grain genetically modified to express Cry1F protein, conferring resistance to certain lepidopteran insect pests, and PAT protein, which confers tolerance to glufosinate-ammonium herbicide. This product was notified in November 2000 by Pioneer Overseas Company, representing Pioneer Hi-Bred International, Inc.. [175] and Mycogen Seeds, an affiliate of Dow AgroSciences LLC.[176] The scope of the notification covers import of this product

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173 Stoneville Pedigreed Seed Company is a company incorporated in the US. Stoneville is the second largest US seed breeder and the world leader of the cotton seed business.

174 See detailed chronology, (Exhibit EC-74).

175 Pioneer HI-Bred International, Inc., is a company incorporated under the law of Iowa, United States. It is one of the largest seed companies in the world and it is a subsidiary of DuPont, one of the biggest US agrobusiness company. In its dealing with the European Communities, Pioneer has been represented by Pioneer Overseas, a company incorporated under the law of Belgium.

176 Dow AgroScience is a company incorporated under the law of Indiana, United States, and a wholly-owned subsidiary of The Dow Chemical Company. Dow AgroScience began as a joint venture in 1989 between The Dow Chemical Company and Eli Lilly and Company that resulted in the creation of DowElanco. In 1997, The Dow Chemical Company acquired 100 percent of DowElanco, and the new wholly owned subsidiary was renamed Dow AgroSciences in 1998. That same year, The Dow Chemical Company purchased Mycogen Seeds and integrated it with Dow AgroSciences. Dow AgroSciences has continued to grow through mergers, acquisitions, and alliances. Dow

and use in processing and as food and feed. Cultivation of Bt corn Cry1F (1507) was, in fact, notified separately in Spain the year after.[177]

271. The Dutch CA requested further additional information on molecular characterisation, allergenicity and toxicity of CRY1F, labelling. Exchanges with the notifier on these issues went on until almost the end of 2002. In two instances, Pioneer required an extension of the time granted by the lead CA to submit further data or information.

272. In November 2002, just after the entry into force of Directive 2001/18, Pioneer updated the notification in line with the requirements of the new legislation. After a further exchange on compositional data, monitoring plan, confidentiality of detection method, the lead CA submitted the full application and its assessment report to the Commission in August 2003.

273. The Commission has circulated the application to the Member States and has received comments and objections from eight of them. These concern issues such as environmental effects, monitoring plan, molecular characterisation, sampling and detection methods, allergenicity and toxicity.

274. After a meeting organised with the competent authorities of the Member States and Pioneer, the Commission in February this year has forwarded the dossier to EFSA for an opinion, together with a summary of the remaining objections from seven Member States. An opinion of EFSA is awaited for later this summer.

xiv) Pioneer/Dow AgroSciences Bt corn Cry1F (1507) – C/ES/01/01[178]

275. As mentioned above, Bt corn Cry1F (1507), after having been notified in November 2000 in the Netherlands for import and use in processing and as food and feed, was also notified the year after in Spain for cultivation. Pioneer Overseas

AgroSciences has purchased Brazil Seeds and Cargill Hybrid Seeds. Dow AgroSciences produces herbicides and biotechnology products.

177 See, below, Section III.D.2(a)(xiv).

178 See detailed chronology, (Exhibit EC-75).

Company, representing Pioneer Hi-Bred International, Inc., and Mycogen Seeds submitted its notification in July 2001.

276. After a preliminary assessment by the Spanish scientific committee, the National Biosafety Committee, the lead CA requested further additional information on molecular characterisation, allergenicity and toxicity of CRY1F, environmental impact, monitoring plan. Exchanges with the notifier on these issues went on until the summer of 2003.

277. In the meantime, after the entry into force of Directive 2001/18, Pioneer updated the notification in line with the requirements of the new legislation. The lead CA submitted the full application and its assessment report to the Commission in August 2003.

278. The Commission circulated the application to the Member States and has received comments and objections from ten of them. These concern issues such as molecular characterisation, detection methods, non target organisms, monitoring plans, toxicity, allergenicity and agricultural practices. Pioneer has submitted further information in response to the comments and objections raised in March this year. Member States have had until 13 May to comment. In the meantime, a meeting between the lead competent authorities of the Member States and Pioneer has been organised by the Commission on 27 April.

xv) Monsanto Roundup Ready corn (NK603) – C/ES/00/01[179]

279. The product at issue here is a grain (*Zea mays*) derived from line NK603, genetically modified to become tolerant to glyphosate herbicide Roundup Ready.[180] Monsanto Europe S.A., on behalf of Monsanto, submitted a notification for this product in Spain in August 2000. The scope of the notification covered import and use, including animal feed.

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179 See detailed chronology, (Exhibit EC-76).

180 NK603 has been obtained by the introduction of a glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene fro *Agrobacterium* sp. Strain CP4 (CP4 CPSPS). The insertion of the genetic material was performed by particle acceleration technology with a *Mlu*I fragment,

280. After clarifications of various nature on the notification itself were requested submitted, the lead CA acknowledged receipt of the notification in January 2001. The National Biosafety Committee assessed the dossier and requested additional information on concerns such as molecular characterisation, nutritional composition, and environmental impact. Exchanges with the notifier on these issues went on until the summer of 2002.

281. In the fall of 2003, Monsanto updated the notification in line with the requirements of Directive 2001/18. The lead CA submitted the full application and its assessment report to the Commission in January 2003.

282. The Commission circulated the application to the Member States immediately afterwards and received comments and objections from ten of them. These concerned issues such as molecular characterisation, compositional analysis, toxicity and allergenicity, detection methods, reference material, monitoring plan, labelling. Monsanto submitted further information in response.

283. After a meeting organised with the competent authorities of the Member States and Monsanto, the Commission forwarded the dossier to EFSA for an opinion in September 2003, together with a summary of the remaining objections from two Member States. EFSA issued its opinion on 25 November 2003 and concluded:

> The Panel has considered information provided on (1) the molecular inserts within the transgenic event, (2) the chemical composition of the GM and non-GM maize, (3) the safety of the proteins expressed and (4) the potential for risks associated with any changes to the toxicological, allergenic and nutritional properties of NK603. Having considered the evidence, the GMO Panel is of the opinion that NK603 maize is as safe as conventional maize and therefore the placing on the market of NK603 maize for food or feed or processing is unlikely to have an adverse effect on human and animal health and, in that context, the environment.

284. Following the positive opinion rendered by EFSA, in February this year the Commission has presented a draft decision for market authorisation of the product to the Regulatory Committee. In the absence of a qualified majority vote in the

isolated in agarose gel from PV-ZMGT32L plasmid, used as a vector. This fragment contains two EPSPS gene for *Agrobacterium* sp. Strain CP4.

Committee, the Commission has presented its proposal for a decision authorising NK603 to the Council on 26 March. The Council's position on this draft decision is expected for late June.

(b) Notifications withdrawn

i) Bejo Zaden red-hearted chicory (RM3-3, RM3-4, RM3-6) – C/NL/94/25/A

285. The notification concerning red-hearted chicory (RM3-3, RM3-4, RM3-6)[181] was introduced in the Netherlands in 1996. After assessment at both national and European Community level, the notification was withdrawn by Bejo Zaden BV[182] by its letter of 1st of April 2003. Bejo Zaden has given two reasons for the withdrawal: first, the absence of a market for these products; and second, the fact that Bejo Zaden preferred not to be associated with GMOs any longer.[183]

ii) Monsanto Roundup Ready corn (GA21) – C/ES/98/01

286. The notification concerning Roundup Ready maize line GA21[184] was introduced in Spain in 1998. After assessment at both national and European Community level, the notification was withdrawn by Monsanto Agricultura Espana S.L., by its letter of 15th of September 2003. Monsanto has given three reasons for the withdrawal: first, the progress in the notification procedure of another Roundup Ready maize to a more advanced stage than the GA21 maize notification; second, the introduction of the new regulations concerning commercialisation of GM products in the

[181] The product consists of chicory (*Chicorium intybus* L.cv. *Radicchio Rosso*) lines RM3-3, RM3-4, RM3-6 and all the hybrids obtained from these lines with non-transgenic chicory.

[182] Bejo-Zaden B.V. is company incorporated in the Netherlands, which focuses entirely on the breeding, production, processing and sale of seeds.

[183] See Exhibit EC-77.

[184] Maize line GA21 has been developed to have tolerance to glyphosate (Roundup) herbicide and was produced by the introduction of a modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene from maize.

European Communities; and third, the change of the company's commercial priorities.[185]

iii) Monsanto Roundup Ready oilseed rape (GT73) – C/F/95/06/01

287. The notification concerning Roundup Ready oilseed rape GT73 was introduced in France in 1995. After discussions between the lead French CA and Monsanto Company, the notification was withdrawn by Monsanto with letter of 15th of January 2003. Monsanto Europe has given two reasons for the withdrawal: first, the prolonged inaction on the notification from the French Competent Authority; and second, the focus on the company's commercial activities placed outside European Communities.[186] The notification in France has been replaced by a new notification in the Netherlands (notification number C/NL/98/11).

iv) Syngenta Bt hybrid corn (Bt-11) – C/ES/98/02

288. The notification concerning Bt-11 maize[187] was introduced in Spain in 1998. After discussions between the lead Spanish CA and Novartis Seeds SA,[188] the notification was withdrawn by Novartis with letter of 20th of May 1999. As the reason for its withdrawal Novartis pointed out the existence of a parallel notification made in France (notification number C/F/96.05.10).[189]

v) Bayer Liberty Link soybeans (A2704-12 and A5547-127) – C/PT/99/01

289. A notification concerning Soya Liberty link was introduced in Portugal in 1999. After discussions between the lead Portugal CA and AgrEvo[190] Portugal, the notification was withdrawn by Bayer's letter of 27th of January 2003. In the

185 See Exhibit EC-78.
186 See Exhibit EC-79.
187 Genetically modified maize expressing insect resistance.
188 See, above, the company's description in Section III.D.2.(a)(viii).
189 See Exhibit EC-80.
190 See, above, the company's description in Section III.D.2.(a)(i).

justification for its withdrawal Bayer pointed to "various reasons".[191] As seen above the product had been previously notified in Belgium (C/BE/98/01) and the evaluation of that notification is ongoing.[192]

vi) Monsanto MaisGuard & Roundup Ready (MON810 & GA21) corn (stack) – C/ES/99/02

290. The notification concerning Roundup Ready maize line GA21 x MON 810[193] was introduced in Spain in 1999. After discussions between the lead Spanish CA and Monsanto Agricultura Espana S.L., the notification was withdrawn by Monsanto with letter of 15th of September 2003. Monsanto has given three reasons for the withdrawal: first, the progress in the procedure of another Roundup Ready maize to a more advanced stage than GA21 maize notification; second, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and third, the change of the company's commercial priorities.[194]

vii) Pioneer Bt corn (MON809) – C/F/95/12-01/B

291. The notification concerning insect resistant *Bt* maize line MON 809[195] was introduced in France in 1995 and circulated at the Community level. After assessment by the Scientific Committee for Plants, the notification was withdrawn by Pioneer Génétique SARL by its letter of 4th of October 2002. Pioneer has given no reasons for the withdrawal.[196]

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191 See Exhibit EC-81.

192 See above, Section III.D.2(a)(x).

193 These maize hybrids are also referred to as MaisGard/Roundup Ready maize. This maize comprises hybrid maize varieties that are produced by traditional breeding of two genetically modified parental inbred lines of maize, one being derived from transformation event GA21 and the second one derived from event MON 810.

194 See Exhibit EC-82.

195 Seeds of an insect-protected maize line MON809 and seeds of any progeny (inbreds or hybrids) derived from this line by conventional purposes. The insect-protected maize line was generated by particle acceleration technology using two plasmids; PV-ZMBK07 and PV-ZMGT10. The transgenic maize line produced expresses the *cry1A(b)* gene (origin - *Bacillus thuringiensis* subsp. *kurstaki*) which encodes a *cry1A(b)* insect control protein (*Btk*). The maize also expresses the CP4-EPSPS gene and protein (5-enoylpyruvylshikimate-3-P synthase) as a selectable marker for growth of transgenics on glyphosate.

196 See Exhibit EC-83.

viii) Zeneca extended shelf life tomato (TGT7-F) – C/ES/96/01

292. The notification concerning genetically modified tomatoes[197] was introduced in Spain in 1996 and circulated at the Community level. After assessment by the Scientific Committee for Plants, the notification was withdrawn by Syngenta[198] with its letter of 24th of September 2001. As the reason for its withdrawal, Syngenta pointed to "the commercial re-positioning" following the above mentioned merger.[199]

ix) Monsanto Roundup Ready corn (GA21) – C/GB/97/M3/2

293. The notification concerning Roundup Ready maize line GA21 was introduced in The United Kingdom in 1997. After discussions between the lead UK CA and Monsanto, the notification was withdrawn by Monsanto with letter of 29th of March 2001. As justification for its withdrawal, Monsanto pointed to "the unexpected commercial constraints" and the parallel notification in Spain.[200]

x) Pioneer Liberty Link and Bt (T25 & MON810) – C/NL/98/08

294. The notification concerning maize T25 x MON810[201] was introduced in the Netherlands in 1998 and circulated at the Community level. After assessment by the Scientific Committee for Plants, the notification was withdrawn by Pioneer Overseas Corporation by its letter of 12th of December 2002. In the justification for its withdrawal Pioneer pointed to "entirely commercial reasons".[202]

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197 The product consists of processing tomato (Lycopersicon esculentum subsp. Mill.) transformed using the Agrobacterium tumefaciens vector system based on the disarmed binary vector Bin 19 to introduce the partial sense polygalacturonase (PG) gene isolated from tomato.

198 See, above, the company's description in Section III.D.2.(a)(viii).

199 See Exhibit EC-84.

200 See Exhibit EC-85.

201 The product consists of maize T25xMON810 derived from conventional crosses. One inbred parent is derived from the progeny of line T25 (with increased tolerance to glufosinate ammonium-based herbicides due to the introduction of the *pat* gene from *Streptomyces viridochromogenes*). The other inbred parent is derived from the progeny of line MON810 (resistant to certain insect pests due to the introduction of the *cry1A(b)* gene of *Bacillus thuringiensis* subsp. *kurstaki*).

202 See Exhibit EC-86.

xi) Pioneer/Dupont high-oleic soybean (260-05) – C/NL/98/09

295. The notification concerning High Oleic Soybean sub line[203] was introduced in Netherlands in 1998. After discussions between the lead Dutch CA and Optimum Quality Grains L.L.C., the notification was withdrawn by Optimum with letter of 12th of December 2002. In the justification for its withdrawal Optimum pointed to "entirely commercial reasons".[204]

xii) Monsanto/Syngenta Roundup Ready sugar beet – C/BE/99/01

296. The notification concerning Roundup Ready sugar beet[205] was introduced in Belgium in 1998. After discussions between the lead Belgian CA on the one hand and Monsanto Europe SA and Syngenta Seeds SA on the other hand, the notification was withdrawn by both companies by their letter of 16th of April 2004. As the reason for their withdrawal, Monsanto and Syngenta pointed to their decision to stop any further development of the Roundup Ready sugar beet derived from event T9100152.[206]

xiii) AgrEvo Maize T14

297. The notification concerning maize T 14 was introduced in France in 1996. After discussions between the lead CA and AgrEvo, the notification was withdrawn by the company.

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203 The product is a subline derived from transformation event 260-05.

204 See Exhibit EC-87.

205 The product is seeds and plants of Roundup Ready sugar beet varieties (Beta vulgaris) and seeds and beet of any progeny derived from line T9100152 by conventional breeding.

206 See Exhibit EC-88.

(c) Products authorised

i) Bayer oilseed rape (MS1/RF1) – C/F/95/01A and Bayer hybrid oilseed rape (MS1/RF2) – C/F/95/01B

298. Oilseed rape MS1/RF1 and hybrid oilseed rape MS1/RF2 were notified by plant Genetic System to France in 1995 for cultivation, import and marketing and were approved at Community level by Commission decisions in June of 1997.[207]

(d) Unknown product application

i) Bayer Liberty Link sugar beet (T120-7)

299. The European Communities has no record of a notification of this product submitted to Denmark or to any other national competent authorities.

2. The requests under the novel food legislation

300. The following will describe the individual requests for food use under Regulation 258/97, as they have been listed by the Complainants.

(a) Pending requests

i) Monsanto Roundup Ready corn (GA21)[208]

301. "GA21 Roundup Ready corn" is a maize variety genetically modified to express tolerance to the herbicide glyphosate.[209] Monsanto submitted a request for food use of the product in the Netherlands in 1998. The dossier was pending at Member

[207] Commission Decision 97/392/EC of 06/06/1997 in OJ L164 of 21/06/1997, pag. 38 (Exhibit EC-89) and Commission Decision 97/393/EC of 06/06/1997 in OJ L164 of 21/06/1997, p. 40 (Exhibit EC-90).

[208] See detailed chronology, (Exhibit EC-91).

[209] Maize line GA21 was produced by the introduction of a modified 5-enolpyruvyl-shikimate-5-phosphate synthase (mEPSPS) gene from maize. EPSPS is an enzyme involved in the shikimic acid pathway for aromatic amino acid biosynthesis in plants and is normally inhibited by glyphosate.

State level for about a year and a half due to requests by the lead CA for completion of the dossier (missing references) and for additional scientific data.

302. The dossier came up to the Community level in January 2000 and was circulated by the COM to all other CAs. Many requested additional information and raised questions, several raised objections mainly on grounds of insufficient data on molecular characterisation and on compositional analysis (substantial equivalence).

303. In May 2000 the Commission requested the opinion of the Scientific Committee on Food (hereinafter the "SCF"). The SCF put requests for additional information to Monsanto related to substantial equivalence issues and to toxicity testing. The SCF finally issued its opinion February 2002. It concluded that

> Having reviewed all the information provided by the petitioner and in the light of current published scientific information it is concluded that from the point of view of consumer health maize grain from maize line GA21 and derived products that are the subject of this application are as safe as grain and derived products from conventional maize lines.

304. In view of the pending legislative proposal for "Food and Feed"[210] Monsanto, in June 2002 on a voluntary basis committed to providing detection and validation methods for its product in collaboration with the Commission's Joint Research Centre (JRC). The amount of data and material and the circumstances of their submission to the JRC had to be negotiated and laid down in an agreement, the conclusion of which took a considerable amount of time (February 2002). All the necessary data were received in proper condition in mid-September of 2003. The pre-validation study was initiated in October and could be concluded only after Monsanto delivered the full data set in the end of November. Some additional testing on the method and materials was carried out in early 2004 the collaborative study of method validation was launched on the 14/04/2004 and is foreseen to be finished by the end of June 2004.

[210] See above Section II.C.3.

ii) Syngenta Bt-11 sweet corn[211]

305. "Bt11 Sweet Corn" is a maize variety genetically modified to produce a toxin against certain insects that are pests for the plant.[212] Novartis submitted a request for food use of this product in the Netherlands in 1999. The Dutch CA requested additional information relating mainly to the antibiotic resistance marker used (PAT protein) and to the toxicity studies done in relation to this protein.

306. In May 2000 the Dutch CA sent its initial assessment report to the Commission who circulated it to all CAs. Four Member States raised objections and several more requested additional information, relating mainly to the above issues as well as to molecular characterisation.

307. The Commission requested the opinion of the SCF in December 2000. The SCF requested further data from Novartis, which Syngenta[213] only supplied in February 2002. The SCF issued its opinion in April 2002 stating that on the basis of the information supplied in the application and further material supplied by the applicant in response to queries raised by Member States and in the light of the published literature, it was to be concluded that Bt11 sweet maize was as safe for human food use as its conventional counterparts.

308. In view of the pending legislative proposal ("Food and Feed"), Syngenta, on a voluntary basis agreed to providing detection and validation methods for its product in collaboration with the Commission's Joint Research Centre (JRC). The amount of data and material and the circumstances of their submission to the JRC were agreed upon in a planning meeting in October 2002. Syngenta started sending data and reference material in the beginning of 2003. The first set of material was inadequate in terms of necessary amounts and the method provided by Syngenta

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211 See detailed chronology, (Exhibit EC-92).

212 Field maize of line Bt11 was transformed to produce a truncated form of the -endotoxin Cry1A(b) of *Bacillus thuringiensis* var. *kurstaki*. This trait confers resistance to several relevant insect pests of maize plants. As a selective marker for transformation, DNA encoding phosphinothricin acetyltransferase (PAT) was also introduced into line Bt11. This results in plants that detoxifythe herbicide glufosinate ammonium and thus resist its action. The transgene cassette was transferred from field maize to sweet maize by traditional breeding methods. Since both lines are derived from one transformation event, the applicant has supplied data derived from experiments on both field- and sweet maize.

213 See, above, the company's description in Section III.D.2.(a)(viii).

performed very poorly in a pre-validation study. Syngenta delivered a proper method and all the necessary materials only by July 2003. The JRC finalised the validation method in October 2003. Throughout the validation process, intensive contact, in which JRC assisted Syngenta through emails and telephone conferences, was maintained.

309. Following the finalisation of the validation method the Commission prepared a proposal for a decision on a market authorisation. The proposal has not obtained a qualified majority in the Regulatory Committee as well as in the Council and is now scheduled to be adopted by the Commission on 19 May.

iii) Bayer Liberty Link soybeans[214]

310. Liberty link soybean is a soy crop tolerant to glufosinate ammonium herbicide.[215] The application was made by PGS[216] with the Belgian CA in February 1999. The European Commission gave notice of the Belgian application to all other Member States in March 1999.

311. In April 1999, the Belgium Biosafety Council requested additional information from the applicant in order to be in a position to proceed with the initial assessment. The request touched upon the issues of substantial equivalence and presence of transgenic pat DNA and pat protein. The request for additional information has partly remained unanswered until now.

312. Meanwhile, the Greek (June 1999) and Italian (July 1999) authorities themselves asked for additional information on various points such as, nutritional and biochemical characterization and toxicity of the transgenic plant. They have not yet received any answer either.

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214 See detailed chronology, (Exhibit EC-93).

215 The application concerns the Liberty Link soybean transformation events A2704-12 and A5547-127. The genetic modification was obtained through the insertion of the Phoshinothricine-Acetyl-Transferase (PAT) gene.

216 See, above, the company's description in Section III.D.2.(a)(ii).

313. In April 2004, the lead CA reminded the applicant again to fully respond to the requests for additional information so that the CA would be able finalize the pending assessment report.

iv) Monsanto MaisGuard & Roundup Ready (MON810 & GA21) corn (stack)[217]

314. Monsanto MaisGuard & RoundupReady is a transgenic hybrid maize which is tolerant to Roundup herbicide and resistant to certain target Lepidopteran insects pests. It is a crossing (stack event) of the genetically modified maize lines MON810 and GA21.[218] The application was made in the Netherlands by the Belgium Monsanto Services International S.A./N.V in March 2000.

315. Subsequently, the European Commission informed the other Member States of the application in the same month (March 2000).

316. The Dutch Health Council (*Gezondheidsraad*) requested additional information from Monsanto in July 2000. The request was partly answered in February 2002. However, issues such as molecular characterization of inserted DNA from transgenic parent lines, the determination of flanking DNA or compositional analysis, still remain unanswered.

v) Pioneer/Dow AgroSciences Bt corn Cry1F (1507)[219]

317. Genetically modified "Bt Cry1F maize grain line 1507" is tolerant to the herbicide glufosinate ammonium and resistant to Lepidopteran insect pests.[220] The application was jointly submitted by the US-American Pioneer Hi-Bred International, Inc. and Mycogen Seeds c/o DowAgroSience LLC. The application was made in the Netherlands in February 2001.

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217 See detailed chronology, (Exhibit EC-94).

218 The genetic modification was obtained through in insertion of genes encoding CRY1A(b) protein of *Bacillus thuringiensis* subsp. *Kurstaki* and mEPSPS protein.

219 See detailed chronology, (Exhibit EC-95).

220 The genetic modification was obtained through the introduction of CRY1F gene of *Bacillus thuringiensis* and *pat* gene of *Streptomyces viridochromogenes* encoding phosphinothricin-N-acetyltransferase.

318. In the same month, the European Commission communicated the application to the other Member States.

319. The Dutch Health Council (*Gezondheitsraad*) asked Pioneer Overseas Corporation for additional information in June 2001. Pioneer gave their final answer in February 2003. Subsequently, i.e. between February 2002 and July 2003, there was ongoing correspondence between Pioneer Overseas and the Dutch Health Council on additional information to be submitted by the applicants. The correspondence was, *inter alia*, about experiments to identify potential properties of putative fusion proteins and the presentation of field trials in selected regions.

320. The Health Council finalized the initial assessment report in November 2003. In this report, the Council came to the conclusion that the consumption of 1507 maize as well as foods and food ingredients derived from it were as safe for humans as the consumption of the non-genetically modified counterparts.

321. The European Commission forwarded the initial assessment report to the Member States for comments in December 2003 and received replies from eleven Member States. The replies contained reasoned objections against the initial assessment by seven Member States. On 26 March 2004 Pioneer forwarded the complete dossier (including responses to the objections and comments raised by Member States to EFSA). In parallel Pioneer undertook the steps to ensure the production of certified reference material by the JRC (Geel) and for the validation of a detection method by the (JRC).

vi) Monsanto Roundup Ready corn (NK603)[221]

322. "NK603 Roundup Read Maize is a maize variety genetically modified to express tolerance to the herbicide glyphosate. Monsanto submitted a request for food use of the product in the Netherlands in 2001. The Dutch authority requested completion of the dossier (missing references) and additional information on molecular characterisation and compositional analysis. The Dutch authority

[221] See detailed chronology, (Exhibit EC-96).

completed its evaluation in November 2002 and sent its initial assessment report to the Commission.

323. The Commission circulated the dossier to all Member States in January 2003. Three raised objections and several others requested additional information. The Commission requested the opinion of Scientific Panel on GMOs of EFSA in July 2003.

324. In parallel to replying to the above outstanding issues and in view of the pending legislative proposal ("Food and Feed"), Monsanto, on a voluntary basis agreed to providing detection and validation methods for its product in collaboration with the Commission's Joint Research Centre (JRC).

325. On the basis of an agreement (February 2003) Monsanto submitted validation material to the JRC in October 2003. The method validation process was completed in April 2004.

326. EFSA Scientific Panel on GMOs issued its opinion, which also dealt with the release into the environment aspects of the notification pending under Directive 2001/18. As seen above, the EFSA stated that NK603 maize was as safe as conventional maize and therefore the placing on the market of NK603 maize for food or feed or processing was unlikely to have an adverse effect on human and animal health and, in that context, the environment.[222]

327. Following the EFSA opinion the Commission presented a draft decision for a market authorisation to the Regulatory Committee in April 2004. As the proposal did not obtain a qualified majority in that committee, the decision will now be transmitted to the Council.

[222] See above Section III.D.2(a)(xv).

(b) Requests withdrawn

i) Bejo-Zaden transgenic radicchio rosso

328. The request concerning transgenic *Radicchio Rosso* salad for human consumption[223] was introduced in the Netherlands in 1998. After assessment at the national level, the request was withdrawn by Bejo Zaden BV by its letter of 27th of May 2003. As justification, Bejo Zaden has pointed to the fact that it preferred not to be associated with GMOs any longer, because of the negative response from the market.[224]

ii) Bejo-Zaden transgenic green hearted chicory

329. The request concerning transgenic green hearted chicory for human consumption[225] was introduced in the Netherlands in 1998. After assessment at the national level, the request was withdrawn by Bejo Zaden BV by its letter of 27th of May 2003. As justification, Bejo Zaden has pointed to the fact that it preferred not to be associated with GMOs any longer, because of the negative response from the market.[226]

iii) Pioneer/Dupont high-oleic soybean (260-05)

330. The request concerning High Oleic Soybean[227] sub-lines was introduced in the Netherlands in 1998. After discussions between the lead Dutch Competent Authority and Optimum Quality Grains L.L.C., the request was withdrawn by

223 The genetic modification of *Radicchio rosso* lines RM3-3, RM3-4, RM3-6 was obtained through the insertion of the *bar* gene coding for a protein phosphinothricin acetyl transferase (PAT); *barnase* gene coding for ribonuclease; and *neo* gene coding for the neomycin phosphotransferase II.

224 See Exhibit EC-97.

225 The genetic modification of green hearted chicory was obtained through the insertion of the bar gene product phosphinothricin-N-acetyl transferase (PAT); *barnase* gene from *Bacillus amyloliquefaciens* coding for ribonuclease; and *neo* gene coding for the neomycin phosphotransferase II (NPT-II).

226 See Exhibit EC-98.

227 The product is a subline derived from transformation event 260-05.

Optimum with letter of 12th of December 2002. In the justification for its withdrawal, Optimum pointed to "entirely commercial reasons."[228]

iv) Zeneca extended shelf life tomato (TGT7-F)

331. The request concerning genetically modified tomatoes[229] was introduced in the United Kingdom in 1998. After assessment at the national level, the request was withdrawn by Syngenta, the company funded by the merger between Zeneca and Novartis, by its letter of 24th of September 2001. As the reason for its withdrawal Syngenta pointed to "the commercial re-positioning" following the above mentioned merger.[230]

v) Pioneer Liberty Link and Bt (T25 & MON810)

332. The request concerning foods and food ingredients derived from crosses between genetically modified maize lines T25 and MON810[231] was introduced in the Netherlands in 2000. After discussions between the lead Dutch CA and Pioneer Overseas Corporation, the request was withdrawn by Pioneer with letter of 12th of December 2002. In the justification for its withdrawal, Pioneer pointed to "entirely commercial reasons."[232]

228 See Exhibit EC-99.

229 The tomato line TGT7F was transformed via the *Agrobacterium tumefaciens* mediated transformation using the plasmid pJR16S to insert gene PG encoding polygalacturonase and neomycin phosphostranferase gene *npt* II producing the enzyme APH(3')II.

230 See Exhibit EC-100.

231 The product consists of maize T25xMON810 derived from conventional crosses. One inbred parent is derived from the progeny of line T25 (with increased tolerance to glufosinate ammonium-based herbicides due to the introduction of the *pat* gene from *Streptomyces viridochromogenes*). The other inbred parent is derived from the progeny of line MON810 (resistant to certain insect pests due to the introduction of the *cry1A(b)* gene of *Bacillus thuringiensis* subsp. *kurstaki*).

232 See Exhibit EC-101.

vi) Monsanto/Syngenta Roundup Ready sugar beet

333. The request concerning Roundup Ready sugar beet T9100152[233] was introduced in the Netherlands in 1999. After discussions between the lead Dutch CA on the one hand and Monsanto Europe SA and Syngenta Seeds AB on the other hand, the request was withdrawn by both companies by their letter of 16th of April 2004. As the reason for its withdrawal Monsanto and Syngenta pointed out their decision to stop any further development of the Roundup Ready sugar beet derived from event T9100152.[234]

3. Other applications

334. In order to complete the picture of product applications under the EC approval system, the following will briefly list those applications which have not been mentioned in the Complainants' requests for establishment of a panel.

(a) Pending

335. Apart from the ones mentioned by the Complainants, there a seven more notifications under Directive 2001/18 (release into the environment) which have been submitted and which are in the process of being evaluated either at Member State or at Community level. The seven products are:

- Monsanto Maize (MON810 x NK603) – C/ES/04/01[235]
- KWS SAAT AG /Monsanto Sugar Beet – C/DE/00/8[236]
- Monsanto Maize (MON810 x NK603) – C/GB/02/M3/3[237]
- Monsanto Maize (MON810 x NK603) – C/DE/02/9[238]
- Monsanto Maize (NK603) – C/ES/03/01[239]

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233 The modification of sugar beet was obtained through the introduction of genes encoding the proteines CP4 5 enolpyruvyl-shikimate-3-phosphate synthase (CP4 EPSPS).

234 See Exhibit EC-102.

235 See Status Report (Exhibit EC-103).

236 See Status Report (Exhibit EC-104).

237 See Status Report (Exhibit EC-105).

238 See Status Report (Exhibit EC-106).

- Bayer Rice (LLRICE62) – C/GB/03/M5/3[240]

- Bayer Cotton (LLCotton25) – C/ES/04/02[241]

336. As can bee seen from the attached status reports the evaluation of these notifications is proceeding smoothly in accordance with the provisions of Directive 2001/18.

337. Furthermore, there is one additional request pending under the Novel Food Regulation 258/97, namely Monsanto's request for food use of maize MON 863/810. The request has been introduced in Germany in 2003, has quickly moved up to the Community level and is currently pending at EFSA.

(b) Withdrawn

i) Bejo-Zaden Chinese cabbage – C/NL/96/05

338. The notification concerning Chinese cabbage was introduced in the Netherlands in 1996. After assessment at both national and European Community level, the notification was withdrawn by Bejo Zaden by its letter of 15th of April 2003. Bejo Zaden has given two reasons for the withdrawal: first, the absence of a market for these products; and second, the fact that Bejo Zaden preferred not to be associated with GMOs any longer.[242]

4. Member State Safeguard Measures

339. The European Communities refers to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment. All of the following Member State measures are maintained to protect human, animal or plant life or health or the environment from possible harmful effects of GMOs, as explained above, the issues including : toxicity; allergenicity; horizontal

239 See Status Report (Exhibit EC-107).
240 See Status Report (Exhibit EC-108).
241 See Status Report (Exhibit EC-109).
242 See Exhibit EC-110.

gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; etc. It emerges from the history of each notification, and the various discussions that took place at Community and national level, that Member States adopted measures because they did not agree with one or more aspects of the risk assessment conducted by the Community and/or because of the specific circumstances in which specific legislators were operating as regards the level of acceptable risk.

(a) MS1 x RF1 (France)

340. Pursuant to Directive 90/220/EC, Article 13, the company Plant Genetic Systems N.V. [243] submitted a notification to the competent authorities of the United Kingdom (reference C/UK/94/M1/1) for the placing on the market, for growing and obtaining seeds of a certain GM oilseed rape.[244]

341. The notification and an assessment report prepared by the competent authorities of the United Kingdom were forwarded to the Commission, which forwarded them to the competent authorities of the Member States. The competent authorities of some Member States raised objections. The Commission adopted a decision pursuant to Directive 90/220/EC and the United Kingdom issued a final consent for the placing on the market of the product.[245] Pursuant to Directive 90/220/EC, Article 16 (since replaced by Directive 2001/18/EC, Article 23), France adopted a

243 See, above, the company's description in Section III.D.2.(a)(ii).

244 Living seeds of a hybrid swede-rape (*Brassica napus* L. *oleifera Metzq*.) derived using :
(a) the progeny of the male sterile swede-rape line MS1Bn (B91-4) cultivar Drakkar containing the barnase gene from *bacillus amyloliquefaciens* coding for ribonuclease, the bar gene from *streptomyces hygroscopicus* coding for phosphinothricin acetyl transferase, the neo gene from *Escherichia coli* coding for neomycin phosphotransferase II, the promoter PSsuAra from *arabidopsis thaliana*, the promoter PNos from *agrobacterium tumefaciens*, the promoter PTA29 from *nicotiana tabacum*; and
(b) the progeny of the fertility restoration swede-rape line RF1BN (B93-101) cultivar drakkar containing the barstar gene from *bacillus amyloliquefaciens* coding for ribonuclease inhibitor, the bar gene from *streptomyces hygroscopicus* coding for phosphinothricin acetyl transferase, the neo gene from *Escherichia coli* coding for neomycin phosphotransferase II, the promoter PSsuAra from *arabidopsis thaliana*, the promoter PNos from *agrobacterium tumefaciens*, the promoter PTA29 from *nicotiana tabacum*

temporary and provisional measure prohibiting the sale of the notified product in France.[246]

342. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which this Member State measure may be adopted or maintained include, but are not necessarily limited to: persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

(b) Topas 19/2 (France, Greece)

343. Pursuant to Directive 90/220/EC, Article 13, the company ArgEvo UK Crop Protection[247] submitted a notification to the competent authorities of the United Kingdom (reference C/UK/95/M5/1) for the placing on the market of seeds of a certain GM oilseed rape.[248]

344. The notification and an assessment report prepared by the competent authorities of the United Kingdom were forwarded to the Commission, which forwarded them to the competent authorities of the Member States. The competent authorities of some Member States raised objections. The Commission adopted a decision pursuant to Directive 90/220/EC and the United Kingdom authorities issued a final consent for the placing on the market of the product.[249] Pursuant to Directive 90/220/EC, Article 16 (since replaced by Directive 2001/18/EC, Article 23), France

245 Commission Decision 96/158/EC, Exhibit US-97.

246 Exhibit US-59, Exhibit US-60.

247 See, above, the company's description in Section III.D.2.(a)(i).

248 Seeds of spring swede rape (*Brassica napus* L. spp. o*leifera*) derived from traditional breeding crosses between non-genetically modified swede rape and a line resulting from transformation event Topas 19/2 which has been transformed using plasmid pOCA/AC containing :
(a) a synthetic *pat* gene coding for phosphinothricin acetyltransferase under the regulation of 35S promoter and terminator sequences from cauliflower mosaic virus, and
(b) an *npt II* gene coding for neomycin phosphotranferase II under the regulation of the nopaline synthase promoter and on actopine synthase terminator sequence.

249 Commission Decision 98/291/EC, Exhibit US-97.

and Greece adopted temporary and provisional measures prohibiting the sale of the notified product on their territory, and in the case of Greece, prohibiting imports.[250]

345. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which these Member State measures may be adopted or maintained include, but are not necessarily limited to: persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

(c) Bt-176 (Austria, Luxembourg, Germany)

346. Pursuant to Directive 90/220/EC, Article 13, the company Ciba-Geigy Limited[251] submitted a notification to the competent authorities of France (reference C/F/94/11-03) for the placing on the market of a certain GM maize.[252]

347. The notification and an assessment report prepared by the competent authorities of France were forwarded to the Commission, which forwarded them to the competent authorities of the Member States. The competent authorities of some Member States raised objections. The Commission adopted a decision pursuant to Directive 90/220/EC and the French authorities issued a final consent for the placing on the market of the product.[253] Pursuant to Directive 90/220/EC, Article 16 (since replaced by Directive 2001/18/EC, Article 23), Austria, Luxembourg and

250 Exhibit US-59, Exhibit US-60, Exhibit US-69.

251 See, above, the company's description in Section III.D.2.(a)(viii).

252 Inbred lines and hybrids derived from a maize (*Zea mays* L.) line (CG 00256-176) which has been transformed using plasmids containing :
(i) one copy of the *bar* gene, from *Streptomyces hygroscopius* (encoding a phosphinothricin acetyltransferase) under the regulation of the 35S promoter and the 35S terminator from the cauliflower mosaic virus (CaMV);
(ii) two copies of a synthetic truncated gene encoding an insect control protein representing the active portion of the CryIA(b) δ-endotoxin, from *Bacillus thuringiensis subsp. kurstaki* strain HD1-9 and containing intron # 9 from the maize phosphoenolpyruvate carboxylase gene;
the first copy is under the regulation of a promoter from the maize phosphoenolpyruvate carboxylase gene and the CaMV 35S terminator, and the second copy under the regulation of a promoter derived from a maize calcium-dependent protein kinase gene and the CaMV 35S terminator;
(iii) the prokaryotic gene *bla* (coding for a β-lactamase conferring resistance to ampicillin) under prokaryotic promoter.

Germany adopted temporary and provisional measures prohibiting the sale of the notified product on their territory[254].

348. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which these Member State measures may be adopted or maintained include, but are not necessarily limited to: horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

(d) MON 810 (Austria, Italy)

349. Pursuant to Directive 90/220/EC, Article 13, the company Monsanto Europe S.A. submitted a notification to the competent authorities of France (reference C/F/95/12-02) for the placing on the market of a certain GM maize.[255]

350. The notification and an assessment report prepared by the competent authorities of France were forwarded to the Commission, which forwarded them to the competent authorities of the Member States. The competent authorities of some Member States raised objections. The Commission adopted a decision pursuant to Directive 90/220/EC and the French authorities issued a final consent for the placing on the market of the product.[256] Pursuant to Directive 90/220/EC, Article 16 (since replaced by Directive 2001/18/EC, Article 23), Austria adopted temporary and provisional measures prohibiting the sale of the notified product on its territory.[257]

253 Commission Decision 97/98/EC, Exhibit US-97.

254 Exhibit US-52, Exhibit US-63, Exhibit US-65.

255 Inbred lines and hybrids derived from maize line MON 810 containing the *cry*IA(b) gene from *Bacillus thuringiensis* subsp. *kurstaki* under the control of the enhanced 35S promoter from cauliflower mosaic virus and an intron from the gene coding for the heat shock protein 70 from maize.

256 Commission Decision 98/294/EC, Exhibit US-97.

257 Exhibit US-54.

351. The company had also notified the product for food use to the Commission under the simplified procedure under Regulation 258/97[258]. Italy adopted measures suspending the commercialization and use of the product in Italy.[259]

352. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which these Member State measures may be adopted or maintained include, but are not necessarily limited to: horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; development of resistance; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

(e) T25 (Austria, Italy)

353. Pursuant to Directive 90/220/EC, Article 13, the company AgrEvo France[260] submitted a notification to the competent authorities of France (reference C/F/95/12/07) for the placing on the market of a certain GM maize.[261]

354. The notification and an assessment report prepared by the competent authorities of France were forwarded to the Commission, which forwarded them to the competent authorities of the Member States. The competent authorities of some Member States raised objections. The Commission adopted a decision pursuant to Directive 90/220/EC and the French authorities issued final consent for the placing on the market of the product.[262] Pursuant to Directive 90/220/EC, Article 16 (since replaced by Directive 2001/18/EC, Article 23), Austria adopted temporary and provisional measures prohibiting the sale of the notified product on its territory[263].

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258 OJ C 200/16 of 26.6.98.

259 Exhibit US-67.

260 See, above, the company's description in Section III.D.2.(a)(i).

261 Seeds and grains of genetically modified maize (*Zea mays* L.) with increased glufosinate ammonium tolerance derived from the maize line HE/89 transformation event T25 which has been transformed using plasmid pUC/Ac containing :
(a) a synthetic *pat* gene coding for phosphinothricine acetyl transferase under the regulation of a 35S promoter and terminator sequences from Cauliflower Mosaic Virus, and
(b) a truncated beta-lactamase gene missing about 25 % of the gene from the 5' end, which when complete, codes for betalactam antibiotic resistance and the Col E1 origin of replication of pUC.

262 Commission Decision 98/293/EC, Exhibit US-97.

263 Exhibit US-53.

355. The company had also notified the product for food use to the Commission under the simplified procedure under Regulation 258/97.[264] Pursuant to Article 12 of Regulation 258/97 Italy adopted measures suspending the commercialization and use of the product in Italy.[265]

356. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which these Member State measures may be adopted or maintained include, but are not necessarily limited to: horizontal gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

(f) MON 809 (Italy)

357. Under the simplified procedure under Regulation 258/97 Monsanto notified its product MON 809 to the Commission,[266] and Italy pursuant to Article 12 of Regulation 258/97 adopted measures suspending the commercialization and use of the product in Italy.[267]

358. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which this Member State measure may be adopted or maintained include, but are not necessarily limited to: toxicity or allergenicity; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

264 OJ C 181/22 of 26.6.99, Exhibit CDA-25.
265 Exhibit US-67.
266 OJ C 181/22 of 26.6.99, Exhibit CDA-25.
267 Exhibit US-67.

(g) Bt-11 (Italy)

359. Under the simplified procedure under Regulation 258/97 Novartis[268] notified its product Bt-11 to the Commission,[269] and Italy, pursuant to Article 12 of Regulation 258/97 adopted measures suspending the commercialization and use of the product in Italy.[270]

360. Referring to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment, the main reasons for which this Member State measure may be adopted or maintained include, but are not necessarily limited to: toxicity or allergenicity; biodiversity; monitoring; labelling; co-existence; and eventually human and animal health; etc.

5. Conclusion

361. The detailed account that has been provided in this section clearly shows that each product application has its own individual history. Different concerns and considerations were at stake, and both the competent authorities involved and the applicant, acted and reacted in differing manners. Risk issues that were discussed and considered corresponded to the current debate on these issues in the international scientific and regulatory fora.

268 See, above, the company's description in Section III.D.2.(a)(viii).
269 OJ C 181/22 of 26.6.99, Exhibit CDA-25.
270 Exhibit US-67.

III. LEGAL ARGUMENTS

A. Outline of arguments

362. In this Chapter the European Communities will respond to the various legal claims and arguments of the Complainants as comprehensively and systematically as it can in the light of the time available and their disparate nature.

363. The European Communities will first seek to clarify the nature of the measures at issue in this proceeding and discuss in general terms the relevant law (Section B below).

364. The European Communities will then respond (Section C below) to the most concrete and readily apprehended of the categories of claims brought by the Complainants, that there has been a failure to consider without undue delay a series of applications for approval of individual GMOs. The applications about which each of the Complainants complains differ between them but the claims have sufficient common elements to allow them to be considered together.

365. Since the claims relating to the alleged general suspension or "moratorium" concerning the approval of GMOs in the European Communities appear to the European Communities to rely on arguments that will have been considered in relation to the product-specific delays, these claims are best dealt with after the product-specific delays (Section D below).

366. Thereafter, the European Communities will deal with the third group of claims brought by the Complainants, those addressed to the temporary suspensions at the level of EC Member States of the EC-wide authorisations for the marketing of GMOs (Section E below). Again, the precise measures about which each of the Complainants complains differ between them but the claims have sufficient common elements to allow them to be considered together.

367. Next, the European Communities addresses the claims relating to the special and differential treatment provisions in Article 10.1 of the *SPS Agreement* and Article 12 of the *TBT Agreement* (Section F below).

368. Finally, because of its potential application to a number of the claims the European Communities discusses the general exception clause in Article XX of the GATT 1994 separately (Section G below).

369. By responding for the most part to the Complainants' claims and arguments together, the European Communities does not concede that any of the Complainants may rely on claims and arguments brought and developed by any of the others but not brought or developed by it.

B. Preliminary issues

370. The Complainants' cases raise a number of difficult issues of application and interpretation of the *WTO Agreement.* Before setting out its response to the various legal arguments made by the Complainants, the European Communities considers that it is necessary to address briefly a number of preliminary issues. The first issue to be discussed is the precise nature of the measures at issue and their relationship to the EC GMO legislation. The second issue relates to the WTO legal provisions that may be applicable to these measures and other law that may be relevant.

1. Measures at issue

371. As the European Communities has made clear throughout these proceedings, it has considerable difficulty in understanding precisely which measures the Complainants are complaining about with their first and second claims. This was one factor that led it to request the Panel to issue a preliminary ruling. In response, the Complainants have insisted, and the Panel ultimately found, that the requests adequately defined the measures at issue and needed no improvement.

372. These panel requests all contain a first complaint against the existence of an alleged "moratorium" or "general suspension" of approval procedures and a second group of complaints against alleged failures to consider for approval certain specific applications for authorisation of interest to each of the Complainants (and which vary between them).

373. As set forth in the factual part, the European Communities has not adopted any "moratorium" on the approval of GMOs and nor has it suspended the application of its GMO legislation. The Complainants have been unable to identify an instrument or other text in which such a "moratorium" is brought into effect. The Complainants' assertions about a "moratorium", or a "suspension of procedures" or any "failure to consider applications" are all in reality complaints about delay.

374. Delay is a failure to act in a timely manner. As will be argued in this submission, such failure can be reviewed under the *WTO Agreement* only to the extent that the *Agreement* provides for obligations to act in a timely manner. Such obligations are "procedural" in character, and they concern the timely functioning of a defined process. Any failure to comply with such obligations constitutes a review able omission to act.

375. The Complainants, however, to a large extent, allege the violation of obligations that are not procedural in character and do not encompass omissions or failures to act. These obligations require the existence and address the content of acts (as opposed to omissions) as measures.

376. It is evident that the Complainants' have real difficulty in identifying the existence of an act or a measure. In reality they are addressing omissions. This is apparent from their attempts to re-define their claims in their first written submissions as compared to the matters raised in their requests for the establishment of a panel.[271]

377. The Complainants do in fact recognise in their first written submission that the EC GMO legislation is not contested in these proceedings. For example, the US states that:

> To be clear, with respect to the general and product-specific moratoria, the United States is not asking the Panel to make findings on the WTO-consistency of the EC novel foods and deliberate release approval legislation per se. Instead, the United States is asking the Panel to make findings on the EC's general and product-specific moratoria: the suspension of consideration of applications for, or granting of, approval of any and all biotech products under the EC approval system.[272]

378. And Argentina states that:

> Argentina is consequently not questioning the Community directives and regulations per se, but is merely pointing out the EC is failing to apply its own legislation, thus that failing to approve any biotech agricultural products since 1998. [273]

379. Similarly, Canada begins its legal analysis of the measures it attacks without addressing any part of the EC GMO legislation. Canada indicates that it is "challenging three distinct measures or categories of measures", namely (a) the across-the-board *moratorium* on the approval of biotech products; (b) the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I of Canada's Panel Request, resulting in a market ban on those products; and (c) the *EC Member State national measures* identified in Annex II of Canada's Panel Request.[274]

380. The European Communities will object vigorously to any attempt by the Complainants to extend or broaden the scope of these proceedings by redefining the first two measures at issue as "marketing bans". The only "ban" in place in the European Communities is the prohibition to market GMOs that have not undergone a prior assessment in accordance with the requirements of Community law. The fact that GMOs cannot be marketed until approved is an intrinsic feature of EC GMO legislation (indeed, of any approval system). It is not the object of these proceedings, and it has to be clearly distinguished from allegations about delays in the assessment procedures.

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271 See first written submission of the US, para 67, First written submission of Canada paras 141, 142 , 506 and 507

272 First written submission of the US, para 68.

273 First written submission of Argentina, para 195.

274 First written submission of Canada, para 141.

381. Once the acts complained of are correctly characterised as delay, they cannot amount to a ban. The Complainants' submissions blur this fundamental point, and they seem to insinuate (although never overtly state) that the EC authorisation procedures for GMOs are little more than a façade to prevent the marketing of GMOs. The European Communities rejects any such allegation. The EC legislation is designed as a rigorous system for the assessment of GMOs prior to their marketing, and it is being applied as such. That legislation is fully consistent with international standards. EC legislation and policy is not intended to prevent the marketing of GMOs.

382. In conclusion, the European Communities considers that the consistency of the EC GMO legislation, its approval systems as such and the ban on marketing non-approved products contained in the EC GMO legislation with the *WTO Agreement* is not within the jurisdiction of the Panel and that the Panel must confine its findings to the measures identified in the Complainants' panel requests.

2. Applicable law

383. As explained in the previous section, the measures at issue in this case concern alleged delays in the examination of applications for approval of GMOs. In WTO law there are two agreements that contain disciplines on approval or conformity assessment procedures, the *TBT Agreement* and the *SPS Agreement*. Various provisions of GATT 1994 may also be applicable to actions taken under approval or conformity assessment procedures.

384. The Complainants focus almost exclusively on the *SPS Agreement.* It is clear, however, that the *SPS Agreement* was not drafted with products having the particular characteristics of GMOs in mind. The *SPS Agreement* does not refer to genetically modified organisms or any similar products, although it refers to and defines in detail the kinds of risk and products to which it is to apply. The risks posed by GMOs are different, as will be explained below.

385. The European Communities accepts that there is no reason in principle why an agreement could not apply to products that were not commercially available when

the agreement was drafted. But the *SPS Agreement* applies to measures to prevent certain kinds of risks and its provisions are specifically designed to regulate such measures. To the extent that the risks are of a different nature, as is partially the case of GMOs, the provisions of the *SPS Agreement* are simply not designed to address such risks. The scope of the *SPS Agreement* is limited, as will be explained below, to measures adopted to prevent an exhaustive list of narrowly defined risks.

386. The issues arising out of the existence of GMOs go far beyond the risks envisaged and regulated by the *SPS Agreement*. Indeed they deserve their own agreement, and so a specific agreement has been negotiated outside the WTO context and subsequent to the conclusion of the *WTO Agreement*. It is the Biosafety Protocol which lays down the most pertinent provisions to any consideration of problems related to GMOs.

387. Accordingly, the European Communities will discuss below the pertinence of various WTO agreements and the Biosafety Protocol to the groups of measures at issue in this case.

(a) The *SPS Agreement*

i) The scope of the SPS Agreement

388. The Complainants assert that all the measures that they have identified, and even the EC GMO legislation, fall within the scope of the *SPS Agreement*. The European Communities considers that although some aspects of the alleged measures could be said to fall within the *SPS Agreement* it is plain that other aspects do not.

389. Article 1 of the *SPS Agreement* (entitled *General Provisions*) provides:

> 1. This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement.
>
> 2. For the purposes of this Agreement, the definitions provided in Annex A shall apply.

> 3. The annexes are an integral part of this Agreement.
>
> 4. Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement.

390. Annex A of the *SPS Agreement* (entitled *Definitions*), point 1, provides in relevant part:

> 1. Sanitary or phytosanitary measure – Any measure applied :
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

391. There is a footnote (4) to the whole of Annex A to the *SPS Agreement* that states:

> For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" includes weeds; and "contaminants" include pesticides and veterinary drug residues and extraneous matter.

392. It is clear from these provisions that the *SPS Agreement* was not intended by its drafters to apply to all products and all risks in all circumstances – it has a limited and defined scope of application. Article 1.1 of the *SPS Agreement* describes what the agreement "applies to" and refers specifically to "sanitary and phytosanitary measures." Article 1.2 of the *SPS Agreement* provides that the definitions in Annex A of the Agreement apply, and Article 1.3 confirms that the annexes are an integral part of the Agreement. Annex A, point 1 of the Agreement defines a "sanitary or phytosanitary measure". Article 1.4 of the Agreement refers to measures that are "not within the scope" of the *SPS Agreement.* In relation to any given matter,

therefore, there is a threshold issue to be decided: does the matter fall within the scope of the *SPS Agreement*? If a matter falls outside the scope of the *SPS Agreement* then it cannot be inconsistent with that agreement. To determine whether a given matter falls within the scope of the *SPS Agreement* the starting point must be point 1 of Annex A.

393. This defines the scope of the agreement by reference to the purpose – or objective – of the measure, that is the reasons justifying the measure. Because of their central role in defining the scope of the *SPS Agreement* and thus its applicability to the measures that are the subject of the present case, the European Communities will examine below in some detail the relevant objectives listed in the sub paragraphs (a) to (d) of paragraph 1 of Annex A.

ii) SPS objectives

394. Annex A defines an SPS measure as "any measure applied to protect" or "to prevent or limit" certain risks. The definition does not refer to "any measure that protects" human or animal or plant life or health; or to any measure "that has the effect of protecting". The drafters chose not to use such a form of words. This was intentional, since it was done consistently in the opening words of each of sub-paragraphs (a) to (d). This means that the scope of the *SPS Agreement* does not depend on the effect of a measure, but on the purposes – or objectives – of that measure.

395. These objectives relate to the protection of different things - animal or plant life or health; human or animal life or health; human life or health - and other damage. In each case, reference is made to protection from certain specified risks or damage. These provisions have not been properly interpreted and applied by the Complainants, who have taken insufficient care to address the intention of the drafters.

396. A further characteristic of these provisions is the repeated use of the words "arising from", which indicates a requirement of causality. The absence of the word "arising" in sub-paragraph (d) does not change the meaning. It is implicit, given

that without the word "arising" the phrase is grammatically incorrect and that in the other language versions the equivalent of the word "arising" ("resultants" in Spanish and "découlant" in French) is present in sub-paragraph (d) as it is in sub-paragraphs (a) to (c). These words direct the interpreter to a question of what the consequences of a certain situation may be. For example, the fact that a measure is adopted because an additive is in a food does not of itself bring that measure within the *SPS Agreement.* Something more is needed. The measure must be applied with the objective of preventing risks (to human or animal life or health) "arising from" the fact that a food contains an additive.

397. The European Communities described some of the risks that might arise from GMOs in Section II.A.4.d above under two headings. These were risks to human health and risks to the environment. These risks differ significantly from the risks which are referred to in paragraph 1 of Annex A as the European Communities will now illustrate with a discussion of some of the terms used.

- Foods, beverages or feedstuffs

398. Sub-paragraph (b) concerns certain things "in foods, beverages or feedstuffs." A food is something that is intentionally ingested by a human for nutritional purposes; a beverage is something that is drunk; and a feedstuff is something that farmed animals are intentionally permitted to ingest for nutritional purposes. It is clear that paragraph (b) does not encompass products that are not "foods, beverages or feedstuffs". A GMO seed to be used in agriculture is not a "food, beverage or feedstuff". It is destined to be planted in the ground, not eaten by humans or fed to animals. A GM sowing seed cannot fall within sub-paragraph (b). Similarly, a crop or plant is not in itself necessarily a food. It may be processed into something that becomes a food, but that does not make the crop or plant itself a food. A GMO crop or plant does not therefore necessarily fall within sub-paragraph (b). Similarly, a crop or plant is not necessarily a "feedstuff" for animals – that depends on whether or not it is destined for such use, and whether or not the crop will first be processed. Finally, the impact of a GMO on wild flora and fauna does not fall

within sub-paragraph (b), because it does not relate to foods, beverages or feedstuffs.

♦ Additives

399. The word "additive" is not defined in the *SPS Agreement.* The *SPS Agreement* does, however, refer to international standards, and specifically, for example, to the Codex Alimentarius Commission.[275] The Panel should therefore refer to the Codex for the purposes of determining the meaning of "additive" in sub-paragraph (b).

400. According to the Codex a food additive is :

> any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.[276]

401. The GMOs with which this case is concerned are not "additives" within this definition. Nor is a gene an additive – whether introduced by recombinant DNA technology or by conventional breeding. Genes are not substances. They are instructions for the creation of substances.

♦ Contaminants

402. Similarly, the GMOs with which this case is concerned are not "contaminants" within the meaning of sub-paragraph (b).

403. The Codex defines a contaminant as :

> any substance <u>not intentionally</u> added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does

[275] For example, *SPS Agreement*, Articles 3 and Annex A, point 3.

[276] Codex standard 192, 1995.

> not include fragment, rodent hairs and other extraneous matter[277]. (emphasis added)

404. Both the GMOs and the proteins produced by the GMOs with which this case is concerned will be intentionally present in food. Thus they cannot fall within this definition of contaminant.

♦ Toxins

405. Similarly, according to the same Codex standard the definition of a contaminant implicitly includes naturally occurring toxicants produced as toxic metabolites of certain microfungi that are not intentionally added to food (mycotoxins). "Mycotoxin and phytotoxins" are subclasses of contaminants. Since all of the GMOs with which this case is concerned were intentionally created, they cannot fall within this definition of toxin.

406. The toxic effect of an insecticidal crop on the target pest itself also cannot fall under sub-paragraph (b), since it is not possible to seek to kill target pests and at the same time seek to protect the life and health of those very same pests. Moreover, the crop is not a "feedstuff" *vis a vis* the pest. The same is true in respect of non-target organisms, since the crop is not a "feedstuff" *vis a vis* such organisms.

♦ Diseases, disease-carrying organisms or disease-causing organisms

407. The International Office of Epizootics (IOE), which is also expressly referred to in the *SPS Agreement*[278], defines a disease as:

> the clinical and/or pathological manifestation of infection.[279]

408. A GMO is not infected or an infection and is not, in itself, a disease. Nor is it a disease-carrying organism or generally considered a disease-causing organism.

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277 Codex standard 193 rev 1, 1995.

278 *SPS Agreement*, Annex A, point 3 (b).

279 International Animal Health Code, 2002.

409. One of the risks that have been identified in GMOs is, as described above, that they may produce allergens. It may be doubted whether allergies are diseases according to the above definition. They are better described as medical conditions, as is, for example, obesity. However, the risk is not so much that the GMO will cause an allergy (which would already be present in the subject) but that it would provoke the allergic reaction. The GMO is therefore no more a disease-causing organism than any other food that could cause obesity.

♦ Pests

410. Under the International Plant Protection Convention (IPPC) 1997, which is also expressly referred to in the *SPS Agreement*,[280] a pest is defined as:

> any species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products.

411. In order to be a pest within the meaning of the *SPS Agreement*, the relevant GMO would have to be "pathogenic" or "injurious" – that is, it would have to do more than merely interact in some way with humans, animals or plants.

iii) Conclusion on the scope of the SPS Agreement

412. For the reasons set out above and in particular the limited objectives of the *SPS Agreement*, it is clear that some of the risks which arise from GMOs are covered by the *SPS Agreement* while others are not.

413. The European Communities considers that if a WTO Member acts for two different objectives, one of which falls within the scope of the *SPS Agreement*, and the other of which does not, there are in effect two different measures for WTO purposes. This is so even if the two different objectives are sought to be achieved by a measure reflected in a single document. The measure (or part thereof) taken for any of the reasons enumerated in the *SPS Agreement* falls within the scope of that *Agreement*. The measure (or part thereof) taken for other reasons falls outside the scope of the *SPS Agreement*.

[280] *SPS Agreement*, Annex A, point 3 (c).

414. That this must be so can also be seen when a measure is viewed from the perspective of implementation. Where a regulation of a Member that pursues an SPS objective and also a non-SPS objective is found to fall within the scope of the *SPS Agreement* and inconsistent with it (because the way in which the SPS objective is dealt with conflicts with the rules in the agreement), the finding could be implemented by removing the SPS objective and the elements of the measure that derive therefrom while maintaining the non-SPS objectives and the elements of the measures that derive therefrom. Thus there would remain a measure pursuing a non-SPS objective and imposing resulting requirements. From this perspective it is clear that there are in effect two measures, one of which is required to be withdrawn and the other which may be maintained.

iv) The objectives of the EC GMO legislation and the contested measures

415. The briefest review of European Communities legislation in this area indicates that there is no precise match with the objectives and scope of the *SPS Agreement*. The objectives of legislation in the European Communities are generally expressed in the recitals to the legislation. It is to these recitals that the Panel must look to determine whether or not the objective of such legislation is the same as that of the *SPS Agreement.*

416. Directive 90/220 focuses on environmental protection. It uses the word "environment" or an equivalent at least 20 times in its recitals; Directive 2001/18 uses the term at least 29 times. It is repeatedly stated that one of the purposes of the EC GMO legislation is to protect the environment. By contrast, Annex A of the *SPS Agreement* does not address environmental protection (unlike the *TBT Agreement* which expressly refers to the environment in Article 2.2, for example). It is clear that when the drafter of an international agreement uses a term in one instrument but not in another then it must have intended to exclude that term from the latter instrument. This is referred to as the maxim *expressio unius est exclusion*

alterius.[281] The *SPS Agreement* was not intended to address the prevention of risks to the environment.

417. The common and ordinary meaning of the word "environment" is broad and it includes the protection of biodiversity. It extends beyond the narrow definitions to be found in Annex A of the *SPS Agreement*. It does not focus on a short term risk to the life or health of a particular animal or plant. It is based on a long term perspective acquired by stepping back from the problem and considering the big picture. It takes into consideration the situation of a whole range of living organisms and other matters. It is concerned not just with each one of these different things, but also, at the same time, with the plethora of relationships between these different things. It is concerned with the overall balance and equilibrium of natural systems over time. Biodiversity is a leading example of an environmental issue.

418. As discussed in Section II.A.4.d of the factual part of this submission, GMOs give rise to a series of concerns that are addressed by the EC GMO legislation, including the protection of the environment as well as human health. The distinction between the two is reflected in the Biosafety Protocol, which expressly recognises the potential adverse effects of GMOs on biological diversity. That some of these concerns fall outside the defined scope of the *SPS Agreement* can be illustrated by reference to the three main relevant GMO characteristics that occur in the first generation GMOs that are the subject of these proceedings, namely herbicide tolerance, insecticidal properties, and antibiotic resistance and the risks relating to these characteristics, which will now be examined in turn.[282]

- Herbicide tolerance

  - *Agricultural persistence (pest).*

[281] See Sir Robert Jennings and Sir Arthur Watts (eds), *Oppenheim's International Law*, 9th edition (1992), at p. 1279

[282] The following discussion is designed to illustrate the problems that are particularly relevant to the discussion of the products the subject of this case but is not intended to be exhaustive of all the concerns that may arise in connection with GMOs.

419. A crop may be resistant to herbicide. In the right place at the right time the crop is not a pest. However, in the wrong place (such as a neighbouring field) or at the wrong time (such as the following year in the same field sown with a different crop) the plant may be unwanted. The unwanted plant may compete with other crops. Its herbicide resistant trait could give it a selective advantage. It could thus adversely affect or injure other crops. As such, it could become a pest. It might choke or stunt other crop plants. If it did not affect the "life or health" of other crop plants, it could at least cause "other damage" (essentially economic) within the meaning of sub-paragraph (d). Invasiveness or persistence could be exacerbated by cross-breeding and the development of herbicide resistance in plants other than the original crop plant. It could also be exacerbated by the development of multiple resistance. Thus, this limited aspect of a measure may be considered to have been taken to prevent or limit other damage arising from the establishment or spread of pests, within the meaning of sub-paragraph (d). This aspect of a measure therefore falls within the *SPS Agreement.*

§ *Natural persistence (pest).*

420. For the same reasons, some of the effects of invasiveness or persistence of the GMO adversely affecting wild flora may fall within sub-paragraph (d) of the *SPS Agreement*, the other damage being damage to the wild flora concerned. However, natural persistence also has other effects that are not so much damage to wild flora as damage to the ecological balance – or indeed biodiversity. This damage would fall outside the *SPS Agreement.*

§ *Human or (farmed) animal health (GMO).*

421. A measure taken to protect human or animal health from risks arising from the modified gene in foods, beverages or feedstuffs, on the grounds that such modified gene might cause disease, may fall within sub-paragraph (b) and may come within the scope of the *SPS Agreement.* However, another important human health concern arsing from GMOs is that they may produce allergens, and this, as has been explained above, falls outside the scope of the *SPS Agreement.*

§ *Human or (farmed) animal health (herbicide use).*

422. The point of a herbicide resistant crop is that the farmer can use a herbicide to kill weeds without killing the crop. The introduction of herbicide resistant crops could in some cases lead to the increased use of herbicide, or to the use of novel GMO-specific herbicides. Such use of herbicide could have a negative impact on human or animal life or health. These problems could be exacerbated by cross-breeding and the development of resistance or multiple resistance. The negative effects of the increased use of herbicide on human health do not fall within sub-paragraph (c) of point 1 of Annex A because the herbicide is not a "disease carried by animals, plants or products thereof" and because the risk arises even if the GMO plant is not a pest. They may, however, fall within sub-paragraph (b) insofar as the risk is of excessive levels of contaminants in foods, beverages or feedstuffs. This aspect of the measure therefore may fall within the scope of the *SPS Agreement.*

§ *Wild flora and fauna (herbicide use).*

423. Such specific use of herbicide could also have a negative impact on wild flora and fauna in the field and in the vicinity of the field. These problems could be exacerbated by cross-breeding and the development of resistance or multiple resistance. This risk arises, however, even if the GMO plant is not a pest. The injury is caused not by the GMO plant, but by the herbicide. This aspect of a measure does not therefore fall within sub-paragraphs (a) or (d), because it does not concern a pest. It does not fall within sub-paragraph (c) because it does not relate to human health. It does not fall within sub-paragraph (b) because it does not relate to foods, beverages or feedstuffs. This aspect of a measure therefore falls outside the scope of the *SPS Agreement.*

§ *Cross-breeding.*

424. Cross-breeding with wild flora could eventually lead to the elimination of certain flora that currently exist. This would be an issue of plant life or health, or other damage. This risk arises, however, even if the GMO plant is not a pest. In cross-breeding, the GMO plant does not injure the wild flora with which it cross-breeds – it cross-breeds with it. This aspect of a measure does not therefore fall within sub-paragraphs (a) or (d), because it does not concern a pest. It does not fall within sub-paragraph (c) because it does not relate to human health. It does not fall within sub-paragraph (b) because it does not relate to foods, beverages or feedstuffs. It would, therefore, fall outside the scope of the *SPS Agreement.*

- Insecticidal properties

§ *Agricultural insect resistance (pest).*

425. The GMO crop kills susceptible target insects (pests). Target insects that are not susceptible will have a selective advantage. A population of resistant target insect pests could develop. This is not really a question of the establishment or spread of a pest. The pest is already established and will not spread to areas where it is not established. The concern is rather that the characteristics or genetic make up of the pest will change as a result of the cultivation of the GMO crop. Thus, this concern falls outside the *SPS Agreement.*

§ *Spread of insect resistance trait into wild flora (pest)*

426. Spread of insect resistance into wild flora could result in the development of an insect resistant wild population which could become invasive which could result in a damage to biodiversity. The novel Bt resistant wild plant would not be a pest per se, as defined in the IPPC, since it will primarily affect insects and other organisms of the trophic chain. Measures aiming at preventing such damage therefore falls outside the scope of sub-paragraph (d) of the *SPS Agreement.*

§ *Human or (farmed) animal health (GMO).*

427. A measure taken to protect human or animal health from risks arising from the modified gene in foods, beverages or feedstuffs, on the grounds that such modified gene might cause disease, falls within sub-paragraph (b) and is therefore within the scope of the *SPS Agreement.* However, to the extent that allergies are not diseases, measures taken to protect against such risks fall outside the scope of the *SPS Agreement.*

§ *Human or (farmed) animal health (insecticide use).*

428. In the event of resistance, it may become necessary to use more or different insecticides. This may adversely affect human or animal life or health. This aspect of a measure would fall within sub-paragraph (b) insofar as the risk is of excessive levels of toxin in foods, beverages or feedstuffs (that is, in the case of farmed animals). This aspect of a measure may therefore fall within the scope of the *SPS Agreement.*

§ *Wild fauna (GMO).*

429. A measure applied to protect non-target organisms (wild fauna) from risks arising from the insecticide in the GMO does not fall within sub-paragraph (a) because it does not concern a pest; or a disease. It does not fall within sub-paragraph (b) because the toxin is intentionally in the GMO and because it does not concern foods, beverages or feedstuffs. It does not fall within sub-paragraph (c) because it does not concern human health. It does not fall within sub-paragraph (d) because it does not concern a pest. It therefore falls outside the scope of the *SPS Agreement.*

§ *Wild fauna (insecticide use).*

430. In the event of resistance, an increased use of insecticides may adversely affect the life or health of wild fauna. This would not, however, be a risk arising from the entry, establishment or spread of a pest. It would be a risk arising from steps taken to *prevent* the spread of a pest. It would not therefore fall within either sub-

paragraph (a) or sub-paragraph (d). It would not fall within sub-paragraph (b) because it would not concern a food, beverage or feedstuff. It would not fall within sub-paragraph (c) because it does note relate to human health. It therefore falls outside the scope of the *SPS Agreement.*

♦ *Antibiotic resistance*

431. The concern is that the antibiotic resistant trait in the GM crop or product DNA might be transferred to bacteria, particularly in the digestive tract of humans or animals, and that this might negatively impact on clinical and veterinary medicine, which relies heavily on antibiotics (and therefore on the absence of resistance to antibiotics).

432. Plant DNA is not an organism, although the plant within which it is contained is, as long as it is living. Plant DNA in foods, beverages or feedstuffs, but no longer in an organism, is not a matter that falls within the scope of sub-paragraph (b), because it is not an *organism*. Even if the plant DNA would still be in an organism, and its ingestion would eventually contribute to the development of antibiotic resistance, it would not be the plant DNA that caused disease. The disease would have to come from some other entirely independent source. The development of antibiotic resistance may make more disease a possibility, but it does not cause the disease itself. This matter does not therefore fall within sub-paragraphs (a) or (b). It does not fall within sub-paragraphs (c) or (d) because it does not concern a pest. It therefore falls outside the scope of the *SPS Agreement.*

v) Conclusion on the objectives of the EC GMO legislation and measures

433. It is clear from this discussion that some of the objectives of the EC GMO legislation (both original and revised) and the measures taken thereunder fall within the *SPS Agreement* whereas others fall outside its scope. Any measure or part of any measure adopted for reasons that fall outside the scope of the *SPS Agreement* is not governed by the *SPS Agreement* and cannot be inconsistent with that *Agreement.*

(b) The scope of the *TBT Agreement*

434. The environmental and related objectives of the EC GMO legislation and measures taken thereunder which are not governed by the *SPS Agreement* may nevertheless have to be assessed by reference to the *TBT Agreement.* At first sight the *SPS Agreement* and *TBT Agreement* may appear to be mutually exclusive. Article 1.5 of the *TBT Agreement* provides that:

> The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.

435. It may be thought that once a measure is classified as a sanitary or phytosanitary measure the *SPS Agreement* will apply to the exclusion of the *TBT Agreement.* This may be why the US has not made any claim under the *TBT Agreement* (although it has "reserved the right" to do so).[283] Canada has stated that it is making arguments on the *TBT Agreement* "in the alternative" "if the Panel finds that the *product-specific marketing bans* are not SPS measures".[284] In an apparent afterthought it adds in a footnote that :

> Nevertheless, to the extent that the Panel determines that parts of the measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's TBT claims are to be considered *cumulative* rather than alternative, vis-à-vis its SPS claims.[285]

436. Similarly, Argentina also makes its arguments under the *TBT Agreement* in the alternative to its principal arguments under the *SPS Agreement.*[286]

437. The Complainants implicitly recognise that the *SPS Agreement* may not apply to all the "measures" they address. For the reasons set out above they are correct, and the Panel must also consider the TBT arguments raised by Canada and Argentina.

438. The claim that the *TBT Agreement* cannot apply to any measure that may, even to a limited extent, also pursue an SPS objective is inconsistent with the provisions of to the *SPS Agreement* (in particular Article 1.2 and Annex A).

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283 First written submission of the US at footnote 156.

284 First written submission of Canada, para. 323.

285 First written submission of Canada, para. 144, footnote 210 (emphasis added).

286 See first written submission of Argentina, paras 23, 24 and 594.

439. The *WTO Agreement* is a single agreement and the individual parts of which it is composed (the agreements annexed to it) must be interpreted as an integrated whole.[287] The various provisions apply cumulatively and must be interpreted consistently. As the Appellate Body stated in *Korea – Dairy Safeguards*:[288]

> We agree with the statement of the Panel that:
>
> It is now well established that the *WTO Agreement* is a "Single Undertaking" and therefore all WTO obligations are generally cumulative and Members must comply with all of them simultaneously … .

440. The EC submits that a closer examination of the two agreements reveals that the addition of an SPS objective to a measure does not exclude the application of the *TBT Agreement* to non-SPS aspects of that measure.

441. The *SPS Agreement* applies to the extent that SPS objectives are pursued and the *TBT Agreement* applies to the extent that non-SPS objectives are pursued. Since the scope of the *SPS Agreement* is defined in terms of objectives pursued, a measure that pursues multiple objectives must be considered to be a series of measures.

(c) The scope of GATT 1994 and its relationship to the *TBT Agreement* and the *SPS Agreement*

442. As is apparent from their preambles, the *TBT Agreement* and the *SPS Agreement* were drafted so as to further the objectives of the GATT and to provide more precise rules to apply in certain well defined and problematic areas. The GATT 1994 is a general agreement applicable to many types of measure. The scope of Articles III:4 and XI:1, which have been invoked in these proceedings, is not defined so much in terms of the *type* of measure under examination but rather by the *effects* of the measure.

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[287] Appellate Body Report, *Brazil – Desiccated Coconut*, p. 12. ("Unlike the previous GATT system, the *WTO Agreement* is a single treaty instrument which was accepted by the WTO Members as a "single undertaking").

[288] Appellate Body Report, *Korea – Dairy Safeguards*, para 74.

443. The residual nature of GATT 1994 is apparent from the General Interpretative Note to the agreements in Annex IA of the *WTO Agreement*. This provides that

> In the event of conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the Agreement Establishing the World Trade Organization (referred to in the agreements in Annex 1A as the "*WTO Agreement*"), the provision of the other agreement shall prevail to the extent of the conflict.

444. This has also been recognised by the Appellate Body, which has repeatedly held that panels should first (but not exclusively) address the Annex IA agreement that deals most specifically with the issue under consideration.[289]

445. Thus, if any measure, or any aspect of a measure does not fall under the *TBT Agreement* or the *SPS Agreement*, there remain the residual disciplines of the GATT 1994 to ensure that the measure cannot be used for purposes that are protectionist or otherwise inconsistent with the GATT 1994.

446. The *SPS Agreement* and the *TBT Agreement* also contain a number of specific references to the GATT that address the issue of whether a measure that is inconsistent with a provision of those agreements may nonetheless be justified by the general exception provisions of the GATT 1994.

447. The concluding recital of the preamble to the *SPS Agreement* states that:

> *Desiring* therefore to elaborate rules for the application of the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).[1]

> [1] In this Agreement, reference to Article XX(b) includes also the chapeau of that Article.

448. This recital expresses an intention to elaborate on the relevant provisions of Article XX of GATT 1994 and thus to exhaust its applicability, or at least that of its paragraph (b), with respect to SPS aspects of measures. This is further confirmed by Article 2.4 of the *SPS Agreement*, which provides that:

[289] Appellate Body Report, *Chile – Price Band*, para 194, Appellate Body Report, *EC – Bananas*, para. 204.

> Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

449. These provisions imply that the *SPS Agreement* is confined to those aspects of measures that pursue SPS objectives and thus those aspects of measures taken by Members that do not pursue SPS objectives must be considered to fall outside the *SPS Agreement* and thus potentially under the *TBT Agreement* and the GATT 1994.

450. On the other hand, if the Complainants were right in their implicit view that as soon as a measure pursues an SPS objective, even if only as one amongst many, it falls under the *SPS Agreement* to the exclusion of other agreements, the above reasons for considering that Article XX of GATT 1994 is not applicable to the *SPS Agreement* would not apply.

451. The *TBT Agreement* only contains a general reference to the GATT in its preamble. On the one hand the first recital expresses a desire to further the objectives of the GATT. More significantly, however the preamble recognises:

> that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement;
>
> and
>
> that no country should be prevented from taking measures necessary for the protection of its essential security interest;

452. These recitals recall the language of Articles XX and XXI of the GATT and thus indicate that these general exception provisions also apply to the *TBT Agreement*.

(d) WTO and other international agreements

453. In its very first decision the Appellate Body concluded that "the General Agreement is not to be read in clinical isolation from public international law".[290] This principle applies to all covered agreements. Notwithstanding this ruling, which has subsequently been applied in a number of cases,[291] the Complainants in these proceedings treat the factual and legal issues concerning the authorisation and international trade of GMOs as though they are regulated exclusively by WTO rules, in isolation from other developments in international law. The Complainants make no reference to public debates at national and international levels on the conditions under which the production or consumption of GMOs is to be authorised. They ignore the large number of states – including Switzerland - which have prohibited the commercial cultivation of all GMOs and all imports. And they make no reference whatsoever to the relevant rules of public international law (*lex specialis*) which have been adopted to regulate the concerns and requirements which arise from the particular characteristics of GMOs.[292]

454. In particular, the Complainants ignore the norms of international law reflected in the Biosafety Protocol on the precautionary principle and on risk assessment. The European Communities submits that in accordance with earlier Appellate Body decisions these norms must be taken into account in the interpretation and application of WTO rules. The assessment of the European Communities' actions be reference to the *SPS Agreement*, the *TBT Agreement*, and GATT 1994 cannot ignore these other norms of international law.

455. The Appellate Body has set out the proper approach to the interpretation and application of WTO agreements in *US - Shrimp*.[293] The Appellate Body overturned

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290 Appellate Body Report, *US – Gasoline*, p. 621. See generally J. Cameron and K. Gray, "Principles of International Law in the WTO Dispute Settlement Body", 50 ICLQ 248-298 (2001).

291 See for example Panel Report, *Argentina – Definitive Anti-Dumping Duties on Poultry from Brazil*, para. 7.21.

292 See above Section II. B.

293 See generally D. Brack, 'The Shrimp-Turtle Case: Implications for the Multilateral Environmental Agreement-World Trade Organization Debate', 9 *YbIEL* 13 (1998); H. Mann, 'Of Revolution and Results: Trade and Environmental Law in the Afterglow of the Shrimp Turtle Case', 9 *YbIEL* 28 (1998); R. Howse, 'The appellate body rulings in the Shrimp/Turtle case: a new legal baseline for the trade and environmental debate' 27 *Columbia Journal of Environmental Law* 491 (2002).

the panel's first instance decision because that body "did not follow all of the steps of applying the 'customary rules of interpretation of public international law' as required by Article 3.2 of the DSU".[294] The customary rules of international law are reflected in Articles 31 and 32 of the 1969 Vienna Convention on the Law of Treaties, and they include the requirement to take into account other relevant rules of international law, in addition to the context of the treaty itself. According to the Appellate Body the rules of customary law "call for an examination of the ordinary meaning of the words of a treaty, read in their context, and in the light of the object and purpose of the treaty involved".[295] The Complainants have failed to apply this approach.

456. There can be no doubt that the WTO agreements - including the *SPS Agreement*, the *TBT Agreement* and the GATT 1994 – must be interpreted and applied by reference to relevant norms of international law arising outside the WTO context, as reflected in international agreements and declarations.

457. The Biosafety Protocol is the international agreement which is most directly relevant to the matters raised by the present proceedings. It is described in more detail in Section II.B.3 of the factual part of this submission. The Protocol has been ratified by the European Communities and signed by Argentina and Canada. Although the Protocol has not been invoked in previous WTO dispute settlement proceedings, there is ample authority to support the proposition that the Protocol and the *SPS Agreement* (as well as the *TBT Agreement* and GATT 1994) are so closely connected that they should be interpreted and applied consistently with each other, to the extent that is possible (as is the case in this dispute). One leading commentator has identified the very great dangers of treating the two sets of instruments as unconnected:

294 Appellate Body Report, *US - Shrimp*, para. 114.

295 *Ibid.*

> It is apparent that any legal finding on trade restrictions on LMOs that simply ignores the existence and operation of the protocol will result in amplified criticism of what is often felt to be excessively intrusive WTO law and a predominance of the trade paradigm, and this will erode further the legitimacy of the trading system in the view of public opinion. In WTO adjudication and negotiations a doctrine is required that is able to bring about a reasonable connection between the two equally legitimate concerns and systems. How do the instruments relate to each other?[296]

458. In public international law the instruments relate to each other through the processes of interpretation. As the same commentator has put it:

> The process of interpretation involves certain margins to take into account the rights and obligations stipulated in the protocol when interpreting a WTO agreement. In particular, it is conceivable to construe the provisions and risk assessment [required by WTO agreements] in light of the more advanced and better rules on risk assessment and risk management of the protocol.[297] (emphasis added)

459. The European Communities proceeds on the basis that there is no *a priori* inconsistency between the WTO agreements (*SPS Agreement*, *TBT Agreement*, GATT 1994) and the Protocol, that the two instruments are complementary, and that the Protocol's provisions on precaution and risk assessment inform the meaning and effect of the relevant provisions in the WTO agreements. The negotiators of the Biosafety Protocol were acutely aware of its relationship with WTO agreements and cannot have intended that there should be an inconsistency of approach. Reasonable governments have concluded that the authorisation of GMOs (including import requirements) requires a particular approach, and they can hardly have intended that approach to be inconsistent with WTO rules. The European Communities submits that the application of its internal measures is fully consistent with the WTO agreements, and that this is confirmed by the requirements of the Biosafety Protocol.

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296 T. Cottier, "Implications for trade law and policy: towards convergence and integration", in C. Bail, R. Falkner & H. Marquard, *The Cartagena Protocol on Biosafety: Reconciling Trade in Biotechnology with Environment and Development?* (2002, Royal Institute of International Affairs), p. 466 at 473.

297 *Ibid.*, p. 478. See also R. Howse and J. Meltzer, "The significance of the protocol for WTO dispute settlement", in *The Cartagena Protocol on Biosafety*, 483 at 496.

C. The product-specific delays

460. As the European Communities has explained above, in reality the Complainants are attacking what they consider to be undue delay in the conduct of the EC approvals system for GMOs. They generally refer to this as a "moratorium". They also allege, more specifically, that there is a failure to apply (or a suspension) of the approval system in respect of a number of specific applications (which differ between them). As explained above, the European Communities considers it appropriate to commence with this second group of complaints, which are referred to as the alleged "product-specific delays".

461. As will be shown in this section, the product specific delays do not constitute a violation of the *SPS Agreement.* In particular, they are not "undue delays" within the meaning of Article 8 and Annex C point 1(a) of the *SPS Agreement.* Furthermore, there is no violation of Article III:4 of the GATT 1994.

1. The measure

462. The European Communities would note at the outset that not all of the applications for which the Complainants allege there are product-specific delays are actually still in existence. As explained in Section II. D above, nineteen of the applications listed by the Complainants have been withdrawn or abandoned. The Panel should not therefore address them, since the issue is now moot and the complaints must be considered inadmissible.[298]

[298] This follows from Article 3.3 DSU which states that the basic aim of the dispute settlement system is "the prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements *are being* impaired by measures taken by another Member." [emphasis added]. Any recommendations or rulings by the DSB shall therefore "be aimed at achieving a satisfactory settlement of the matter" (Article 3.4 of the DSU) which cannot be the case if there is no matter to settle (i.e. if no measure is being applied). In the same vein, DSU Article 3.7 provides that "before bringing a case a Member shall exercise its judgment as to whether action under these procedures would be fruitful. The aim of the dispute settlement mechanism is to secure a positive solution to a dispute."

2. *SPS Agreement*

463. In order to explain that the alleged delays or failure to apply the approval system comes under the *SPS Agreement,* Canada goes to some length to explain why acts *and omissions* can come under the *SPS Agreement.*[299] The European Communities does not exclude that an omission or failure to act could be subject to the *SPS Agreement*, but denies that this is so in the present case. Whether a specific omission or failure to act constitutes a violation of the *SPS Agreement* depends on the nature of the obligation in question which is alleged to have been violated.

464. More specifically, the European Communities submits that a failure to deal with a product application within a specified timeframe (that is a delay) can give rise to a violation of the *SPS Agreement* only if *inter alia* two conditions are fulfilled: first, the approval system in question must be a sanitary or phytosanitary measure within the meaning of Article 1 of the *SPS Agreement;* and second, the alleged failure to deal with the application - or to deal with it in a specific manner - must be inconsistent with corresponding obligations set out in the *SPS Agreement.*

465. As regards the first condition, it has been stated above, that the EC legislation on GMOs can be considered to constitute a sanitary or phytosanitary measure only to the extent it addresses risks coming under point 1 of Annex A of the *SPS Agreement.*

466. As regards the second condition, it should be recalled that Article 1.1 second sentence of the *SPS Agreement* states that

> Such measures shall be developed and applied in accordance with the provisions of this Agreement. [emphasis added]

467. Thus, certain provisions of the *SPS Agreement* relate to the *development* of sanitary or phytosanitary measures and others to their *application.*

468. Challenging the failure to deal with applications for authorisation within a specific timeframe or in a specific manner is a challenge against the application of a sanitary or phytosanitary measure.

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[299] First written submission of Canada, para. 157 *et seq.*

469. The European Communities submits that among the various provisions which the Complainants alleged to have been violated only Article 8 together with Annex C of the *SPS Agreement* can be applied to the facts of this case. As regards all other provisions cited by the Complainants, they contain obligations concerning the *development* of a sanitary or phytosanitary measure (i.e. the SPS measure itself), not its *application*. As the European Communities will explain below, the alleged delay in completing the approval procedures for certain applications does not constitute, itself, a sanitary or phytosanitary measure, and, thus, these provisions do not apply.

(a) Alleged violations of Article 8 and Annex C

470. The European Communities agrees with Argentina's analysis that a violation of obligations set out in Annex C simultaneously represents a violation of Article 8.[300] In line with that logic, the discussion which follows on individual provisions of Annex C means that if those provisions have not been violated then there can be no violation of Article 8 of the *SPS Agreement*.

471. Annex C applies to control, inspection and approval procedures. Footnote 7 specifies that

> Control, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification.

472. Point 1 of Annex C begins by stating:

> 1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> (a) […][emphasis added]

473. It then sets forth a catalogue of different obligations. The Complainants allege the violation of a number of these obligations.

474. To the extent that it addresses risks coming under point 1 of Annex A of the *SPS Agreement*, the European Communities accepts that the approval system set up

under the relevant EC GMO legislation is a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures".[301] The procedures it sets forth are designed to ensure that adverse effects on human health and the environment are avoided. To the extent this is done by verifying and assessing the risks coming under the *SPS Agreement*, those procedures can be said to be applied in order "to check and ensure the fulfilment of sanitary or phytosanitary measures."

i) Annex C point 1(a)

475. All three Complainants allege a violation of Annex C point 1 (a). That provision states the following:

> (a) such procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products;

476. The provision sets out two obligations, namely (1) to undertake and complete procedures without undue delay and (2) to do so in no less favourable manner for imported products than for like domestic products. All three Complainants claim a violation of the first, but only Argentina claims a violation of the second. The European Communities considers that these obligations are distinct and are to be treated separately.

♦ Undue delays

477. The European Communities will first discuss the concept of "undue delays" before turning to its application to the facts of the present case.

§ *Concept of undue delays*

478. The European Communities agrees with Canada and the United States that the words "undue delays" are to be interpreted in accordance with the general rules of

300 First written submission of Argentina, para 294.

301 First written submission of the United States, para. 88. First written submission of Canada, para. 230. First written submission of Argentina, para. 231 *et seq.*

international law on treaty interpretation. The words must be interpreted in accordance with the ordinary meaning to be given to its terms in their context and in the light of the object and purpose of the treaty.[302]

479. Out of the rather lengthy list of meanings of the words "undue" and "delay" as offered by the New Shorter Oxford English Dictionary,[303] Canada and the United States arbitrarily settle on the choice of "an unjustifiable and excessive hindrance." While not objecting to the choice of "unjustifiable", the European Communities does not see the necessity of adding "excessive" nor does it agree with the choice of "hindrance" as opposed to, for example, "period of time lost by inaction or inability to proceed." It does, however, agree that both the reason for the delay and its duration are relevant considerations in determining whether any delay is "undue."[304]

480. As is clear from a plain reading of the provision, the meaning of the words "undue delays" is not to be inferred from the domestic legislation of the WTO Members. The argument of both Argentina and the United States,[305] that an "undue delay" exists when and because the procedural delays set forth in the EC legislation have been exceeded is without any merit. Had the drafters of the *SPS Agreement* intended to give the words "undue delay" meaning by reference to (incorporation of) domestic law they would have used a different wording. It is not the purpose of the *SPS Agreement* to elevate national legislation to the level of international law. Equally, it is not the role of the dispute settlement organs (but that of national courts) to enforce that legislation. In any event, even though this question is outside the scope of the dispute, the European Communities would not agree that the procedural time limits in the relevant legislation have not been observed, and is not aware of any single instance of administrative or judicial complaint about this issue.

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302 First written submission of Canada, para. 237. First written submission of the United States, para. 89.

303 As listed by Canada and the United States, idem : *"*undue*"* : inappropriate, unsuitable, imroper ; unrightful ;unjustifiable. "delay*"* : hindrance to progress ; (a period of) time lost by inaction or inability to proceed.

304 First written submission of the United States, para. 89.

305 First written submission of the United States, para. 139. First written submission of Argentina, para. 313.

481. Secondly, delays may occur for reasons completely outside the realm of science. To take the example of a case of *force majeure*: an earthquake destroying the building of a competent authority including all archives containing the pending applications. Any delays in re-constituting the application files would not be considered "undue" or "unjustifiable." For the same reason other causes for delay of a non-scientific nature, such as legislative changes or lack of resources, need to be assessed on their own merits. The Complainants' assertion, therefore, that a delay is "unjustified" if it is caused by a measure that is not based on scientific evidence[306] cannot be accepted and must be rejected.

482. Thirdly, in the view of the European Communities, to the extent that delays are due to scientific considerations, but of the kind that fall outside the scope of application of the *SPS Agreement*, the assessment of whether such delays are "undue" does not come under Annex C point 1 (a). It would instead have to be made under the corresponding provisions of other WTO agreements. In any event, the Panel may not consider such delays "undue" merely on the basis that they are caused by risk considerations which do not come under Annex A point 1 of the *SPS Agreement.*

483. Finally, as a last point on the concept of "undue delay", it is obvious that the European Communities cannot be held liable for any delays that occurred for reasons lying in the sphere of the applicant (i.e. the companies requesting authorisations for their products).

§ *No "undue" delays in the individual applications*

484. To establish that there have been "undue delays", the Complainants assert that the individual applications have been stalled at various levels of the procedure without any explanation or justification.[307] As Canada puts it

> An unjustified general suspension of an approval procedure is on its face an "excessive" delay.[308]

306 First written submission of Canada, para. 239. Similarly, first written submission of the United States, para. 90

307 First written submission of the United States, paras. 138 *et seq.* First written submission of Canada, paras. 292 *et seq.*

485. As has been shown in considerable detail in Section II.D of this submission and in relation to each individual application, none has been stalled and none has been subject to a "general suspension" of the approval process.

486. What has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to the applicants. All of these requests were related to issues of risk assessment, risk management and sometimes risk communication concerning the individual product in question. Some of the requests focussed on risk issues falling outside the scope, others on risk issues coming within the scope of Annex A point 1 of the *SPS Agreement.* Some requests were based on existing legislation, others on (stricter) requirements as set out in the European Communities' new legislation. Where requests were based on new legislation at a time where that legislation had not yet entered into force, they were conditioned on the applicant's voluntary agreement or were slightly delayed to await the entry into force of that legislation. There is nothing unusual in such an approach, which is common to many legal systems facing transitional arrangements where one set of rules are to be replaced by another. Moreover, where the requests caused delays, their duration varied considerably, and sometimes they were for reasons lying in the sphere of the requesting authority or body and sometimes for reasons lying in the sphere of the applicant.

487. On a level of principle, the European Communities submits that it is legitimate to request additional information necessary for the completion of a risk assessment and/or the compliance with certain standards of risk management and risk communication as they have been established by a regulator and as they apply to the given product in question. To the extent such requests cause delay, these are justified and therefore not "undue."

488. That principle applies generally to any product that goes through an approval or inspection procedure designed to ensure that this product is safe. It applies *a fortiori* when the product in issue is based on a new technology which is generally

[308] First written submission of Canada, para. 243.

untried and untested and which is recognised by the international Community to have characteristics which inherently require prudence and caution.

489. It is hard to imagine that the Complainants would disagree with this view given that such requests also frequently occur in their own approval processes for GMOs (or other products). To name but two examples: Monsanto's application for a genetically modified wheat variety has been pending in Canada as well as in the United States since 2002.[309] Due to requests for additional information (presumably related to risk assessment and risk management issues) the respective competent authorities have not reached any final conclusion on the applications.[310] Similarly, as set out in a table attached, many of the applications in the United States for individual crop varieties which have been genetically modified to be insect-resistant have taken a long time due to such requests for additional information by the competent authorities.[311] In the circumstances it cannot be said that these delays are "undue".

490. Furthermore, such requests do not become "illegitimate," as Argentina argues, if and because they are based on requirements that were not expressly set out in the legislation applicable at the time of the filing of the application.[312] As has been stated before, the *SPS Agreement* is not an agreement - and the DSB is not an organ - to enforce domestic legislation. Whether such requests could be made under the existing legislation or not, is a question of EC law and, as such, a matter for courts in the European Communities, which would have to analyse the requests in the light of the overriding goals of public policy pursued by the relevant

309 On 10 May 2004, a spokesperson for Monsanto Canada announced that the company was deferring indefinitely its attempts to win government approval for Roundup Ready wheat because the business case for it was poor. By that date, the company had not yet decided whether to withdraw its application to the federal government of Canada for approval of the product. It was noted that the product had not been grown commercially in either Canada or the United States and was still working its way through the governmental approval process in the U.S. as well. "The Globe and Mail", Tuesday May 11, 2004 at pages A1 and A9.

310 For Cananda, see at <http://www.inspection.gc.ca/english/plaveg/bio/monsane.shtml> (Visited 12 May 2004); for the United States see at < http://www.aphis.usda.gov/bbep/bp/petday.html> (Visited 12 May 2004). See under petition n° 11.02-353-01p Monsanto. According to this website the petition has been withdrawn on 3 March 2004.

311 See Exhibit EC-111.

312 First written submission of Argentina, para. 317.

legislation. For the Panel, the issue is whether such requests are legitimate under the standards of the *SPS Agreement.*

491. For the same reasons, and contrary to what Argentina asserts, such requests do not become "illegitimate" where they are put in the form of a legislative requirement to re-submit an up-dated dossier.[313] In any event, if Argentina considered the relevant provision in Directive 2001/18 (Article 35) to be inconsistent with the *SPS Agreement* it should have attacked the EC legislation as such.

492. In light of the above and on the basis of the documentation put to the Panel (and which the European Community is ready to complement as necessary), the European Communities submits that no "undue delays" have occurred in any of the pending applications. To the extent there were delays and these were caused by requests for additional information, those requests were justified on the basis of standards of risk assessment, risk management and risk communication, which not only the European Communities but the international Community has endorsed.[314] In any case, for the purposes of determining whether these delays have been "undue" under Annex C point 1 (a) of the *SPS Agreement*, only those causes of delay that relate to risks defined in Annex A point 1 of the *SPS Agreement* can be reviewed by the Panel.

313 First written submission of Argentina, para. 318.

314 See, for example, the *Codex Alimentarius* - Principles for the risk analysis of foods derived from modern biotechnology (Exhibit EC-44), which provide : that "a pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of a quantity that would withstand scientific peer review" (paragraph 12); that "risk management measures may include, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring" (paragraph 19); and that "specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials;" etc. (paragraph 21). As is evidenced in the detailed chronologies submitted by the European Communities, the delays – if any – in the processing of applications for the authorisation of GM food under Regulation (EC) No 258/97 can, in most if not all cases, be demonstrated to result either from the failure or time taken by the applicant in supplying either the qualitatively or quantitatively appropriate data for the purpose of the safety assessment, and/or the reference materials, and/or the analytical methods required for the purpose of risk management measures.

493. Further and in the alternative, even if any "undue delays" may have occurred in the past, which is denied, no such "undue delays" are occurring under the new EC legislative framework.

- Treatment no less favourable

494. Argentina claims that there has been a violation of the obligation in point 1(a) of Annex C to undertake and complete procedures in no less favourable manner for imported products than for like domestic products.

495. It seems clear from the wording of this provision that the obligation set forth is one of "national treatment." Imported products are not to be treated less favourably than domestic ones.

496. Instead of analysing the treatment accorded to imported and domestic products, however, Argentina refers to an alleged difference in treatment between "biotech agricultural products" and "novel non-biotech products" and between the treatment given to biotech products "before and after the *de facto* moratorium."[315] Neither has anything to do with national treatment.

497. A "national treatment" issue would arise if the European Communities, in the application of its approval system treated imported GMOs differently from domestic GMOs. This is not the case. All products are being treated equally, irrespective of their provenance or intended provenance.

498. The European Communities submits that Argentina has not established a case of violation of Point 1(a) of Annex C to the extent it refers to the obligation to undertake and complete procedures in no less favourable manner for imported products than for like domestic products.

[315] First written submission of Argentina, para. 321 *et seq.*

ii) Annex C point 1(b)

499. Argentina and the United States allege that the European Communities has violated its obligations under Annex C point 1(b) of the *SPS Agreement.* That provision sets forth the following obligations:

> the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request;
>
> when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies;
>
> the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary;
>
> even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests;
>
> and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained

500. To establish that the European Communities has violated these obligations, Argentina and the United States offer nothing beyond mere assertion that the European Communities has not done what it is required to do under the different obligations.[316] No detailed argument has been put forward which can be responded to in a meaningful way.

501. As the Appellate Body observed as early as its report in *US –Wool Shirts*:

> we find it difficult, indeed, to see how any system of judicial settlement could work if it incorporated the proposition that the mere assertion of a claim might amount to proof [317]

502. The United States asserts that no standard processing period has been published. It concedes that such a period is laid down in the relevant legislation, but then claims (or appears to claim) that specific standard processing periods should have been

316 First written submission of Argentina, para. 324 ; first written submission of the United States, para. 141 *et seq.*

317 Appellate Body Report, *US – Wool Shirts*, page 13.

published under what it calls "the product specific moratoria."[318] What the United States calls "product specific moratoria" are individual applications subject to their own particular facts. It is difficult to see how a "standard" processing period, other than the one laid down in the legislation could be set out for these collectively.

503. Argentina argues :

> The EC has not been able to ensure compliance with [the terms of Annex C point 1 letter b] by the competent bodies, because in some cases the body did not promptly determine whether the documentation was complete, and in other cases did not inform the applicant of the results of the procedure or of the current stage of the products.[319]

No evidence is offered in support of these allegations.

504. The United States, on its side, also considers it enough simply to allege that applications are being stalled and no explanations are being given.

505. It is the Complainants' burden to establish a *prima facie* case. It is not for the European Communities to respond to allegations that are entirely unsubstantiated. However, notwithstanding the failure of the Complainants to particularise or support their allegations, the European Communities has submitted detailed chronologies and all relevant documents in respect of each application referred to by the Complainants. This documentation demonstrates that the allegations of the United States and Argentina are unfounded.

iii) Annex C point 1(c)

506. Argentina, in not more than one short paragraph, alleges a violation of the obligations contained in Annex C point 1 (c). That provision states

> information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs;

507. Argentina argues

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318 First written submission of the United States, para. 142.

> the conduct of the EC in delaying the examination of the applications submitted or in requiring successive submissions under the terms of subsequent legislation is in violation of the provisions of this paragraph.[320]

508. To the extent that these allegations can be said to fall within the provision at issue (which is not the case for delay) the European Communities refers to its arguments made above under point (i). The precise information requirements which are necessary for appropriate approval procedures is a question of standards set forth under the *SPS Agreement* itself. Furthermore, if Argentina considered the requirement to re-submit an up-dated dossier as laid down in the relevant legislation, as incompatible with the *SPS Agreement,* it should have attacked that legislation itself.

iv) Annex C point 1(e)

509. Argentina alleges a violation of the obligations contained Annex C point 1(e). That provision states:

> any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary

510. To the extent Argentina's argument relates to the EC GMO legislation itself, the European Communities considers that this is not the measure at issue and sees no reason to reply.

511. Argentina offers no arguments beyond the mere assertion that

> the application of the EC's control, inspection and approval procedures as they have been applied since 1998 does not meet the requirement of a limitation to what is reasonable and necessary for the control, inspection and approval of a product.

512. The European Communities submits that Argentina has not established a *prima facie* case of a violation.

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319 First written submission of Argentina, para. 324.

320 First written submission of Argentina, para. 325.

(b) Alleged violation of other provisions of the *SPS Agreement*

513. As described above, the alleged delays (or failure to act within a specific timeframe) in the approval process can be reviewed under the *SPS Agreement* as an issue of *application* of a sanitary or phytosanitary measure and more specifically, of the approval system set up under the EC GMO legislation.

514. In addition to Article 8 and Annex C, however, the Complainants allege the violation of a number of other provisions of the *SPS Agreement*, including Articles 5.1, 5.5, 5.6, Articles 2.2 and 2.3 (to the extent they cover the same obligations as set out in more detail in the preceding Articles)[321] and Article 7. On the basis of these provisions they allege the violation of obligations relating not to the *application* of an SPS measure but to the *development* of such a measure, or even its very existence. The Complainants are thus challenging the sanitary or phytosanitary measure itself, not its application.[322]

515. This seems an improbable line of attack, since the Complainants have repeatedly stated that they are not challenging the EC GMO legislation as such. Thus, what they are challenging as a sanitary or phytosanitary measure under the above provisions is a different measure. In fact, what the Complainants try to construe as a "SPS measure" under these provisions, is the very same failure to take final decisions on certain GM products which they have challenged as the *application* of a SPS measure under Article 8 before. As a matter of logic it is clear that alleged behaviour cannot be an SPS measure itself as well as the application of another SPS measure.

516. The European Communities submits that a delay of the kind alleged here cannot constitute a sanitary or phytosanitary measure in the sense of Annex A point 1. An

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321 One could argue on whether Article 2.2 and 2.3 do not also contain obligations relating to the application of a measure rather than to its development. Indeed, these provisions could be understood to constitute leges generalis to the obligations contained in Article 8 and Annex C in the same way they constitute leges generalis to Article 5.1, 5.6 and 5.5. However, the question can be left open, since the Complainants have alleged a violation of these provisions on the basis of the obligations set out in more detail in Article 5.1, 5.5 and 5.6 which do not refer to the application of a SPS measure.

322 Article 7, however, does not contain "substantive" obligations concerning a sanitary and phytosanitary, but procedural obligations (publication) regarding that measure. The above arguments, however, apply mutatis mutandis.

SPS measure under this definition presupposes the existence of an act, whether formal or informal. To apply it to a delay or to an omission is impossible as is evidenced in the Complainants' evident difficulty in construing the intent (i.e. objective) and content of the alleged delay or omission.[323]

517. In conclusion, as the alleged "measure" is a failure to act within a timeframe (i.e. a delay), the above provisions do not apply as they are premised on the existence of a sanitary or phytosanitary measure. Such a situation, however, cannot constitute a sanitary or phytosanitary measure itself, but can only be addressed as the application of such a measure.

3. GATT 1994 – Article III:4

518. Additionally, Canada and Argentina allege that the product-specific delays violate Article III:4 of the GATT 1994.

519. Article III:4 of the GATT 1994 reads:

> The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.

520. The European Communities concurs with Canada and Argentina that the three cumulative elements that need to be satisfied in order for a violation of Article III:4 to be established are:

i) that the imported and domestic products at issue are 'like products';

ii) that the measures at issue are 'laws, regulations, or requirements affecting their internal sale, offering for sale, purchase, transportation, distribution, or use';

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323 First written submission of the United States, para. 135 and paras.74 *et seq.*; First written submission of Canada paras. 257 and paras.159 *et seq.*; First written submission of Argentina, para. 209.

iii) that the imported products are accorded 'less favourable' treatment than that accorded to like domestic products.[324]

521. It follows that if any one of these elements is not satisfied there can be no violation of Article III:4 of the GATT. In connection with the present case, the European Communities will show that the Complainants are mistaken in the way that they categorise the measures at issue as "laws, regulations, or requirements". Furthermore, it will show that there has, in any event, been no less favourable treatment of imported products compared to like domestic products. Therefore, no violation of Article III:4 exists.

(a) The measures at issue are not "laws, regulations or requirements"

522. The first condition which has to be satisfied to establish a violation of Article III:4 of the GATT is that the measures must constitute "laws, regulations or requirements" within the meaning of Article III:4.

523. Canada tries to address this issue by saying that it is the "approval legislation applicable to biotech products" that "is a 'law, regulation or requirement'". It adds that "the products specific marketing bans are inextricably linked to the requirement for pre-marketing approval set out in Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97".[325]

524. Argentina merely assumes that the product-specific delays are "requirements" and cites to this end all the GATT/WTO jurisprudence on action by private parties. It fails to explain how this squares with the delays in the specific approval procedures for which it invokes a violation of Article III:4 of the GATT.

525. The European Communities considers the correct qualification of this first condition is of fundamental importance because it conditions the application of the two other requirements under Article III:4. In the present case the European Communities considers that the measures at issue under Article III:4 cannot be

[324] Appellate Body Report, *Korea – Various Measures on Beef*, para. 133.

[325] First written submission of Canada, para. 302 and 303.

qualified as the European Communities' "approval legislation applicable to biotech products". As pointed out above,[326] the measures challenged by Canada and Argentina are alleged delays in dealing with specific requests for approval within a specified timeframe. These measures are not in themselves "laws, regulations or requirements".

526. If the Complainants had challenged the European Communities' approval system as such, they might have claimed that the less favourable treatment derived from the fact that certain products (GMOs) were subject to an authorisation, whilst others "like" products (non-GMOs) were not. But they have not done so.

(b) Imported products are not accorded less favourable treatment than like domestic products

527. The critical premise of a violation of Article III of the GATT is discrimination between the category of products that are produced abroad and imported and the like category of products that are produced domestically. A violation of Article III can only occur if it can be shown that foreign products are treated less favourably than domestic like products, so as to afford a competitive advantage to the domestic like products.[327] Under paragraph 4 of Article III:

> The words "less favourable treatment"… call for effective equality of opportunity for imported products in respect of the application of laws, regulations or requirements affecting the internal sale, offering for sale, purchase, distribution or use of products.[328]

528. In the present case there will only be a violation of Article III:4 if the measures at issue, the product-specific delays, can be said to adversely affect the competitive opportunities on the EC market of the categories of products which are subject to each application for approval. That is, it would be necessary to show discrimination between imported Bayer oilseed rape MS8/RF3, Monsanto Roundup Ready oilseed rape GT73, Monsanto Roundup Ready cotton (RRC1445), Monsanto Bt Cotton (531), Monsanto Roundup Ready corn (NK603), and Bayer

326 Section III.A.B.1.
327 Appellate Body Report, *Canada – Periodicals*, page. 18.
328 Panel report, *Section 337*, para. 5.11.

Liberty Link soybeans (A2704-12 and A5547-127) and their domestically produced equivalents .[329] Less favourable treatment can only be established if it could be shown that the European Communities has taken more time to authorise the importation of the GMOs at issue than to authorise their domestic cultivation or processing.

529. This cannot be shown, because it has not happened. For example, as to the six notifications in respect of which Canada and Argentina allege delays in violation of Article III:4, they relate to both imported and domestic GMOs. In particular, Bayer oilseed rape MS8/RF3 has been notified for "cultivation and import in the European Communities for all uses as any other oilseed rape (food, feed and industrial use)";[330] whilst Monsanto Bt Cotton (531) and Monsanto Roundup Ready cotton (RRC1445) have both been notified for "cultivation and marketing into the European Union … for the purposes of production, importation, storage and processing to non-viable products for industrial, food and feed uses".[331] Similarly, Monsanto Roundup Ready oilseed rape GT73, Monsanto Roundup Ready corn (NK603) and Bayer Liberty Link soybeans (A2704-12 and A5547-127) have been notified for import and use in the European Communities.[332]

530. There has been no distinction or difference in the treatment of products on grounds of origin.

531. Nor can it be said that there has been "less favourable treatment" in a *de facto* manner. All notifications have been submitted by companies that were or are incorporated in the European Communities.

532. For example, Bayer oilseed rape MS8/RF3 and Bayer Liberty Link soybeans (A2704-12 and A5547-127) were originally notified by Plant Genetic Systems, a Belgian company which was later bought by Aventis CropScience. Aventis CropScience was the result of the merger two European chemical companies,

329 See, most recently, Panel Report, *Canada – Wheat and Grain*, para. 6.184.
330 See the SNIF (Exhibit EC-63, attachment 37).
331 See point 1(c) of the SNIF of these products, (Exhibit EC-65, attachment and Exhibit EC-66, attachment 21).
332 See the SNIF of these products (Exhibit EC-70, attachment 24, Exhibit EC-76, attachment 7).

Rhône Poulenc and AgrEvo. Aventis CropScience was subsequently acquired by the German company Bayer CropScience.

(c) The only "like" products to imported GMOs are domestic GMOs

533. The other condition which must be satisfied for a violation of Article III:4 of the GATT to be established is that the imported and domestic products at issue must be 'like products'. To assess whether a country can treat imported products "less favourably" a term of comparison of domestic origin has to be chosen.

534. Canada and Argentina have chosen as terms of comparison for the Article III:4 analysis "the Specific Products and their respective domestically-grown non-biotech counterparts" [333] and "imported biotech products and 'non-biotech' domestic products".[334] Canada and Argentina therefore proceed on the basis that there is no difference between GM products and their non-GM conventional counterparts.

535. This approach is misconceived. In the context of marketing approval legislation the "like" product has to be a product which is similarly subject to the approval procedure. Conventional, non-GM products are not subject to the same approval procedure. And the international Community has, through the Biosafety Protocol, recognised that GM products are such that they require their own, distinct authorisation procedure.

536. In this case, the European Communities submits that the only "like" product to a given imported GM product is the same GM product cultivated or processed domestically.[335]

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333 First written submission of Canada, heading VII.B.1.(b).

334 First written submission of Argentina, heading III.a.

335 The fact that it is not possible to conduct an analysis under Article III of GATT without even considering the competitive relationship between the imported good and the same domestic good is also confirmed by the existing case law. In *US – Gasoline*, for instance, the two products of comparison were "the chemically-identical imported and domestic gasoline" (Panel Report, *US – Gasoline*, para. 6.9.). In *Canada – Periodicals*, as there were no imports of split-run editions of periodicals because of an import prohibition in place, the Panel and the Appellate Body had to revert to "hypothetical imports of split-run periodicals" (Appellate Body Report, *Canada – Periodicals*, pp. 20-21.).

537. As seen above, the scope of each of the six notifications for which Canada and Argentina allege delays that violate Article III:4, cover both imported and domestically produced GMOs.

538. Thus, in order to establish a violation of Article III:4 of the GATT in this case, Canada and Argentina must establish that the product-specific delays provide "less favourable treatment" for imported GM products as compared with domestically produced GM products. They have failed to do so.

4. Conclusion

539. For the above reasons, the European Communities rejects the claims made by Argentina, Canada and the United States that the alleged product-specific delays are inconsistent with the *SPS Agreement* and the alternative claims by Argentina and Canada that these measures are inconsistent with the *TBT Agreement* as well as the purported reservation by the United States of its "right" to make such claims. The European Communities also rejects the claims made by Argentina and Canada of a violation of Article III:4 of the GATT 1994.

D. The "general suspension"

540. In this Section the European Communities will present its arguments on the alleged general suspension of the approval process.

541. As has been shown in the factual part there is no suspension of the approval process and there has never been. All applications have been maintained even if requests for additional information and the replies to such requests have caused delay in some instances. The Complainants' claims that all approval processes have been systematically stalled are without merit. No evidence on the existence of a "moratorium" has been identified.

542. Moreover, even if could be said that a repeated pattern in the treatment of individual applications existed, any such pattern could not be a challengeable measure under the *WTO Agreement.*

543. In the absence of a measure the European Communities does not consider it necessary to address the arguments of the Complainants regarding a violation of the *SPS Agreement* or of the *TBT Agreement*.

1. The "measure" at issue

544. There is no disagreement between the parties that the European Communities has never adopted any formal act putting in place a moratorium on the authorisation of GMOs. There also exists no informal act of any kind – a policy bulletin, administrative guidance or any instrument of that kind - providing for a "moratorium" to be applied.

545. What the Complainants seem to argue is the existence of an alleged practice of suspending the consideration of applications and approvals, in the form of a repeated pattern of systematic behaviour. Such a practice is not based on any document even informal/non binding in nature.

2. There is no general suspension

546. This submission has shown that each application has been addressed individually based on standards of risk assessment and risk management which the European Communities had either already set out in existing legislation or was putting in place through new legislation. In some cases concerns about non-compliance with these standards have caused delays. There is no consistent practice in respect of the applications as a whole. Each has been taken on its own merits.

(a) The lack of evidence of "the EC's failure to approve any biotech products for nearly five years"

547. The United States and Canada both rely on the "evidence" of the "EC's failure to approve any biotech products for nearly five years." They do so with differing arguments. Two general remarks are called for.

548. First, even if it were true that no "biotech product" had been approved for nearly five years, that fact alone could not prove the existence of a practice consisting in the temporary halting of the consideration of applications and the granting of approvals. The absence of a final approval does not mean that an approval process has been suspended. What has to be demonstrated is that the process has been halted "across the board" (as the Complainants put it) or with regard to "any and all biotech products" (as the Panel itself has put it)[336]. Both the United States and Canada make several references to the applications being "stalled". As shown in Section II.D, there are many cases of progress at various levels which demonstrate that this allegation is wrong and even the Complainants appear to acknowledge this in their submissions.[337]

549. Second, it is a fact that between 1998 and today thirteen GM food products were placed on the market under the simplified procedure foreseen in Regulation 258/97. It is striking, in this regard, that the Complainants change their approach and definitions to suit their arguments. Canada concedes that "since 1999, five biotech products have been placed on the market through the simplified procedure for substantial equivalence under Article 5 of Regulation 258/97." But it goes on to dismiss that fact on the basis that "this procedure does not involve the Regulatory Committee, nor does it require Council action".[338] There is no validity to this distinction.

i) Insufficient evidence offered by the U.S.

550. To prove a suspension across the board, the United States presents arguments on the twenty-seven products listed in the Annexes to the Request for establishment of a Panel, which are currently pending either under Directive 2001/18 or under Regulation 257/97 (in reality only twenty-three of these are still pending, see Section II D 1(a) leaving out the seven other products that are also pending (see Section II D 3)). For the purposes of proving a practice applying to "any and all

336 Panel Preliminary Ruling, para. 26.

337 First written submission of the Unites States, para. 2; first written submission of Canada, para. 56.

338 First written submission of Canada, para. 57.

biotech products" it is necessary to provide the detailed evidence for all of them. The United States has not done so.

551. Second, the United States, with regard to the applications for release into the environment, asserts that these products were stalled under Directive 90/220. The United States does not consider it necessary to determine whether they are still "stalled" under Directive 2001/18. For the purposes of proving a practice of suspension it is not sufficient to provide a superficial and incomplete account of what happened to some of the products (but not all) in relation to that period of time when the old EC legislation was in place. Directive 90/220 has long been replaced. The WTO dispute settlement does not provide for remedies in respect of past measures, not least where they are no longer in existence.[339]

ii) Insufficient evidence offered by Canada

552. The Canadian argument evidence the difficulty of transforming an argument as to delay into a claim of suspension or "moratorium". Indeed, several of the applications which have not been dropped have moved on to the next stage in the approval process and plainly are not stalled. To get around this difficulty, which is potentially fatal to its case, Canada resorts to claims of delay or accuses individual instances or actors in the approval process of not having acted appropriately: it accuses Member States of blocking the approval process,[340] the Commission of failing to submit to the Council,[341] and the Regulatory Committee of not voting in favour.[342] The actions of these individual instances or actors constitute discrete steps in an internal decision-making process. As such they are not susceptible to be reviewed as measures *as such* by domestic judicial instances and much less by the WTO dispute settlement bodies.

339 See also above Section III. C. 1. on the issue of "products withdrawn."
340 First written submission of Canada, para. 48.
341 *Ibid.*
342 First written submission of Canada, para.53.

(b) The lack of evidence of different statements made by different actors

553. All three Complainants offer a wide variety of statements from many different sources that are intended to support the claim that there has been a suspension of the approval process. The Complainants appear to rely on four Commission documents of an official or internal nature, one Commission press release, approximately six statements from various Commissioners, one statement from five Member States, two statements from Member State officials, one from a Member of the European Parliament and a note of the General Secretariat of the Council. None of these statements provides evidence of the existence of a *de facto* "moratorium".

i) Statements as evidence under WTO law

554. The Complainants do not claim that these statements constitute measures. They rely on them as evidence in support of their claim that there has been a practice of temporarily halting the approval process. The statements cannot create a practice where none exists.

555. The dispute settlement bodies under GATT 1947 and under the *WTO Agreement*s have been faced with the evidentiary value of "statements" in a number of cases. There are those that addressed the question of whether certain statements can constitute challengeable measures or otherwise have a binding legal effect. The panel in the case *US – Section 301 Trade Act*, made it clear that :

> A sovereign State should normally not find itself legally affected on the international plane by the casual statement of any of the numerous representatives speaking on its behalf in today's highly interactive and inter-dependant world.[343]

556. There are cases where statements have constituted evidence of a Member's wrongful action. This happened, for example, in the *Japan Semi-Conductor* case. The panel referred to a position paper of the Japanese Government which contained

"its own description of its measures" as well as to statements made by the same during the proceedings.[344] The panel relied on these statements as "further confirmation" of the involvement the Japanese Government was found to have had in dumping.[345] Thus the paper constituted a further element confirming a set of facts that had already been found to exist. No equivalent document has been relied upon in this case.

ii) Comments on the content of statements

557. If the Panel were to look at an official government position on the issue in question in the present case then it should have regard to what the European Communities officially stated at the consultations with the Complainants and formally now repeats, namely that there is no "moratorium".[346]

558. The Complainants rely on a broad range of statements which either do not represent the official position of the European Communities or do not confirm the existence of a practice of suspending the approval process, or both.

559. What comes closest to an official governmental position in the sense of the *Japan Semi-Conductor* case is the Commission Communication of 2004. In that Communication it is plainly stated that no authorisations have been granted since 1998 with the exception of notifications under the simplified Procedure of the Novel Food Regulation.[347] But the Communication does not confirm the existence of a "suspension of the approval process". It says the very opposite, namely that an "interim approach" has been applied. It explains that "authorisation procedures under the Novel Foods Regulations are being finalised in line with the interim approach…" and also that "applications under Directive 2001/18/EC are currently being processed in accordance with the authorisation procedure."

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343 Panel Report, *US – Section 301 Trade Act*, para. 7.118. On a similar line, see Panel Report, *Japan – Film*, para. 10.43: «..not every utterance by a government offficial…can be viewed as a measure of a Member government."

344 Panel Report, *Japan – Semi Conductor*, paras. 112 and 116

345 Panel Report, *Japan – Semi Conductor*, para. 116.

346 See Opening Statement at consultations on 19 June 2003 (Exhibit EC-112), see also Press Release of 13 May 2003 (Exhibit EC-113).

347 Exhibit CDA-33, p.3.

560. As regards all other statements, the European Communities submits that in the light of the above case law they do not have any value as evidence of a practice. In any event, however, none of these statements actually proves the existence of a practice of suspension of the approval process.

561. As regards the statements made by EC or even Member State officials, two observations may be made. First, it is one thing to describe a situation and quite another to assert the existence of a practice in legal terms. The mere fact that individual applications have not resulted in a final decision on a market authorisation for some time may well be perceived from the outside as a situation of "standstill." The reason for this situation, namely the fact that there are requests for additional information on complex issues of risk assessment and management, is not of the kind to alter general perception.

562. Second, those references to a "moratorium" or "de facto moratorium" for the great majority were made in the context of the legislative changes still being under way. All imply that once that process is finished the transition period will end. The process is now completed. The statements do not establish a "moratorium" that is currently in existence.

563. Finally, the European Communities would want to address specifically the issue of the declaration made by five Member States in the Council on the occasion of the adoption of the Common Position on what was later to become Directive 2001/18. The United States claims that the declaration "announced" a "moratorium."

564. The declaration must be read in full.[348] It reflects the application by these Member States of the precautionary approach to individual applications. The precautionary

[348] The full wording is the following:
"The Governments of the following Member States (Denmark, Greece, France, Italy and Luxembourg), inexercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs),
Given the need to put in place a tighter, more transparent framework, in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling,
Given the need to restore public and market confidence,
Point to the importance of the Commission submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorisations for growing and placing on the market suspended."

approach has been adopted by the European Communities as a whole in its decision to put in place a more stringent framework legislation (a decision, which by now, it has fully implemented).

565. For the purposes of the approval process, these five Member States form part of two bodies (the Regulatory Committee and the Council) among others that have established roles in the decision-making process. Their actions in these bodies form part of the decision-making procedure and do not by themselves constitute measures with a legal effect. Even if the Complainants had shown (which they have not) that these Member States have been blocking in the past - and would systematically block in the future - the approval process, that action would still not demonstrate the existence of a consistent practice. These Member States have participated in the safety evaluation of each application, like the other Member States. They have, like all others, raised comments and objections where they saw concerns. They have voted on the basis of their assessment of the safety issues at stake. Thus, in the most recent of these votes, two of these five Member States have voted in favour of an authorisation.[349]

3. A pattern of suspension is not a challengeable measure

566. In any event, even if on the basis of the above "evidence" it could be said that there has been a systematic suspension of the approval process, a kind of "repeated pattern" of stalling individual applications, such a pattern could not as such constitute a challengeable measure under the *WTO Agreement*.

567. The argument would be that the "measure" challenged would be a practice, and more specifically a practice not laid down in any document whether formal or informal in character. WTO case law establishes that this would not be a challengeable measure.

568. Where Complainants have tried to challenge a practice *as such* independently of any instrument (formal or informal), their claims were found to be inadmissible. In

[349] See statement of Commission spokesperson Reijo Keminnen of 31 April 2004 on the vote in the Regulatory Committee on Monsanto Maize NK 603, EXHIBIT –EC 114.

the case *US – Steel Plate* India, argued that practice was a "repeated pattern of similar responses to a set of circumstances" and that at some point repetition turned into a "procedure", and hence into a measure.[350] The panel dismissed the challenge as inadmissible. It stated :

> That a particular response to a particular set of circumstances has been repeated, and may be predicted to be repeated in the future, does not, in our view transform it into a measure. Such a conclusion would leave the question of what is a measure vague and subject to dispute itself, which we consider an unacceptable outcome.[351]

569. That ruling is supported by the case law on challenges against informal measures *as such* and the underlying *rationale* on which that case law is based. In these cases the measure challenged usually was an instrument or document of some sort. The "plan or course of action intended to achieve some object" (i.e. definition for a "measure") was set out in that instrument. Once it could be shown that the instrument was effectively applied or put into operation "in a manner equivalent to mandatory requirements" [352] and constituted the "root of WTO inconsistent behaviour,"[353] a Member would be required to "eliminate" it in same the way it would have to eliminate a WTO inconsistent legislation. The practice, in these cases, served as evidence that the rules set out in the instrument in question were actually being applied as if binding.[354]

570. On the basis of this case law it is evident that the claim against the "general suspension" is inadmissible. Indeed, even if a repeated pattern of similar responses - of not considering or not approving the individual GM product applications -

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350 Panel Report, *United States – Anti-Dumping and Countervailing Measures on Steel Plate from India*, at para 7.22.

351 Idem. Similarly, in *US – Export Restraints*, the panel dismissed a challenge against a practice finding that it did "not appear to have independent operational status such that it could independently give rise to a WTO violation as alleged by Canada, " see Panel Report, *United States – Measures Treating Exports Restraints as Subsidies*, at para. 8.126.

352 Panel Report, *Japan – Trade in Semi-Conductors*, at para. 109.

353 Appellate Body, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, para. 82

354 See, in particular, Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, para. 97

could be demonstrated (which is not the case), it would still not constitute "a separate measure that could independently give rise to a WTO violation."[355]

4. Conclusion

571. In conclusion the European Communities submits that the Complainants have not established that there is a general suspension of the approval process. Even if they had established that there was some kind of repeated pattern of not considering applications and not granting approvals any such pattern could not constitute a challengeable measure under the *WTO Agreement.*

E. The EC Member State Safeguard Measures

572. The European Communities recalls that the Member State safeguard measures are limited exceptions to product authorisations of GM products that have been adopted for the whole of the European Communities (following a specific notification by a specific company of a specific product). The Member States concerned subsequently had doubts about the appropriateness of the Community-wide authorisations and adopted national safeguard measures as provided for in the EC GMO legislation. These are provisional measures pending a full assessment at European Communities level, which will eventually lead either to a modification of the Community-wide authorisation or a termination of the national safeguard measures. This will now be done in the light of the changes in Community legislation.

573. It should be noted that all of these national safeguard measures were adopted under Article 16 Directive 90/220 (with one exception adopted under Article 12 of Regulation 258/97). These measures continue to exist under Article 23 of Directive 2001/18 and are being reviewed under that provision.

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[355] Panel Report, *United States – Anti-Dumping and Countervailing Measures on Steel Plate from India,* at para. 7.24.

574. In this light, the current situation is a provisional and temporary one, and the measures in place may be considered, for the purposes of WTO law, as provisional or temporary measures, based on the precautionary principle.

575. Given the reasons for these measures, they fall in part within the scope of the *SPS Agreement* and in part outside the scope of the *SPS Agreement.* To the extent that they fall within the scope of the *SPS Agreement,* they would essentially fall to be assessed under Article 5.7. Article 5.7 excludes Article 5.1 of the *SPS Agreement,* rather than being an exception to it. However, no inconsistency with Article 5.7 has been alleged by the Complainants, and the Member State measures are in any event consistent with it. Furthermore, there is no basis for reaching the conclusion that the Member State measures are inconsistent with the other provisions of the *SPS Agreement* to which the Complainants refer.

576. As regards the *TBT Agreement,* the Member State measures are not technical regulations within the meaning of that *Agreement* and for that and other reasons cannot be inconsistent with Article 2 of that *Agreement.*

577. Finally, the Member State measure are also fully consistent with Article III:4 of the GATT 1994, in particular because they do not provide less favourable treatment to imported products than to like domestic products.

1. *SPS Agreement*

(a) Scope

578. The European Communities refers to Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment; to Section III.B.3 (a) of this submission, which analyses the scope of the *SPS Agreement*; and to Section II.D.4 which summarises the Member State measures. It results from that analysis that each of the Member State measures was adopted for some reasons that fall with the *SPS Agreement,* and some reasons that do not fall within the *SPS Agreement.* The measure or part of the measure adopted for

reasons that fall outside the scope of the *SPS Agreement* cannot be inconsistent with that Agreement. Only the measure, or part of the measure, adopted for reasons that fall within the scope of the *SPS Agreement* require further analysis.

(b) Provisional measures under Article 5.7 *SPS Agreement*

579. Article 5.7 of the *SPS Agreement* provides :

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organisations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time. (emphasis added)

580. Not every provision of the *SPS Agreement* automatically applies or is relevant to every measure that falls within the scope of the *SPS Agreement*. Rather, within the *SPS Agreement*, different provisions have different scopes or sub-scopes. The scope of a specific SPS provision is *objectively* defined by its own terms.

581. For example, Article 7 and Annex B of the *SPS Agreement* apply to generally applicable regulations, as provided in footnote 5. They do not apply to SPS measures that are not generally applicable. Thus, if a Member wishes to bring before a panel a question about the publication of an SPS measure that is *not* generally applicable, it is futile for that Member to invoke an inconsistency with Article 7 and Annex B. The action or inaction complained of falls outside the scope of those provisions. The complaining Member must find some other relevant provision. Conversely, if a Member wishes to bring before a panel a question about the publication of an SPS measure that *is* generally applicable, the relevant provisions are Article 7 and Annex B. If the complaining Member invokes inconsistency with some other provision, such as, for example, Article 8 and Annex C, it would simply be invoking the wrong provision.

582. There are other examples of provisions of the *SPS Agreement* that have a limited scope : Article 8 and Annex C of the *SPS Agreement* are limited in scope to control,

inspection and approval procedures; Article 3 concerns harmonisation; Article 4 concerns equivalence; and so on.

583. It is up to a complaining Member to invoke what is objectively the relevant provision. If the complaining Member invokes the wrong provision, the responding Member may draw the attention of the panel to the correct provision. If there is a dispute about what the relevant provision is, the panel must settle that threshold question. The Panel must determine whether the measure complained of falls within the scope of the provision referred to by the complaining Member, or rather within the scope of the provision referred to by the responding Member. The Panel must settle that threshold issue by reference to the terms of the *SPS Agreement* that define the scope of the two provisions. *At this stage of the analysis the conditions set out in the provisions - on the basis of which the Panel will subsequently determine whether or not there is an inconsistency with what it has determined is the relevant provision - are irrelevant.*

584. Article 5.7 of the *SPS Agreement* has a limited scope that is defined by its own terms – it applies only to provisional measures. If, objectively, a measure is "provisionally adopted" and therefore falls within the scope of Article 5.7, whether or not it is consistent with or justified by that provision may then – and only then – be determined by the Panel by reference to the four conditions set out therein.

585. The situation is no different than that in relation to many other provisions of the *WTO Agreement*s whose scope is objectively defined and limited, particularly as regards provisional measures. Such provisions contain their own specific rules and exhibit their own specific logic, context and purpose – and it is only on this basis that challenged provisional measures can be properly assessed as a matter of WTO law. For example, a provisional anti-dumping measure falls within the scope of Article 7 of the *Anti-dumping Agreement* and may be referred to a panel only if it has a significant impact within the meaning of Article 17.4 of the *Anti-dumping Agreement*. Such a measure must be assessed in the light of Article 7 of the *Anti-*

dumping Agreement.[356] Precisely the same is true in respect of Article 17 of the *SCM Agreement.*[357]

586. The European Communities draws the attention of the Complainants and the Panel to the fact that in this case the Member State measures to which the Complainants refer are provisional measures within the meaning and scope of Article 5.7 of the *SPS Agreement.* For the purposes of this part of its argument, the European Communities need make no assertions about whether or not any of the four conditions set out in Article 5.7 are met – only that the Member State measures are provisional measures.

587. In these circumstances, the European Communities might or might not have the burden of making a *prima facie* case in support of its position that the Member State measures are provisional measures. However, for this limited purpose the question of who has the burden in respect of the four conditions set out in Article 5.7 of the *SPS Agreement* is irrelevant as a matter of law.

588. That this is the correct analysis is confirmed by the *Japan – Apples* case. In that case Japan sought to rely on Article 5.7 of the *SPS Agreement* only in the alternative – that is, only in the event that the panel rejected Japan's arguments with respect to Article 2.2 of the *SPS Agreement.* The Appellate Body was careful to stress that it was only in this particular context that the panel assigned a burden of proof to Japan that also extended to the question of whether or not the four conditions set out in Article 5.7 of the *SPS Agreement* were met. The Appellate Body was also careful to stress that this assignment of the burden of proof to Japan by the panel was not challenged on appeal[358]. In the present case, the European Communities does not make its argument regarding Article 5.7 of the *SPS Agreement* only if the Panel finds that the measures infringe some other provision of the *Agreement.* Rather, the European Communities raises this matter as a

356 See, for example, Panel Report, *Mexico-HFCS*.

357 See, for example, Panel Report, *US-Softwood Lumber*.

358 Appellate Body Report, *Japan – Apples*, paras 175 and footnote 316. The Appellate Body was referring only to the parties. . The European Communities argued that the complaining party had the burden of proof under Article 5.7 – see para. 111 of the Report.

threshold issue that the Panel must settle first, just as the Panel must settle the threshold question of what is the true scope of the *SPS Agreement* itself.

589. In fact, the case that the European Communities now sets out to the effect that, objectively, the Member State measures were "provisionally adopted" within the meaning of Article 5.7 of the *SPS Agreement* is far more than a mere *prima facie* case – the facts speak for themselves and are incontrovertible.

590. Article 16(1) of Directive 90/220/EC provides in relevant part :

> Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. (emphasis added)

591. Article 12(1) of Regulation (EC) No 258/97 provides in relevant part :

> Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. (emphasis added)

592. The Court of Justice of the European Communities has confirmed that, as a matter of Community law, measures adopted on the basis of such provisions are temporary measures.[359] Furthermore, the provisional nature of the measures is also generally reflected in the measures themselves,[360] as well as the national laws on which they are based.[361] The United States, Canada and Argentina actually agree with this objective characterisation of the Member State measures.[362]

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359 Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others*, judgment of 9 September 2003 (not yet published in the European Court Reports), para. 109.

360 See, for example, in relation to Bt-176: Journal Officiel du Grand-Duché de Luxembourg [Luxembourg Official Journal] of 28 February 1997, page 618: "Sont interdites à titre provisoire I'utilisaiton et la vente du produit identifié ci-après" [The use or sale of the following products is provisionally prohibited].

361 The French measures were adopted on the basis either of Article L533-6 of the Environmental Code (Livre/Book V Titre/Title III Chapitre/Chapter III) or of Article 16 of LOI no 92-654 du 13 juillet 1992 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés [Law on the Use and Release of GMOs] (J.O n° 163 du 16 juillet 1992). The Austrian measures were adopted on the basis of § 60 of Gentechnikgesetz [Gene Technology Law] GTG,

593. It follows that, to the extent that the provisions of Article 5 of the *SPS Agreement* are relevant at all for the Panel's assessment (which the European Communities would not accept), all of the measures adopted by the Member States of the European Communities, to the extent that they fall within the scope of the *SPS Agreement*, were adopted on the basis of Article 5.7 of the *SPS Agreement.*

594. Neither the United States nor Canada nor Argentina assert that any of the measures adopted by the Member States are inconsistent with Article 5.7 *SPS Agreement.* There is therefore no basis for the Panel to conclude that these national measures are inconsistent with the relevant provisions of the *SPS Agreement*.

(c) Member State measures not inconsistent with Article 5.7 of the *SPS Agreement*

595. The Complainants having not invoked any inconsistency with Article 5.7 of the *SPS Agreement*, there is no obligation for the European Communities to respond on this point, nor any burden of proof on the European Communities concerning the four conditions set out in that Article. However, for the assistance of the Panel, the European Communities would briefly summarise the position in this respect as follows.

596. First, for the purposes of the specific assessment carried out by the national legislator, notably that legislator's appreciation of the level of acceptable risk, it may be considered, from that specific perspective and for the purposes of WTO law only, that relevant scientific evidence was or is insufficient. This point is examined in further detail below with respect to the alleged inconsistency with Article 5.1 of the *SPS Agreement.*

BGBl. Nr. 510/1994. The Luxembourg measure was taken on the basis of Article 27 of Loi du 13 janvier 1997 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifies [Law on the Use and Release of GMOs]. The German measure was adopted on the basis of § 20 of the Gesetz zur Regelung der Gentechnik [Law Regulating Gene Technology]. The Italian measure was taken directly on the basis of Article 12 of EC Regulation 258/97. The Greek measure was taken on the basis of Article 12 of Joint Ministerial Decision No 88740/1883. All these provisions either expressly use the word "provisionally" (à titre provisoire (France/Luxembourg); vorübergehend (Austria); προσωρινή (Greece)), or state, in the case of Germany, that acts are adopted only until a decision of the European Commission or the Council is adopted.

597. Second, the Member States adopt and maintain the measures on the basis of available pertinent information. That includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. Such information relates to the potentially harmful effects of GMOs as summarised in Section II.A.4. of this submission, which sets out the possible harmful effects of GMOs on human health and the environment; in Section III.B.3 (a) of this submission, which analyses the scope of the *SPS Agreement*; and in Section II.D.4 which summarises the Member State measures

598. Third, Member States and the European Communities are engaged in an ongoing process by which they are seeking to obtain the additional information necessary for a more objective assessment of the risk. Further research is constantly ongoing and the science is developing all the time. During the relevant period, the European Communities legislation was also amended to reflect this constantly evolving situation.

599. Fourth, the measures are subject to a process of review within a reasonable period of time. That review is still ongoing, both at Community and Member State level. The question of what a reasonable period of time is when conducting such assessments depends on all the circumstances – and is considered in further detail below in respect of the alleged inconsistency with Article 5.1 of the *SPS Agreement*.

(d) No inconsistency with Article 5.1 *SPS Agreement*

600. The United States, Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 5.1 of the *SPS Agreement*.[363] The European Communities does not agree.

601. Article 5.1 of the *SPS Agreement* provides :

[362] First written submission of the United States, para. 156. First written submission of Canada, paras. 379 and 380. First written submission of Argentina, para. 456.

[363] First written submission of the United States, paras. 169 to 173; First written submission of Canada, paras. 389 to 394; First written submission of Argentina, paras. 478 to 484.

> Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.

602. Article 5.7 of the *SPS Agreement* contains specific rules regarding provisional measures, and it is by reference to these rules, not the rules in Article 5.1, that the Member State measures must be assessed. Article 5.1 of the *SPS Agreement* contains rules concerning risk assessments other than in relation to provisional measures. Article 5.7 applies to measures provisionally adopted. The first sentence of Article 5.7 involves an "assessment", given that the second sentence of Article 5.7 refers to a "more objective assessment", meaning a more objective assessment than the assessment made on the basis of the first sentence of Article 5.7 of the *SPS Agreement*. It follows that when a risk assessment in relation to measures that are not provisional is to be carried out, it will be carried out on the basis of Article 5.1 of the *SPS Agreement*, but that when provisional measures are adopted, an assessment should be made in conformity with Article 5.7 of the *SPS Agreement*.

603. This analysis was effectively confirmed with particular force by the Appellate Body in the *EC-Hormones* case. The Appellate Body stressed that Articles 2.2 and 5.1 of the *SPS Agreement* must constantly be read together.[364] At the same time, the Appellate Body stressed that the relationship between Articles 3.1 and 3.3 of the *SPS Agreement* was one of exclusion, not exception.[365] Taking these two propositions together, it necessary follows that the relationship between Articles 2.2 (which contains wording substantially identical to that of Article 3.1) and 5.7 of the *SPS Agreement* is also one of exclusion; and that therefore the relationship between Articles 5.1 and 5.7 is equally one of exclusion. In these circumstances, the relevant provision for assessing the Member State measures in this case is Article 5.7, and there is no basis for the Panel to find an inconsistency with Article 5.1 of the *SPS Agreement*.

364 Appellate Body Report, *EC-Hormones*, para. 180.
365 Appellate Body Report, *EC-Hormones*, para. 104.

604. Should the Panel consider Article 5.1 of the *SPS Agreement* relevant to an assessment of the Member State measures – a determination that the European Communities would consider wrong as a matter of law – then the European Communities would point out, in the alternative, that those Member State measures were based on an assessment appropriate to the circumstances within the meaning of that provision. The words "appropriate to the circumstances" make it clear that Members have a certain degree of flexibility in meeting the requirements of Article 5.1.[366] The circumstances in the present case are that relevant scientific evidence was or is insufficient. Scientific evidence means information collected using scientific method and evidenced or recorded in some way. Scientific method involves experimentation, observation and the collection of data – "a process characterised by systematic, disciplined and objective enquiry and analysis, that is, a mode of studying and sorting out facts and opinions."[367] That takes time. Particularly when it is also necessary to assess "risks in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die."[368] This is all the more true when the risks extend to environmental issues. When sufficient time has elapsed, and subject always to possible dissenting views, scientists will be in a position to state that "scientific evidence establishes that the risk to humans, animals or plants from X is Y", where Y is an evaluation of likelihood or probability or potential or possibility.[369] Armed with this information, the legislator will be able to carry out its task, by determining whether or not Y corresponds to an acceptable level of risk, given any relevant benefits associated with the GMO, as well as the reversibility of any steps taken, and act accordingly. An adequate risk assessment is thus one delivered by a reputable source, that unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and that has withstood the passage of time and is unlikely to be revised.

366 Appellate Body Report, *EC-Hormones*, para. 129.
367 Appellate Body Report, *EC-Hormones*, para. 187.
368 Appellate Body Report, *EC-Hormones*, para. 187.
369 Appellate Body Report, *Australia – Salmon*, para. 123; Appellate Body Report, *EC-Hormones*, para. 184.

605. Thus, "insufficient" scientific evidence means "insufficient" for something – that something being the production of a risk assessment adequate for the purposes of the legislator who must decide whether or not a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A, point 1 of the *Agreement.*[370] Those provisions refer to the *risks* arising from certain matters. There is therefore a link between the risk with which the legislator is concerned, and the sufficiency of the scientific evidence. The sufficiency of the evidence cannot be examined in a vacuum, but in relation to the protection goals sought by legislators. The higher the level of acceptable risk, the more likely that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long time, that the scientific evidence is insufficient, and that a measure is warranted.[371] This analysis is confirmed by the words "reasonable period of time" in Article 5.7 of the *SPS Agreement.*

606. What a reasonable period of time may be in any case depends on all the circumstances. If the assessment is taking place in the context of a very long time frame (as in the present case); in relation to changes that may have a permanent effect (as in the present case); and in relation to changes that are being introduced at an exponential rate compared to the past (as in the present case); then a relatively long period of time may be necessary. As the Appellate Body has stated

> "… a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned."[372]

607. This is all the more so if changes to rules of general application are necessary in order to meet the legitimate concerns of scientists and legislators.

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370 Appellate Body Report, *Japan – Apples*, para 179.

371 Appellate Body Report, *Australia – Salmon*, para. 125, especially the final sentence.

372 Appellate Body Report, *EC-Hormones*, para. 124.

608. The present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching. The relevant risks are clearly more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[373]

609. The European Communities submits that, as a matter of WTO law, having regard to the specific concerns and risks of the legislators in adopting the various national measures complained of, those legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes, and that the Member State measures were therefore possible. This being so, there is in any event no basis for the assertion that those legislators acted inconsistently with Article 5.1 of the *SPS Agreement*.

610. In any event, in the alternative, the European Communities does not accept that the Member State measures are inconsistent with Article 5.1 of the *SPS Agreement.* Contrary to what the Complainants assert, the Member State measures are based on risk assessments within the meaning of that provision, as is clear if the history of matters that led to the Member States adopting and maintaining those measures is given full and fair consideration. "Based on" does not mean the same thing as

373 Appellate Body Report, *EC-Hormones*, para. 186.

"conform to."[374] Member States are not required to have conducted their own risk assessments.[375] That the Member States may have drawn their own conclusions from the relevant risk assessments does not make those conclusions any more or less "based on" risk assessments. Nor does it necessarily mean that there is no rational relationship between those risk assessments and the Member State measures. The same risk assessment, as a matter of WTO law, might "sufficiently warrant – that is to say, reasonably support" – more than one possible SPS measure, depending, *inter alia*, on the specific circumstances of the legislator. There may be both mainstream scientific opinion – on which responsible and representative governments may base themselves; and divergent scientific views – on the basis of which equally responsible and representative government may act.[376]

(e) No inconsistency with Article 5.6 *SPS Agreement*

611. Canada asserts that the Member State measures to which it refers are inconsistent with Article 5.6 of the *SPS Agreement*, but only on the basis of an assumption about the appropriate level of protection within the European Communities. If Canada is mistaken on this point, Canada does not make its Article 5.6 argument, but makes its Article 5.5 argument instead.[377] Within the European Communities jurisdiction, the appropriate level of protection is a matter of the domestic law of the European Communities, a matter that is immaterial to the present case. Within the WTO jurisdiction the appropriate level of protection may be established in any manner consistent with the provisions of the *WTO Agreement*s. Canada thus being mistaken on this point, it does not make its Article 5.5 argument, but its Article 5.6 argument. The European Communities will therefore respond to Canada's Article 5.5 argument.

612. Furthermore, the European Communities does not agree that Article 5.6 is relevant to the specific rule provided for in Article 5.7 of the *SPS Agreement*. The appropriate level of protection referred to in Article 5.6 of the *SPS Agreement*

374 Appellate Body Report, *EC-Hormones*, para. 166.
375 Appellate Body Report, *EC-Hormones*, para. 190.
376 Appellate Body Report, *EC-Hormones*, paras. 193 and 194.
377 First written submission of Canada, paras. 395 to 405.

refers to that established pursuant to Article 5.1 of the *SPS Agreement.* Furthermore, even if Article 5.6 would be relevant to the application of Article 5.7 of the *SPS Agreement*, it is self-evident that the necessity of the measure would have to be judged by reference to the insufficiency of scientific evidence, and the reasonable period of time necessary. As such, therefore, it adds nothing to the requirements of Article 5.7 of the *SPS Agreement.*

(f) No inconsistency with Article 2.2 *SPS Agreement*

613. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 2.2 of the *SPS Agreement.*[378] The European Communities does not agree.

614. Article 2.2 of the *SPS Agreement* provides :

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

615. Article 2.2 of the *SPS Agreement* excludes from its scope of application the kinds of situations covered by Article 5.7.[379] The European Communities has already explained why it considers that the Member State measures to which Canada refers, if they fall to be assessed under Article 5 at all, would have to be assessed by reference to Article 5.7, rather than Article 5.1 of the *Agreement.* For precisely the same reasons Article 5.7, rather than Article 2.2 of the *Agreement* is the provision to which Canada should have referred in order to properly understand the justification for the Member State measures. The European Communities has also already explained why "necessity" can only be judged within a relevant time frame, taking into account any insufficiency in scientific evidence. Scientific principles include the principle that conclusions should be based on repeatable experiment, observation and the collection of data – matters that cannot be settled immediately,

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[378] First written submission of Canada, paras. 406 to 411; First written submission of Argentina, paras 485 to 493.

[379] Appellate Body Report, *EC-Hormones*, para. 104, in respect of Articles 3.1 and 3.3 of the *SPS Agreement* – Article 3.1 containing language essentially identical to that in Article 2.2.

but which require a reasonable period of time. Measures adopted on the basis of Article 5.7 of the *SPS Agreement* are based on scientific principles, because they are based on the need to allow sufficient time for sufficient scientific evidence to be collected. There is therefore no basis for the Panel to conclude that the Member State measures are inconsistent with Article 2.2 of the *SPS Agreement.*

(g) No inconsistency with Article 5.5 *SPS Agreement*

616. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 5.5 of the *SPS Agreement.*[380] The European Communities does not agree.

617. Article 5.5 of the *SPS Agreement* provides in relevant part :

> With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

618. Article 5.7 of the *SPS Agreement* contains an express rule that effectively excludes Article 5.5. The European Communities has already explained why it considers that the Member State measures to which Canada refers, if they fall to be assessed under Article 5 at all, must be assessed by reference to Article 5.7 of the *Agreement.* For precisely the same reasons Article 5.7, rather than Article 5.5 of the *Agreement* is the provision to which Canada should have referred in order to properly understand the justification for the Member State measures. There is therefore no basis for concluding that the Member States have acted inconsistently with Article 5.5 of the *SPS Agreement.*

619. Furthermore, the European Communities would observe that Article 5.5 of the *SPS Agreement* falls to be considered essentially and at least in the first place by reference to the conduct of the European Communities. The European

380 First written submission of Canada, paras. 412 to 442; First written submission of Argentina, paras. 494 to 523.

Communities has not behaved in an arbitrary manner or made unjustifiable distinctions such as those referred to in Article 5.5.

620. In any event, the European Communities does not agree that Austria's different response in the case of Bt-11 compared to T25, Bt-176 and MON810 is necessarily arbitrary or unjustified. It is not only the type of crop and GM trait that may be relevant factors in an assessment. There are other factors that may be relevant, such as the precise use that is proposed for a given crop or product (particularly whether for cultivation or processing), as well as the precise arrangements proposed for risk monitoring and management, and for labelling. No two assessments are identical in all respects. Nor does the European Communities agree that Austria's different response in the case of maize on the one hand and oilseed rape on the other hand is arbitrary or unjustified. These are two entirely different species. A Member State's response to a particular risk is likely to be conditioned by the situation prevailing on its own territory, which may well be different for different species. Austria, for example, is characterised by extensive mountain regions, with relatively fragile flora and fauna and agricultural systems, and such differences could well explain why Austria considers its actions to be justifiable. Exactly the same comments may be made with regard to France's different response in the cases of oilseed rape and maize; Greece's different response to MS1xRf1 and Topas 19/2; and Italy's different response to Bt-176. In the absence of any arbitrary or unjustifiable distinctions, there is no inconsistency with Article 5.5 of the *SPS Agreement.* The Complainants have failed to address any of the above points, and therefore they have failed to discharge their burden of proof in relation to these matters.

621. Furthermore, the European Communities does not accept that a difference in treatment between GM products and other products is by definition always arbitrary or unjustified. GM products are objectively different from other products, and different treatment may therefore be objectively justified.

622. There is no discrimination or disguised restriction on international trade resulting from the Member State measures to which Canada and Argentina refer and which fall within the scope of the *SPS Agreement.* There is no arbitrary or unjustifiable

difference in treatment. The provisional measures adopted by the Member States, if they fall to be assessed under Article 5 at all, should be considered to have been based on assessments conducted in accordance with the first sentence of Article 5.7 of the *SPS Agreement*. Canada has failed to substantiate in any meaningful way its bare assertion that the Member State measures have had a disproportionate impact on producers located outside the European Communities. The Member States have not disregarded or ignored the available scientific opinions – all that has happened is that specific legislators have assumed the specific responsibilities imposed on them in the particular circumstances of different Member States, in assessing the sufficiency of scientific evidence in the light of the concerns and risks to be considered. In the context of WTO law, these are the only relevant considerations, and they do not disclose any inconsistency with Article 5.5 of the *SPS Agreement*.

(h) No inconsistency with Article 2.3 *SPS Agreement*

623. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 2.3 of the *SPS Agreement.*[381] The European Communities does not agree.

624. The assertion is that the Member State measures are inconsistent with Article 2.3 of the *SPS Agreement* because they are inconsistent with Article 5.5 of the *SPS Agreement*. These claims are therefore entirely consequential to the claims in respect of Article 5.5 of the *Agreement.* As the European Communities has explained in the preceding section, the Member State measures are not inconsistent with Article 5.5 of the *SPS Agreement.* It follows that, for the same reasons, they are not inconsistent with Article 2.3 of the *SPS Agreement*.

[381] First written submission of Canada, para. 443; First written submission of Argentina, paras. 524 to 526.

2. The Complainants' claims under GATT 1994 are unfounded

(a) There is no violation of Article III:4 of the GATT 1994

625. Argentina and Canada also claim that the national safeguard measures, are inconsistent with Article III:4 of the GATT 1994.

626. As far as the general interpretation of Article III:4 of the GATT 1994 is concerned, the European Communities wishes to refer the Panel to the arguments it has already developed above in connection with the product-specific delays.[382] In this context, the European Communities will only develop in more detail the following points.

i) The law, regulation or requirement at issue

627. The measures at issue are the temporary and limited exceptions introduced by certain EC Member States to the EC-wide authorisation for the import, cultivation and marketing of certain GM products. These are laws regulations or requirements within the meaning of Article III:4 of GATT 1994.

ii) Imported products are not accorded less favourable treatment than like domestic products

628. As set out above, the critical premise of a violation of Article III of the GATT 1994 is that foreign products are treated in a less favourable manner compared to domestic like products, so as to afford a competitive advantage to the domestic like products. In the present case, therefore, a violation of Article III:4 would be demonstrated only if the EC Member State national measures invoked by the Complainants adversely affected the competitive opportunities on the European Communities' markets of foreign oilseed rape MS1/RF1 and Topas 19/2, and maize Bt176, MON810, T25, MON 809 and Bt11, *vis-à-vis* oilseed rape MS1/RF1 and

382 See Section III.C.3.

Topas 19/2, and maize Bt176, MON810, T25, MON 809 and Bt11 grown or processed domestically in the European Communities.[383]

629. In this regard, it should be noted that the scope of each of the EC-wide authorisations whose operation the EC Member State national measures are meant to address, covered at the same time both imported as well as domestic GMOs. Thus, oilseed rape MS1/RF1 is authorised for "growing for obtaining seeds;"[384] oilseed rape Topas 19/2 for import, storage and processing;[385] maize Bt176 for cultivation;[386] maize MON810 and maize T25 for cultivation, import and use as food and in processing.[387] Similarly, maize MON 809 and maize Bt11 were not notified only for imports.[388]

630. Thus, the prohibitions established by the Member States, which are no more than temporary territorial exceptions to the original Commission authorisations, cannot but apply in the same way to oilseed rape MS1/RF1 and Topas 19/2, maize Bt176, MON810, T25, MON 809 and Bt11 which are domestically produced or processed within the Community territory and to those that are imported.

631. It follows from the above that the *raison d'être* of a violation of Article III:4, a "treatment less favourable" for imported than for domestic products, is intrinsically impossible in this case. There is no distinction, or no difference, which is operated on the basis of the origin of the products and therefore there cannot be any "less favourable treatment". Indeed, the European Communities submits that there cannot be a more effective equality of competitive opportunities than a situation, like the present one, in which the ambiguity about the provenance of the commercial interests behind the imported and domestic products is such that the exact same measures apply to each product irrespective of its origin.

632. Nor would it be possible, in the cases at stake, to find that the "less favourable treatment" occurs *de facto* because, for example, the companies whose products

383 See, most recently, Panel Report, *Canada – Wheat and Grain*, para. 6.184.
384 Commission Decision 96/158/EC, Exhibit US-97.
385 Commission Decision 98/291/EC, Exhibit US-97.
386 Commission Decision 97/98/EC, Exhibit US-97.
387 Commission Decision 98/294/EC, Exhibit US-97, and Commission Decision 98/293/EC, Exhibit US-97.

are affected by the national measures are foreign and thus the products are more likely to be imported than domestically produced. Almost all products belong, in fact, to companies that were or are incorporated in the European Communities.

633. In particular, oilseed rape MS1/RF1 was originally notified by Plant Genetic Systems, a Belgian company that is now owned the German company Bayer CropScience. Oilseed rape Topas 19/2 and maize T25 were originally notified by AgrEvo, which was incorporated in the United Kingdom and in France, and is now owned by Bayer. Maize MON810 and MON 809 were notified and still belong to Monsanto Europe S.A.. Only Maize Bt176 and Bt11 were notified by Ciba-Geigy Limited, and now belong to Novartis, both of which are Swiss. However, these products were specifically notified for cultivation and for use as food.

iii) The "like" products to imported GMOs are domestic GMOs

634. The second element of Article III:4 that the European Communities considers not to have been established by Canada and Argentina is the 'like products' criterion. In other terms, in order to assess whether a country can treat "less favourably" imported products, a term of comparison of domestic origin has to be chosen. Canada and Argentina choose as terms of comparison for the Article III:4 analysis in this case, respectively, "the Specific Products and their respective domestically-grown non-biotech counterparts"[389] and "imported biotech products and 'non-biotech' domestic products."[390]

635. As mentioned above, the European Communities considers that in the context of marketing approval legislation, the "like" product has to be a product which is similarly subject to the approval procedure. Choosing a category of like product which is outside the approval procedure, as Canada and Argentina do, amounts to attacking the ratio of the distinction operated by the law which establishes not only the approval system but also the products that must be subject to it. However, the

388 OJ C 181/22 of 26.6.99 (Exhibit CDA-25).

389 First written submission of Canada, heading VIII.B.1.b).

390 First written submission of Argentina, heading V.B.1.a.

European Communities' GMO legislation and its approval system as such are not measures identified in the Complainants' panel requests and cannot be subject to any claim in this proceeding.

636. Furthermore, the European Communities considers that in the case of an approval system that makes no distinction whatsoever between domestic and imported products, the "like" product to be chosen should be the very same product that is produced domestically, unless the complainant can show that the origin-neutral distinction is inherently discriminatory against imported products. In this case, the European Communities submits that the most "like" product to a given imported GMO is that "same" GMO cultivated or processed domestically. This is confirmed by the existing case law.[391] In the present case, thus, recourse to "like" products in the sense of similar products is not necessary because the exact same products as the ones to be imported are to be domestically produced. As seen above, in fact, all the products affected by the national measures are either imported and domestically produced, or are only domestically produced.

637. The European Communities also contests that the "like products" comparison required by Article III:4 can be carried out on the basis of such broad categories and generic terms such as "respective domestically-grown non-biotech counterparts" and "imported biotech products and 'non-biotech' domestic products". The criteria, that the GATT/WTO jurisprudence has developed in order to establish "likeness" between imported and domestic products are of a precise nature and each refer to specific characteristics of given products in a given market. They cannot be bundled together in generic categories without any proof being provided on the specific properties, nature, quality, end-uses, consumers' tastes and habits of each specific product at stake. By so doing, Canada and Argentina ask the Panel to decide the whole issue without any specific evidence related to the products at issue. This has the practical effect of shifting the burden of proof onto the defending party without the complaining parties having first established a *prima facie* case.[392]

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391 See, above, Section III.C.3(c).

392 Panel Report, *Korea – Alcoholic Beverages*, para. 10.75.

(b) Canada has not proven that the Greek safeguard measure is within the scope of Article XI GATT 1994

638. Canada also alleges a violation of Article XI by the Greek measure concerning oilseed rape Topas 19/2 because it "instituted a complete import ban on the EC-approved biotech canola-oilseed rape variety Topas 19/2"[393].

639. The European Communities disagrees with the qualification by Canada of this measure as falling under Article XI rather than Article III:4 of the GATT. In particular, the European Communities does not understand how Canada can classify this measure differently from the other national measures object of its complaint.

640. Earlier in its submission, Canada describes the other measures at issue as "comprehensive bans on the commercialisation of these products" whose effect is that "of preventing all commercial transactions involving these products from taking place."[394] It is clear that the nature and aim of the Greek measures does not differ from those of the other national measures called into question by Canada. The European Communities submits, therefore, that Canada has not discharged its burden of proving that the Greek national measures is not covered by *Note Ad Article III* of the GATT 1994 and that, as such, can be subject to Article XI.

3. *TBT Agreement*

(a) Scope of the *TBT Agreement*

641. Canada and Argentina assert, in the alternative, that certain of the Member State measures are inconsistent with certain provisions of the *TBT Agreement.*[395] The United States purports to "reserve the right to explain, in the alternative" why the Member State measures are inconsistent with the *TBT Agreement.*[396]

393 See first written submission of Canada, para. 469.
394 See first written submission of Canada, para. 450.
395 First written submission of Canada, paras. 473 to 505; First written submission of Argentina, paras. 547 to 592.
396 First written submission of the United States, footnote 156.

i) Not technical regulations

642. Canada and Argentina's assertions are based on the proposition that the Member State measures are "technical regulations" within the meaning of the *TBT Agreement.*[397] The European Communities does not agree. The European Communities considers that the Member State measures are not technical regulations within the meaning of the *TBT Agreement.*

643. Article 1.2 of the *TBT Agreement* provides that, for the purposes of that *Agreement*, the meaning of the terms given in Annex 1 applies. Annex 1 of the *TBT Agreement* is entitled *Terms and their Definitions for the Purposes of this Agreement*, and point 1 provides in relevant part:

> 1. Technical regulation
>
> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

644. The type of measure referred to in this definition is essentially ***normative***. It is one that lays down in relatively abstract terms certain rules, with which products must comply. The text does not envisage an ***administrative*** act that relates to ***a*** specific product from a specific applicant or manufacturer.

645. Directive 2001/18 and Regulation 258/97 are acts that are normative in nature and that might be capable of being technical regulations within the meaning of the *TBT Agreement.* These are types of act susceptible to being notified to the WTO, pursuant, for example, to Articles 2.9 and 2.10.1 of the *TBT Agreement.* Individual administrative acts adopted pursuant to such regulations, which are very numerous, are not themselves technical regulations and are not notified to the WTO by its Members.

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[397] First written submission of Canada, paras. 476 to 480; First written submission of Argentina, paras. 553 to 568.

646. The phrase "applicable administrative provisions" in the first sentence of Annex 1, point 1 of the *TBT Agreement* is significant. It confirms that the applicable administrative provisions will be described in the technical regulation. Provisions requiring notification and authorisation are, for example, administrative provisions. Directive 2001/18 and Regulation 258/97 lay down such provisions. Thus, a technical regulation may lay down such provisions, but the various *outcomes* of such administrative procedures in specific cases in the future are not themselves part of the technical regulation.

647. The measure under scrutiny in *EC-Sardines,*[398] to which Canada and Argentina refer,[399] was entirely different to the Member State measures in the present case. It bore the title "regulation" and took the legal form of a "Council regulation" within the European Communities jurisdiction, that being a normative act of general application.[400] In its title, the function of which is to summarise the essential purpose of the act, the regulation described itself as "laying down common marketing standards". "Laying down" is the same term as that used in Annex 1, point 1 of the *TBT Agreement*, and the word "standard" or a derivative is used 144 times in the *TBT Agreement*. Objectively, the measure was a technical regulation, laying down mandatory standards, and the European Communities did not contest that point.[401] The *EC-Sardines* case therefore offers no support to the assertions made by Canada and Argentina in this case in respect of the Member State measures.

648. The measure under scrutiny in *EC-Asbestos* was also different. The Appellate Body found the provisions of the measure to be "broad" and "general."[402] The Appellate Body also found that a prohibition in itself does not prescribe or impose any characteristics on a product; and that a simple ban on a product *in its natural state* might not constitute a technical regulation within the meaning of the *TBT*

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398 Council Regulation (EEC) No 2136/89 of 21 June 1989 laying down common marketing standards for preserved sardines (OJ 1989 L 212/79).

399 First written submission of Canada, footnote 479; first written submission of Argentina, footnote 290.

400 EC Treaty, Article 249: "A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States."

401 Appellate Body Report, *EC-Sardines*, para. 173.

402 Appellate Body Report, *EC-Asbestos*, para. 64.

Agreement.[403] The Appellate Body placed particular emphasis on the fact that asbestos fibres have no known use in the raw mineral form, so that it was only possible to regulate asbestos by also referring to *products containing* asbestos fibres, as the national measure did. It was for this reason that the Appellate Body concluded that the measure at issue effectively applied "to a large number of products", and could therefore be described as a technical regulation within the meaning of the *TBT Agreement.*[404] The Appellate Body also found that the measure at issue in that case laid down "applicable administrative procedures."[405] Neither of these statements is true in relation to the national measures at issue in the present case. Those national measures essentially ban in its natural state a specific product of a specific manufacturer that has been the subject of a specific notification. They are similar in nature to the ban on asbestos "in its natural state" that the Appellate Body considered could be considered not to constitute a technical regulation.[406] The national measures are not therefore technical regulations within the meaning of the *TBT Agreement.*

ii) No product characteristics

649. The Member State measures are not in the nature of abstract technical regulations destined to apply to all relevant products in the future. They are rather in the nature of concrete administrative decisions taken in response to specific applications made in relation to specific existing products of specific manufacturers. They typically mention the specific reference applied by the Member State in which the specific application was originally made; and the company that notified the product.[407] They do not therefore contain "product characteristics" in the general and abstract sense in which that term is used in Annex 1, point 1 of the *TBT Agreement.* They do not therefore fall within the definition of "technical regulation" laid down in the *TBT Agreement.*

403 Appellate Body Report, *EC-Asbestos*, para. 71.
404 Appellate Body Report, *EC-Asbestos*, para. 72.
405 Appellate Body Report, EC-Asbestos, paras. 73 to 75.
406 Appellate Body Report, EC-Asbestos, paras. 71.
407 For example, in the case of the French measure adopted in respect of MS1 x RF1, "telles que décrites dans la notification C/UK/94/M1/1, présentée par la société Plant Genetic Systems." – translation : "as described in notification C/UK/94/M1/1 presented by Plant Genetic Systems."

iii) Measures do not lay down requirements

650. The Member State measures do not "lay down" "requirements" or product characteristics. To lay down requirements or product characteristics would be to set out rules that future products must conform to. The national measures do not prescribe or impose any such characteristics. For example, contrary to what Canada asserts, the French measure in relation to MS1 x RF1 makes no general statement of any kind about the marketing of oilseed rape in France. Nor does it lay down the product characteristics of MS1 x RF1. Those product characteristics were laid down by the manufacturer that filed the notification, not by the Member State.

iv) No possibility of compliance

651. The words "mandatory compliance" are significant, and they are not interpreted correctly by Canada or Argentina. They mean more than simply that the technical regulation should have the force of law. The word compliance indicates that something should be arranged in such a way so as to be consistent with something else. The something that should be arranged to be consistent is the "product" which falls within the (general) scope of the technical regulation. That is only possible if the technical regulation has a general scope – if it leaves some room for manoeuvre. In the case of the Member State measures, there is no such scope for manoeuvre. The specificity of the procedure means that when an authorisation is refused, the procedure is a dead-end for that product. There is no way for the notified product to comply with the Member State measure. There is no possibility of compliance. This confirms that the true nature of the Member State measures is that they are specific administrative decisions – simple and specific prohibitions, rather than technical regulations of general application, and as such do not fall within the definition of technical regulation set out in the *TBT Agreement*.

(b) No inconsistency with Article 2.1 *TBT Agreement*

652. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 2.1 of the *TBT Agreement.*[408] The European Communities does not agree.

653. Article 2.1 of the *TBT Agreement* provides :

> Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

654. Article 2.1 applies to technical regulations. None of the Member State measures are technical regulations. They cannot therefore be inconsistent with Article 2.1 of the *TBT Agreement.*

655. In any event, even if non-GM product could be considered to be like a GM product (quod non), Article 2.1 of the *TBT Agreement* can only apply to differences in treatment between products that are covered by the technical regulation in question. There will always be a difference in treatment between products that fall within the technical regulation and those that do not. Indeed it makes no sense to say that a technical regulation must accord no less favourable treatment to products to which it does not apply as it does to products to which it does apply.

(c) No inconsistency with Article 2.2 *TBT Agreement*

656. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 2.2 of the *TBT Agreement.*[409] The European Communities does not agree.

657. Article 2.2 of the *TBT Agreement* provides :

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408 First written submission of Canada, paras. 481 to 485; First written submission of Argentina, paras. 569 to 570.

409 First written submission of Canada, paras. 486 to 499; First written submission of Argentina, paras. 571 to 583.

> Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive that necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia : national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia available scientific and technical information, related processing technology or intended end-uses of products.

658. Article 2.2 applies to technical regulations. None of the Member State measures are technical regulations. They cannot therefore be inconsistent with Article 2.2 of the *TBT Agreement.*

659. Canada asserts, quite independently from the question of whether or not the Member State measures may be considered "necessary" within the meaning of Article 2.2 of the *TBT Agreement*, that they were not adopted with the *intention* of protecting human health or safety, animal or plant life or health or the environment.[410] Canada thus makes an assertion about the intent of the Member States in adopting and maintaining these measures. Canada does not explain what other intent it asserts motivates the Member States. Nor does Canada adduce any evidence to support the existence of such other alleged intent(s). Canada thus invites the Panel to find that the reasons given by the Member States, during the discussions leading up to the adoption of the all the relevant Member State measures, in the measures themselves, and in subsequent explanations to the Commission, at the time and today, repeatedly and in writing, with the authority and on the responsibility of numerous Member State scientists and government officials, are not only implausible (according to Canada), but also (according to Canada) lies. That quite extraordinary and very serious allegation is rejected by the European Communities in the strongest terms. This case might be about whether or not certain groups of individuals are or are not mistaken in their assessment of certain matters. The assertion that it is about the alleged existence of a mass conspiracy of dishonesty does not merit further comment.

660. Canada and Argentina assert that the Member State measures to which they refer do not fulfil any of the objectives under Article 2.2 of the *TBT Agreement*, or that

they are unnecessarily restrictive of international trade.[411] Whether or not the Member State measures fulfil their objectives depends on what those objectives are – notably it depends on the level of acceptable risk fixed by the relevant legislator and the provisional or temporary nature of the measures. The European Communities does not accept Canada's simple assertion that the Member State measures make "no contribution" to achieving their objectives. In this respect, Canada's reference to the legislative system of the European Communities is significant, because that legislative system has changed since the events to which Canada refers, and the new legislation makes provision for the review of existing measures. In these circumstances, there is no basis to conclude on the basis of Canada's bare assertions that there is any inconsistency with Article 2.2 of the *TBT Agreement.*

(d) No inconsistency with Article 2.9 *TBT Agreement*

661. Canada and Argentina assert that the national measures to which they refer are inconsistent with Article 2.9, particularly 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement.*[412] The European Communities does not agree.

662. Article 2.9 of the *TBT Agreement* applies to technical regulations. Since none of the Member State measures are technical regulations they cannot be inconsistent with Article 2.9.

663. In fact, in this section of their submissions Canada and Argentina score something of an own goal. That is because the provisions of Article 2.9 provide very strong contextual support for what the European Communities considers to be fairly obvious – namely that the Member State measures are not technical regulations. For example, Article 2.9.2 refers to "the products" – confirming the normative and general nature of a technical regulation. It also uses the future tense - "to be covered", again confirming the essentially prospective nature of a technical

410 First written submission of Canada, paras. 488 to 491.

411 First written submission of Canada, paras. 492 to 499; First written submission of Argentina, paras. 571 to 583.

412 First written submission of Canada, paras. 500 to 504; First written submission of Argentina, paras. 584 to 592.

regulation (as opposed to the retrospective nature of the Member State measures in this case, each being a response to a specific notification by a specific company of a specific product). Article 2.9.3 refers to deviation from international *standards* – again confirming the essentially normative nature of technical regulation. Article 2.10.1 again refers to "the products". Article 2.12 refers to the need to allow a reasonable interval of time so that producers can "adapt their products or methods of production to the requirements of the importing Member." As the European Communities has already explained, this corresponds to the concept of the possibility of compliance with a mandatory technical regulation. It is meaningless in the context of a specific notification by a specific producer of a specific product, leading to a simple and specific refusal to authorise that specific product.

4. Conclusion

664. To briefly conclude generally with regard to the Member State measures. They are provisional and temporary measures in the context of ongoing discussions and legislative changes at Community level, adopted by prudent and rational legislators on the basis of the pertinent available information. To the extent that they fall partially within the scope of the *SPS Agreement*, they fall to be considered under Article 5.7 – a provision not invoked by the Complainants. They are in any event consistent with that provision, and there is no basis to conclude that they are inconsistent with any other provision of the *SPS Agreement.* They do not disclose any inconsistency with GATT 1994, and they are not technical regulations within the meaning of the *TBT Agreement.*

F. The special and differential treatment claims

665. Argentina claims that the European Communities' "moratorium" violates the "special and differential treatment" obligations under Article 10.1 of the *SPS Agreement*[413] and, in the alternative, Article 12 of the *TBT Agreement.*[414] The United States also makes some vague claims that the "moratorium" has blocked

[413] First written submission of the Argetnina, paras. 175 *et seq.*

exports of developing countries, although it fails to cite any pertinent provision of the WTO that it considers may have been violated.[415]

666. The European Communities does not doubt the importance of these provisions and can assure Argentina that it bears them in mind when developing and applying its legislation, including, where relevant, its GMO legislation.

667. Argentina's argument seem to come to nothing more than saying that since the European Communities has violated other provisions of the agreements and this affects Argentina, a developing country, it has consequently also failed to comply with its obligations of special and differential treatment towards developing countries.

668. Thus, in paragraph 186 of its first written submission, Argentina deduces the violation of Article 10.1 of the *SPS Agreement* from the application of the alleged "de facto moratorium". Similarly, in paragraph 445 of its first written submission, Argentina deduces the violation of Article 12.3 of the *TBT Agreement* from the alleged violation of Article 5.2.1 of the same agreement.

669. Since the European Communities does not accept that there is any violation of these other provisions, it follows that there is no violation of the special and differential treatment provisions.

670. In any event, the European Communities does not accept the factual assertion of Argentina and the United States that the measures they are complaining about restrict the exports of developing countries to the European Communities.

671. Trade statistics show that imports from developing countries that have widely adopted GM agriculture have not decreased. On the contrary, imports into the European Communities from Argentina or Brazil (the two of the main developing countries that produce GM crops) of commodities likely to contain GMOs, have steadily increased since 1995/96.

672. Accordingly, these claims are both legally and factually without merit.

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414 First written submission of the Argetnina, paras. 439 *et seq.*

G. Article XX GATT 1994

673. Last, but not least, the European Communities submits that, should the Panel find that any of its measures violate any of the provisions invoked by the Complainants, these are justified under Article XX of the GATT 1994 to the extent that it is relevant or applicable.[416]

674. In particular, the European Communities considers that, if found to be inconsistent with any of the provisions invoked by the Complainants – *quod non* –, product-specific delays, the general suspension and the EC Member States national measures should be found to be justified under Article XX of the GATT 1994 because (1) they come under one of the particular exceptions of paragraphs (b), (d) or (g) and (2) they do not constitute an arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on international trade.

IV. CONCLUSIONS

675. In conclusion, the European Communities requests the Panel to reject the Complainants' claims and to find that:

- The delays in the examination of the applications which are the subject of these proceedings are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994;

- There is no general suspension of the process of authorising GMOs and GM products;

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415 First written submission of the United States, paras.64 *et seq.*

416 See discussion in Section III.B.2(c).

– The EC Member States national measures are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994.

LIST OF EXHIBITS

EC-1 Cartagena Protocol on Biosafety to the Convention on Biological Diversity done in Montreal 29 January 2000.

EC-2 7 Code of Federal Regulations, Section 340.1.

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EC-111	Table showing the time required for the Regulatory Review and Approval of Bt-Transgenic Crop Cultivars by the Environmental Agency and the USDA's Animal Plant and Health Inspection Service (APHIS)
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EC-113	Commission Press Release of 13 May 2003
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