

2000年5月17日第380號法案，運輸和進口法規命令之非官方的翻譯。丹麥環境與能源部。

基因改造生物的運輸和進口法規

根據1991年6月6日第356號法案之第10(2)，13(1)、(2)，14(2)，20(2)，27(1)、(2)，36(4)、(5)節，關於環境與基因工程規定如下：

第一章 通則	Part 1 <i>Scope</i>
<p>第一條(1) 本法令關於：</p> <p>1) 用於研究、大規模試驗、生產、試驗釋放(田間試驗)、教學、展示和其他形式散佈相關基因改造生物資訊之進口和運送(參見母法第10節)</p> <p>2) 對於已獲得其他歐盟會員國允許通過上市之基因改造生物，其在丹麥之上市須通知國家林務與自然局。(參見母法第14節)。</p> <p>(2) 基因改造生物係指植物、動物、微生物；其中微生物包含了細胞培養和病毒，且該遺傳物質已被一種非自然發生的方法改變之(參見附則1)。</p> <p>(3) 可繁殖性基因改造植物是在生活周期中可發生有性或無性繁殖時期之基因改造植物。</p> <p>(4) 牽涉基因改造微生物(含細胞培養和病毒)的活體分成四種等級。(參見附則2)。</p>	<p>Article 1(1). This order concerns:</p> <p>1) Import and transport of genetically modified organisms intended for research, large-scale experiments, production, test release, teaching, display and other types of dissemination of information (see Section 10 of the act).</p> <p>2) Notification of the National Forest and Nature Agency in connection with the marketing in Denmark of genetically modified organisms for which approval has been granted in a another member state in the European Community (see Section 14 of the act).</p> <p>(2) Genetically modified organisms are plants, animals, microorganisms including cell cultures and viruses, in which the genetic material has been altered in a way that does not occur naturally (see Annex 1).</p> <p>(3) Reproductive genetically modified plants are genetically modified plants in a phase of life where sexual or asexual propagation takes place.</p> <p>(4) Activities involving genetically modified microorganisms, including cell cultures and viruses, are classified in four classes (see Annex 2).</p>
<p>第二條(1) 基因改造生物之運輸，若該運</p>	<p>Article 2(1). Transport of genetically</p>

<p>輸符合下列之情形，可不依本法第二部份及母法第十節之規定：</p> <p>1)若實驗室或大規模栽種符合勞動部關於<u>基因工程與工作環境法規</u>之許可或分類地區；或</p> <p>2)在母法第8節之許可範圍內之生產廠房，該生物若於經許可或登記為生產用的廠房內運輸，以該運輸僅限定於廠房內為之。</p> <p>(2) 對基因改造生物之運輸有其他法律之規定或授權時，包括關於有毒(危險)物品之運輸，亦應適用本規則中關於運輸之規定，包括與許可、包裝、標示相關之規定。</p>	<p>modified organisms may be carried out without approval in pursuance of Section 10 of the act and without meeting the requirements laid down in Part 2 of this statutory order if the transport takes place within:</p> <p>1) laboratories and large-scale plants approved or classified in accordance with the Ministry of Labour’s statutory order on genetic engineering and working environment, provided that the transport exclusively takes place within the approved or classified area; or</p> <p>2) production plants covered by approval granted in pursuance of Section 8 of the act if the transport concerns organisms approved or registered for production at the plant, provided that the transport exclusively takes place within the plant.</p> <p>(2) The provisions of the statutory order concerning transport, including the provisions concerning approval, packaging and labelling, shall also apply in cases where rules concerning the transport of genetically modified organisms have been laid down in other legislation or in pursuance of other legislation, including rules concerning the transport of hazardous goods.</p>
<p style="text-align: center;">第二章 運輸和進口許可申請之免除</p>	<p style="text-align: center;">Part 2 <i>Exemptions from approval for transport and import</i></p>
<p>第三條 運輸和進口程序開始前，運送人應進行風險評估。對於基因改造微生物運輸或進口之風險評估，應依照附則3及附則5，判斷該標的應被歸類於哪一個等級。基因改造動物和植物之運送程序應實行完整的評估。</p>	<p>Article 3. Prior to the initiation of transport or import activities, the sender must carry out a risk assessment. In the case of transport or import of genetically modified microorganisms the risk assessment shall be carried out in compliance with Annex 3 and</p>

	Annex 5, according to which the activity will be classified. A concrete assessment of the activity shall be carried out in relation to genetically modified plants and animals.
<p>第四條 基因改造微生物、第一級、第二級和第三級基因改造植物、動物運輸和進口若符合本條(2)項與本法第5-10條關於該生物之包裝、標示之審查，得未依母法第10節獲得事先許可之情形下，進行運輸和進口。</p> <p>(2)運送者應負責風險評估直到完成運送和進口。</p>	<p>Article 4(1). Transport and import of genetically modified microorganisms and of genetically modified plants and genetically modified animals in class 1, class 2 and class 3 may be carried out without prior approval in pursuance of Section 10 of the act, provided that the provisions in paragraph (2) hereof and in Articles 5-10 concerning packaging, labelling, etc of the organism in question are observed.</p> <p>(2) The sender shall keep the risk assessment until transport and import have been completed.</p>
<p>第五條 每一個包裝應使用丹麥語或英語標示，且該標示應能清楚揭示內含基因改造生物。此外基因改造生物的類型及運送者的名字、地址也應清楚標示於包裝上。基因改造微生物，亦應標明微生物的等級(class)。</p>	<p>Article 5. Each packaging unit shall be labelled in Danish or English in such a way that it clearly appears that the unit contains genetically modified organisms. In addition the type of organisms as well as the name and address of the sender must be clearly indicated on the packaging unit. In the case of microorganisms, the microorganism class shall be stated.</p>
<p>第六條 被列入第一級、第二級活體之基因改造微生物，應符合下列關於包裝運輸容器之要求</p> <ol style="list-style-type: none"> 1) 容器應緊密、封閉且不易碎。 2) 容器應能抗壓、抗震等且能預防內容物之釋出。 	<p>Article 6. The following requirements concerning packaging and transport containers shall be met in relation to genetically modified microorganisms which are used for class 1 or class 2 activities:</p> <ol style="list-style-type: none"> 1) The container shall be tight, closed and unbreakable, 2) The container shall be able to resist pressure, shocks, etc and to prevent release of the contents.

第七條被列入第三級之基因改造微生物之包裝和運輸容器應符合下列規定：

- 1) 內外均應有容器
- 2) 內外容器均應不透水。
- 3) 內外容器間應放置可吸收液體的材料；其材料應可吸收內容器內的液體。若一個外包裝內含有一個以上的內包裝，每個內包裝應使用可防震和防液體滲透的材料包裹。
- 4) 外包裝應緊密牢固、封閉、不易碎且能吸收壓力和震動等，且可防止內容物之釋出。

Article 7. The following requirements concerning packaging and transport container shall be met in relation to genetically modified microorganisms which are used for class 3 activities:

- 1) Both an inner and an outer container shall be used.
- 2) Both the inner and the outer container shall be impermeable to liquids.
- 3) Liquid-absorbing material shall be placed between the inner and the outer container. This material shall be able to absorb the quantity of liquid inside the inner container. If more than one inner container are placed in the same outer container, each inner container shall be wrapped in material that can absorb shocks and liquids.
- 4) The outer container shall be tight, closed, unbreakable and able to absorb pressure and shocks, etc and it must prevent release of the contents.

第八條 關於基因改造植物或植物之部分，包裝和運輸時所需用的容器應符合下列規定：

- 1) 包裝應緊密牢固且封閉。
- 2) 包裝應能抗壓、抗震等且應能防止內容物之釋出。
- 3)
(2) 關於可繁殖性基因改造植物或植物之部分，和關於基因改造種子與花粉，其內外包裝都應符合本條規定第一項 (paragraph (1))之規定。

Article 8(1). The following requirements concerning packaging and transport containers shall be met in relation to genetically modified plants or parts of plants:

- 1) The packaging shall be tight and closed.
- 2) The packaging shall be able to resist pressure, shocks, etc and must prevent release of the contents.
- (2) Both an inner and an outer packaging which comply with the requirements stated in paragraph (1) hereof shall always be used in relation to reproductive genetically modified plants or parts of plants and in relation to genetically modified seeds and pollen.

<p>第九條 關於基因改造動物之包裝應符合下列規定：</p> <ol style="list-style-type: none"> 1) 該包裝應是一個動物無法脫逃的籠子或容器。 2) 該籠子或容器應是不易碎的。 	<p>Article 9. The following requirements concerning packaging shall be met in relation to genetically modified animals:</p> <ol style="list-style-type: none"> 1) The packaging shall be a cage or a container from which the animals cannot escape. 2) The cage or container shall be unbreakable.
<p>第十條 若運輸和進口列於第二級或第三級之微生物，可繁殖性基因改造植物或植物之一部，基因改造種子或花粉，或基因改造動物，其運送應附有丹麥語或英語，並用該語言說明意外發生時的處理程序。</p>	<p>Article 10. If transport and import include microorganisms in class 2 or class 3, reproducing genetically modified plants or parts of plants, genetically modified seeds or pollen, or genetically modified animals, the consignment shall be accompanied by instructions in Danish or English specifying procedures to be followed in the event of an accident.</p>
<p>第三部份 運送及進口許可</p>	<p>Part 3 Approval of transport and import</p>
<p>第十一條. 若運輸或進口包含第四級之微生物時，其物品若不符合本法第4條第2項和第5-10條所列之標示、包裝等要求，應優先參照此部份之規定。</p>	<p>Article 11. If transport or import includes microorganisms used in class 4 activities, or if the transport or import does not meet the requirements concerning labelling, packaging, etc laid down in Article 4(2) and Articles 5-10 hereof, prior approval shall be obtained in accordance with the provisions of this part of the order.</p>
<p>第十二條.基因改造生物之運輸及進口應經過國家林業及自然局之許可。</p>	<p>Article 12. Decisions concerning approval of transport and import of genetically modified organisms shall be made by the National Forest and Nature Agency.</p>
<p>第十三條.申請許可應以書面為之，並應包含以下必要之資訊：</p> <ol style="list-style-type: none"> 1) 從事運輸及進口者之姓名與住址； 2) 運輸路線及運輸模式之資訊； 3) 運輸和進口時間之資訊； 	<p>Article 13. Applications for approval shall be in writing and shall include all information necessary for the processing of the applications, including:</p> <ol style="list-style-type: none"> 1) the name and address of the person in charge of transport and import; 2) information about transport route and

<p>4) 基因改造生物，授粉者與受粉者或可能母株之描述，及該生物對公共健康與環境衝擊之資訊(參照附則4)</p> <p>5) 進口及運輸之數量；</p> <p>6) 運輸及進口對環境風險和健康風險之評估(參照附則3及附則5)</p> <p>7) 包裝的性質與標示之設計；</p> <p>8) 即將進行之安全衡量；以及</p> <p>9) 對意外事件之緊急因應計畫。</p>	<p>transport mode;</p> <p>3) information about the time of transport and import;</p> <p>4) a description of donor, recipient or possible parental organisms, a description of the genetically modified organisms, and information about the impact of the organisms on public health and the environment (see Annex 4);</p> <p>5) the volume to be imported and transported;</p> <p>6) an assessment of environmental risks and health risks associated with transport and import (see Annex 3 and Annex 5);</p> <p>7) the properties of the packaging and the layout of the labelling;</p> <p>8) safety measures that will be taken; and</p> <p>9) emergency response plans in the event of accidents.</p>
<p>第十四條(1). 申請人在向國家林業及自然局申請過程中，國家林業及自然局得於必要範圍內要求任何之附加資訊，並得舉辦運輸或進口之公聽會。</p> <p>(2) 國家林業及自然局可以訂定提交附加資訊之期限，並得聲明未於該期限前提交資訊之聲請無效。</p>	<p>Article 14(1). The National Forest and Nature Agency may require additional information to any extent deemed necessary for the processing of the application and may also carry out a public hearing concerning aspects of the planned transport or import.</p> <p>(2) The National Forest and Nature Agency may fix a deadline for the submission of additional information and may also state that the application will lapse if the information is not submitted on or before the deadline date.</p>
<p>第 15 條</p> <p>(1).申請許可應包含申請時所附之說明及資訊評估，包括所有決定依據之要素。此外，申請許可應包括運輸和進口之控管</p>	<p>Article 15(1). Approvals shall include an explanation and an assessment of the information included in the application, including the overall factors on which the</p>

<p>(參照母法第 16 節)。 (2)關於意外事件之緊急因應計畫,應實施必要之控管,此計畫應備用管制關於運送第四級標準之微生物。</p>	<p>decision has been based. In addition, approvals shall contain the conditions on which transport and import may take place (see Section 16 of the act). (2) If necessary conditions may be laid down concerning an emergency response plan in the event of accidents. Such a plan shall always be prepared in relation to transport of microorganisms for use in class 4 activities.</p>
<p>第 16 條 第一項 許可或許可之複本應隨物運送。若有必要啟動緊急因應計畫,此計畫或其複本亦應隨物運送。</p>	<p>Article 16. The approval or a copy of the approval shall accompany the consignment during transport. If an emergency response plan has been requested, this plan or a copy of the plan shall accompany the consignment during transport.</p>
<p style="text-align: center;">第四部分 費用</p>	<p style="text-align: center;">Part 4 <i>Charges</i></p>
<p>第 17 條 申請人於申請過程中應支付費用。費用根據環境和基因工程法案中相關條款予以規定。關於意外事件之緊急因應計畫,應實施必要之控管;此計畫為運送第四級標準之微生物作為備用管制之用途。</p>	<p>Article 17. A charge shall be paid for the processing of applications. The charge will be fixed in accordance with the provisions of the statutory order on charges in relation to the Environment and Genetic Engineering Act in force at any time.</p>
<p style="text-align: center;">第五部分 對運輸及進口之一般預防措施</p>	<p style="text-align: center;">Part 5 <i>General precautions in relation to transport and import</i></p>
<p>第 18 條 第一項 申請基因改造微生物者應通知運送者應使用之包裝、標示等。 第二項 基因改造生物之運送者應確保： (1) 運送之物品需符合第二部份之規定,或符合許可書上第 3 部分條款所規定之限制。 (2) 攜帶基因改造生物者應對於引發意外之預防措施有所了解。</p>	<p>Article 18(1). Persons who requisition genetically modified microorganisms shall inform the sender of the requirements applying to packaging, labelling, etc. (2) Senders of genetically modified organisms shall ensure: 1) that the consignment meets the requirements laid down in Part 2 hereof or the conditions stipulated in the approval granted in pursuance of the provisions of</p>

	<p>Part 3; and</p> <p>2) that the carrier of genetically modified organisms is aware of the precautions to be taken in the event of an accident.</p>
<p>第 19 條</p> <p>第一項 運送或進口基因改造生物者在意外發生時應立即通知當地議會，並通知藥品健康當局當時已經造成之意外，或當時可能造成之基因改造生物之擴散。</p> <p>第二項 若是意外發生在哥本哈根，應通知地方議會或當地健康當局。如果發生在非特列斯堡市，應通知市議會和藥品健康局。</p> <p>第三項 意外發生之通知，應包含下列訊息：</p> <p>(1)和意外相關之特別事項；</p> <p>(2)基因改造生物擴散之單位和數量；</p> <p>(3)所有在評估意外對公共健康與環境衝擊所需之細節；以及</p> <p>(4)以有效的方法衡量以預防意外之負面結果。</p> <p>第四項 意外發生之通知不應減輕或免除任何人防止意外發生之責任，且不應免除恢復原狀或回復最大可能範圍之義務。</p>	<p>Article 19(1). Persons who transport or import genetically modified organisms shall immediately notify the county council in the county where an accident has occurred and shall also notify the Medical Health Officer of accidents which have resulted in or may result in spillage of genetically modified organisms.</p> <p>(2) If an accident happens in the City of Copenhagen, the city council or the local health officer shall be notified. If an accident happens in Frederiksberg Municipality, the municipal council and the Medical Health Officer shall be notified.</p> <p>(3) Notifications shall contain information about:</p> <p>1) particular circumstances relating to the accident;</p> <p>2) the identity and quantities of the genetically modified organism(s) spilled;</p> <p>3) all details necessary to assess the impact of the accident on public health and the environment; and</p> <p>4) the measures taken to prevent negative consequences of the accident in an effective manner.</p> <p>(4) Notification shall not imply any limitation in the duty of the person in charge to try to prevent any consequences of the accident, and shall not imply any exemption from the obligation to restore former conditions to the greatest possible extent.</p>

第六部份 銷售	Part 6 <i>Marketing</i>
<p>第 20 條</p> <p>第一項 當基因改造生物在歐盟其他會員國允許銷售，欲在丹麥進口銷售* (進口、上市?) 時 (參照該法案第 9 部分 (3))，持有許可證者或進口商應通知國家林業及自然局(參照法案第 14 部分 (1))。</p> <p>第二項 前項通知應以書面之方式。如果運銷許可具有條件，則應包括下列資訊：</p> <p>(1)附隨產品之標示；以及</p> <p>(2)產品包裝。</p>	<p>Article 20(1). When genetically modified organisms approved for marketing in another member state in the European Community is to be marketed in Denmark (see Section 9(3) of the act), the holder of the approval or the importer shall notify the National Forest and Nature Agency (see Section 14(1) of the act).</p> <p>(2) Notifications shall be in writing. If the marketing approval contains conditions to this effect, the notification shall include information about:</p> <p>1) the labelling accompanying the product; and</p> <p>2) product packaging.</p>
<p>第 21 條</p> <p>國家林業及自然局應檢查通知是否有執行第 20 條包含在運銷許可中歐盟其他會員國有關標示和包裝之條款規定，且該局得發出命令以強制其履行。</p>	<p>Article 21. The National Forest and Nature Agency shall check that the information contained in the notification submitted in pursuance of Article 20 hereof complies with the provisions on labelling and packaging contained in the marketing approval, and the Agency may issue orders to ensure that this is the case.</p>
第七部分 監督和控訴	Part 7 <i>Supervision and complaints</i>
<p>第 22 條</p> <p>第一項 國家林業和自然局應監督：</p> <p>(1)本法第二部分及第三部分之條款應確實執行；且</p> <p>(2)在許可中擬定執行第三部分條款之限制應確實執行。</p> <p>第二項 本法第三部分及第四部分之條款應監督並予以實施。</p>	<p>Article 22(1). The National Forest and Nature Agency shall supervise:</p> <p>1) that the provisions in Part 2 and Part 3 of this statutory order are observed; and</p> <p>2) that conditions laid down in approvals issued in pursuance of the provisions of Part 3 hereof are observed.</p> <p>(2) The provisions of Part 3 and Part 4 of the act shall otherwise apply to supervision and enforcement.</p>
<p>第 23 條</p>	<p>Article 23(1). It shall not be possible to file</p>

<p>第一項 不應跟其他管理當局提出控訴有關國家林業及自然局第 21 條所制訂之決策。</p> <p>第二項 若環境能源部與國家林業及自然局執行第 12 條所造成之衝突應依母法第五條部份條款處理。</p>	<p>complaints with any other administrative authority concerning decisions made by the National Forest and Nature Agency in pursuance of Article 21 hereof.</p> <p>(2) Complaints concerning decisions made by the National Forest and Nature Agency in pursuance of Article 12 hereof may be lodged with the minister for environment and energy in accordance with the provisions in Part 5 of the act.</p>
<p style="text-align: center;">第八部分 處罰、強迫進入及過渡性條款</p>	<p style="text-align: center;">Part 8 <i>Penalties, entry into force and transitional provisions</i></p>
<p>第 24 條</p> <p>第一項 除非其他法規已有較重之處罰，否則將對下列對象科處罰金：</p> <p>(1)未遵守第 2 條、第 5-10 條和第 18 條者；</p> <p>(2)無法取得第 11 條所述之優先許可者；</p> <p>(3)忽視許可之相關條件者；</p> <p>(4)未根據第 19 條及第 20 條之條款提出通知者；</p> <p>(5)未遵守因執行第 21 條條款所發出之命令者；或</p> <p>(6)未遵守命令所指稱違法事項需重新認證者。</p> <p>第二項 當適用於環境和基因工程法案第 36 部分(2)所述之情況時，處二年以下有期徒刑或拘役。</p> <p>第三項 公司或其他人得負丹麥刑事法規第五部分之刑事責任。</p>	<p>Article 24(1). Unless a higher penalty applies under other legislation, a fine will be imposed on persons who:</p> <p>1) do not comply with Article 2, Articles 5-10 and Article 18 hereof;</p> <p>2) fail to obtain prior approval as stated in Article 11 hereof;</p> <p>3) ignore conditions relating to an approval;</p> <p>4) fail to submit notification in accordance with the provisions of Articles 19 and 20 hereof;</p> <p>5) fail to comply with orders issued in pursuance of the provisions of Article 21 hereof; or</p> <p>6) fail to comply with orders stating that illegal matters must be rectified.</p> <p>(2) The penalty may increase to simple detention or imprisonment for a period of up to two years if the circumstances stated in Section 36(2) of the Environment and Genetic Engineering Act apply.</p> <p>(3) Companies and others may incur criminal liability under Part 5 of the Danish Criminal Code.</p>
<p>第 25 條</p>	<p>Article 25(1). This statutory order shall</p>

<p>第一項 此項法規命令自 2000 年 6 月 5 日起生效。</p>	<p>enter into force on 5 June 2000.</p>
<p>第二項 同時，1991 年 11 月 5 日有關基因改造生物之運輸和進口之法規命令第 732 號應被廢止。</p>	<p>(2) On the same date, statutory order no 732 of 5 November 1991 concerning transport and import of genetically modified organisms shall be repealed.</p>
<p>第三項 制訂執行此條第二項法規命令之決策應維持其效力直至效期結束，或是至制訂一項新的決策以執行此法規命令為止。不遵守在第(2)段所述執行此法規命令之決策者應根據先前生效之條款予以處罰。</p>	<p>(3) Decisions made in pursuance of the statutory order mentioned in paragraph (2) hereof shall remain valid until the expiry of the period stated or until a new decision is made in pursuance of the provisions of this statutory order. Non-compliance with decisions made in pursuance of the statutory order mentioned in paragraph</p>
<p>第四項 在此法規命令尚未生效前為完成有關之許可程序之案件，應根據此法規命令完成其程序。</p>	<p>(2) hereof shall be punished in accordance with the provisions previously in force. (4) Pending cases concerning approval which have not been finally processed by the date on which this order enters into force shall be finally processed in accordance with the provisions of this statutory order.</p>