



ROYAL DECREE

Ministry of Climate and Environment
Minister: Vidar Helgesen

Ref. no.:
Case
no.:
Date: 2 June 2017

Amendment to the regulations relating to a prohibition against the placing on the market of certain genetically modified products in Norway

General introduction to the legislation and evaluation process

No authorisation is required in Norway for the deliberate release of genetically modified organisms (GMOs) that have been authorised in another EEA state in accordance with the EU's GMO Directive (2001/18/EC). The use of such GMOs is also authorised in Norway unless a national decision to prohibit them is made under the Gene Technology Act. The Norwegian authorities may prohibit or restrict placing on the market if in their view it involves a risk to health or the environment, or if placing on the market is otherwise in conflict with the purpose of the Gene Technology Act, provided that their decision is otherwise in accordance with the EEA Agreement, see section 10, sixth paragraph, of the Gene Technology Act and the adaptations set out in Annex XX, item 25 d, to the EEA Agreement. According to the objects clause of the Gene Technology Act, the purpose of the Act is to ensure that the use of genetically modified organisms takes place in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment. In legal terms, all production and use of genetically modified organisms apart from contained use in closed laboratory facilities is considered to be deliberate release.

On the basis of recommendations from the Norwegian Environment Agency, the Ministry of Climate and Environment has recently evaluated ten GMOs. These are five genetically modified carnation lines (Moonlite, Moonvelvet, Moonaqua, Moonberry and SHD-27531-4), all of which have a modified petal colour, the herbicide-tolerant and insect-resistant maize line 1507, and three herbicide-tolerant oilseed rape lines, Ms8, Rf3 and Ms8xRf3. The maize line MON810 was also evaluated at an earlier stage of the process, but because its EU authorisation under the GMO directive has expired, it has not been considered in Norway's final assessments. The Ministry does not intend to object to the EU decision on the five carnation lines. This is considered to be an administrative decision, which will be published in the Norwegian Gazette (*Norsk lysingsblad*) and as a news brief on the Ministry's website, but is not further discussed in this Royal Decree.

The issue at hand concerns a prohibition against placing on the market of the genetically modified maize line 1507 (DuPont Pioneer and Dow AgroSciences LLC) and the three genetically modified oilseed rape lines Ms8, Rf3 and Ms8xRf3 (Bayer CropScience AG). The

authorisations for these four GMOs under the Directive apply only to live GMOs and only for use as feed and for industrial purposes.

Decisions under section 10, last paragraph, second sentence, of the Gene Technology Act do not apply to uses authorised under EU Regulation 1829/2003 on genetically modified food and feed, or to processed (non-living) products, which come within the scope of the Food Act. The EU Regulation has not been implemented in Norwegian law.

Norway has previously prohibited genetically modified rabies and pseudorabies vaccines, maize, chicory, four oilseed rape products and a test kit containing genetically modified bacteria for the detection of antibiotic residues in milk, as set out in the Regulations of 15 December 2000 relating to a prohibition against the placing on the market of certain genetically modified products in Norway.

Description of each GMO, responses from consultation bodies, and Norwegian Environment Agency recommendations

1. Maize line 1507

Pioneer Hi-Bred (USA) developed the genetically modified maize line 1507, which has an inserted *cryIF* gene, derived from a bacterium, which encodes a toxin against insects and confers resistance to attack from certain lepidoptera species. In addition to the gene for this insect toxin, a PAT gene has been inserted into the plant to confer tolerance to the herbicide glufosinate ammonium.

The Norwegian Environment Agency carried out a national public consultation process for maize line 1507 in 2003–2004, parallel to the assessment procedures taking place in the EU. In 2012, in connection with the final phase of the Norwegian evaluation process, the former Norwegian Directorate for Nature Management requested new assessments from the key consultation bodies the Norwegian Scientific Committee for Food Safety (VKM), the Norwegian Food Safety Authority and the Norwegian Biotechnology Advisory Board.

Most of the consultation bodies expressed scepticism to this maize line and recommended a Norwegian prohibition, including the organisation now known as the Network for GMO-Free Food and Feed (No GMO Norway), the Norwegian Confederation of Trade Unions (LO), the Norwegian Farmers' and Smallholders' Union, the Federation of Norwegian Agricultural Co-operatives, the Norwegian Entomological Society, the Norwegian Society for the Conservation of Nature and the Norwegian Biotechnology Advisory Board. Some, such as the VKM, the Institute of Marine Research, the Norwegian University of Science and Technology (NTNU), the Norwegian College of Agriculture (now the Norwegian University of Life Sciences (NMBU)) and the Norwegian Veterinary Institute, took a more positive position on authorisation, although several of these called for further investigation and documentation from the applicant.

The VKM assessment in 2014 concluded that maize line 1507 is essentially identical to unmodified maize except for the inserted traits. In terms of health risks, the VKM pointed to maize line 1507 feed studies on various experimental animals that indicated no negative effects. The VKM concluded there was a low probability that the inserted traits would have toxic or allergenic effects in food or feed. At the same time, the VKM pointed to knowledge gaps regarding effects of the *Cry* toxin on aquatic organisms, but believed that exposure of such organisms in Norway to this toxin would be marginal given the anticipated use of the maize lines as feed and for industrial processing. The Norwegian Food Safety Authority supported the VKM assessment in 2015.

In 2013 a majority of Norwegian Biotechnology Advisory Board members, 15 of 19, recommended that Norway prohibit maize line 1507. The majority attached importance to assessments that GM plants such as maize line 1507 do not contribute to sustainable development in a global context and that this plant is neither of benefit to society in Norway nor ethically justifiable. The majority further asserted that the practice of utilising GM plants such as maize line 1507 serves to increase the use of herbicides, also pointing out that weeds appear to develop tolerance to herbicides more quickly than with maize farming using a conventional production system. Another argument is that maize line 1507 has been given an engineered tolerance to the herbicide glufosinate ammonium, which is deemed to be of a high enough risk to health and the environment that it is prohibited in Norway. Importing maize line 1507 produced by using glufosinate ammonium in another country was perceived by a majority of Norwegian Biotechnology Advisory Board members as posing ethical problems. Two members recommended, however, that Norwegian authorities *not* oppose the EU authorisation of maize line 1507. These members stressed that the European Food Safety Authority (EFSA) had assessed the environmental and health risks and considered this maize line to be safe.

The Norwegian Environment Agency's overall recommendation is based on the Gene Technology Act's combined assessment criteria regarding effects on health and the environment, ethical considerations, sustainability and benefit to society. On 5 April 2016 the Norwegian Environment Agency submitted a recommendation that maize line 1507 should not be prohibited in Norway but that its import for industrial processing and feed should be permitted. The Norwegian Environment Agency concluded that maize line 1507 is as safe as other maize in feed and would pose no increased risk to health and/or the environment in the context of its intended usage. Due to Norway's cold winters, maize has limited survivability and ability to spread. In its assessment of benefit to society, sustainability and ethical considerations, the Norwegian Environment Agency has not found any information regarding the maize line's traits, production or use to be of a nature that would warrant its prohibition pursuant to the provisions of the Gene Technology Act. The Norwegian Biotechnology Advisory Board has subsequently criticised this assessment.

2. *Oilseed rape lines Ms8, Rf3 and Ms8xRf3*

Bayer CropScience AG (Germany) developed the genetically modified oilseed rape lines Ms8, Rf3 and Ms8xRf3. The Ms8 and Rf3 lines have an inserted *bar* gene from a soil bacterium. This gene confers tolerance to the herbicide glufosinate ammonium to these

oilseed rape lines. (This is the same herbicide to which maize line 1507 is tolerant.) The herbicide-tolerant oilseed rape lines also comprise a system for producing hybrid seeds (Ms8xRf3). Hybrid breeding yields unique, productive varieties with good agronomic traits. A steadily increasing proportion of the oilseed rape varieties on the market are hybrid varieties. Oilseed rape is mainly a self-pollinating species, with roughly 70 per cent self-pollination. To produce hybrid seeds, self-pollination must be avoided. The parental line Ms8 is male sterile due to the insertion of a *barnase* gene, while the parental line Rf3 has an inserted *barstar* gene that restores fertility. The inserted traits thus prevent self-pollination during seed production, and hybrid seeds (Ms8xRf3) are derived from crossings between the parental lines Ms8 and Rf3.

The Norwegian Environment Agency carried out national public consultation processes in 1997, 2004 and 2011, parallel to the assessment procedures taking place in the EU. A number of the Norwegian consultation bodies were opposed to authorisation of the oilseed rape lines, pointing among other things to environmental risks in connection with seed spillage and undesired establishment of GM plants and the spread of genes to other oilseed rape and related wild species, including *Brassica juncea*, *Raphanus raphanistrum*, *Brassica rapa ssp. campestris* and others. In 2012–2013 the two major consultation bodies the VKM and the Norwegian Biotechnology Advisory Board were asked to update their assessments in connection with the final phase of the Norwegian evaluation process.

The VKM stated in its 2014 assessment that there were no toxic, allergenic or nutritionally altered traits in the oilseed rape lines Ms8, Rf3 and Ms8xRf3, compared to conventionally bred, unmodified oilseed rape. This health risk assessment was supported by the Norwegian Food Safety Authority, which concluded that the GM oilseed rape lines are as safe as conventional oilseed rape. The VKM environmental risk assessment found that seed spillage during transport, storage and handling of imported oilseed rape may represent potential for outcrossing and further spread of the inserted traits to cultivated crop varieties and wild-growing related species. The VKM characterised the likelihood of this type of spread as very low, however.

The statement of the Norwegian Food Safety Authority from 2015, released after the VKM had carried out its assessment, stated that Norway imports from 7 500 to 10 000 tonnes of whole oilseed rape seeds annually for purposes of feed production. The seeds arrive at different sites around the country. Although a large proportion of these viable oilseed rape seeds are further processed at the import site, up to 25 per cent of the seed shipments are still transported on to other feed facilities, particularly in Trøndelag county and Eastern Norway. Oilseed rape line seeds are typically shipped in containers that are not completely leak-free. Unless more restrictive measures are implemented, the Norwegian Food Safety Authority sees a degree of risk of undesirable seed spillage.

In 2013 a majority of the Norwegian Biotechnology Advisory Board, 19 of 21 members, advised the authorities to prohibit the oilseed rape lines Ms8, Rf3 and Ms8xRf3. The Norwegian Biotechnology Advisory Board referred to the spread of GM oilseed rape seeds during transport, with finds of germinating GM oilseed rape along transport routes in

Canada, the US and Japan. It is therefore conceivable that seed spillage may lead to the establishment of GM oilseed rape in Norwegian nature and cross-pollinating with other oilseed rape and wild species such as *Brassica juncea*, *Raphanus raphanistrum*, *Brassica rapa ssp. campestris* and more.

The Norwegian Biotechnology Advisory Board is of the opinion that it would negatively affect sustainable development if Norway were to permit the import of a GMO produced for use with the herbicide glufosinate ammonium, which is deemed to be of a high enough risk to health and the environment that it is prohibited in Norway. The Norwegian Biotechnology Advisory Board seeks a national prohibition on these oilseed rape lines to send the message that food production should be carried out without the use of harmful herbicides such as glufosinate ammonium. In the view of the majority in the Norwegian Biotechnology Advisory Board it may be perceived as an unethical double standard to establish a practice of allowing people in other countries to be exposed to environmental and health risks we find unacceptable in Norway.

Although the Norwegian Environment Agency believes there is no increased health risk associated with the import and processing of oilseed rape lines for food and feed, in its final assessment dated 18 May 2015 the Agency recommended to the Ministry that viable products of the oilseed rape lines Ms8, Rf3 and Ms8xRf3 should be prohibited in Norway for the uses authorised in accordance with the EU's GMO Directive, mainly on the grounds that their use involves a risk to the environment. In its environmental risk assessment, the Agency's position is that unintended spillage of viable seeds may occur during the transport, handling and processing of oilseed rape raw ingredients. Oilseed rape seeds are small and capable of surviving in soil for many years, subsequently germinating and spreading in Norwegian nature. In the view of the Norwegian Environment Agency, it would reduce biodiversity if the GM plants were to cross-pollinate with other species. Even if seed spillage during transport could be contained through measures and instructions, the Norwegian Environment Agency still sees a significant risk of spread.

Based on input from public consultations, the Norwegian Environment Agency has ascertained that there is currently no demand or need for the GM oilseed rape lines Ms8, Rf3 and Ms8xRf3 in Norway, nor do these oilseed rape lines have traits that make them better suited than other oilseed rape for Norwegian consumers. Placing the oilseed rape lines Ms8, Rf3 and Ms8xRf3 on the market would require implementing measures to prevent seed spillage and promote coexistence throughout the entire value chain. This entails a social cost that outweighs the benefits.

In a global perspective, the Norwegian Environment Agency does not see the production and use of the oilseed rape lines Ms8, Rf3 and Ms8xRf3 as promoting sustainable development. These lines have been conferred tolerance to a herbicide that poses such a high risk to health and the environment that it is prohibited in Norway. The Norwegian Environment Agency also points out that some Norwegians have expressed ethical concerns about the use of GMOs.

Evaluation by the Ministry of Climate and Environment

The legislative basis

The applications have been evaluated in accordance with the provisions of the Gene Technology Act and Chapter II of the Nature Diversity Act. The main purpose of the Gene Technology Act is to ensure that the production and use of genetically modified organisms do not result in adverse effects on health and the environment. At the same time, the Norwegian act differs from legislation in most other countries in that it also includes ethical considerations, sustainability and benefit to society as assessment criteria that must be given considerable weight. In cases where the deliberate release of a GMO is considered to involve a low but identifiable risk to health and/or the environment, the Ministry's position is that taking these three assessment criteria into account in accordance with the Gene Technology Act may have a decisive effect on whether the outcome is authorisation or prohibition of the GMO. Thus, Norway has a wide-ranging set of assessment criteria under the Gene Technology Act, which gives more latitude in processing cases than is the case under EU legislation.

Section 10, second paragraph, of the Gene Technology Act states, "The deliberate release of genetically modified organisms may only be authorised when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development." Evaluations of ethical considerations, sustainability and benefit to society must be based on expert assessments.

Section 10, sixth paragraph, makes an exception from this. According to this provision, authorisation is not required for the placing on the market of a product that has been authorised for placing on the market in another EEA state under the GMO directive. The authorities may nevertheless prohibit or restrict such placing on the market if in their view it involves a risk to health or the environment, or if placing on the market is otherwise in conflict with the purpose of the Gene Technology Act. The objects clause of the Act, section 1, lists ethical and social considerations and sustainable development in connection with the purpose of the Act in addition to health and environmental considerations.

According to section 7 of the Nature Diversity Act, the principles set out in sections 8 to 12 of the Act are to be used as guidelines for the exercise of public authority that will affect biological, geological and landscape diversity.

Section 8 of the Nature Diversity Act states, "Official decisions that affect biological, geological and landscape diversity shall, as far as is reasonable, be based on scientific knowledge of the population status of species, the range and ecological status of habitat types, and the impacts of environmental pressures." The scientific basis for the Ministry's decision in this case is derived from the documentation provided by the producers in their applications, the responses from consultation bodies and the final assessments by the

Norwegian Environment Agency. The Ministry considers that the requirement of section 8 has been met in this case.

Other relevant provisions in sections 8-12 of the Nature Diversity Act are the precautionary principle (section 9) and the requirement to use environmentally sound techniques and methods of operation (section 12).

The EEA Agreement and the WTO agreements

The prohibitions proposed here have also been assessed against Norway's obligations under the EEA Agreement and WTO rules. Under Annex XX, item 25 d, to the EEA Agreement, Norwegian authorities may prohibit or restrict the placing on the market in Norway of GMOs that are authorised in the EU if they have grounds for the view that such GMOs pose a risk to health or the environment or their use would otherwise be in conflict with the purpose of the Gene Technology Act, provided that their decision is otherwise in accordance with the EEA Agreement. The EEA Agreement generally prohibits import restrictions and other measures with a similar effect, but allows for prohibitions on the import or placing on the market of GMOs if such measures are reasoned and justified on grounds such as protection of the life of animals or plants, health, the environment, or public morality, provided that they do not constitute arbitrary discrimination or disguised restrictions on trade.

Relevant agreements under the World Trade Organization (WTO) are the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the General Agreement on Tariffs and Trade (GATT). The SPS Agreement applies to all veterinary and phytosanitary measures that may directly or indirectly affect trade. The point of departure under the SPS Agreement is that Norway has a right to implement measures that are necessary to, among other things, protect the life or health of animals and plants, as long as this is deemed necessary based on scientific risk assessments and is otherwise in accordance with requirements under the SPS Agreement. Measures in accordance with the SPS Agreement are considered to be in accordance with GATT, particularly the general exceptions in GATT Article XX(b) on human, animal or plant life or health.

Furthermore, GATT Article XX(a) allows the authorities to prohibit or restrict the placing on the market of products if this is deemed necessary to protect public morality, provided that the other requirements of the chapeau to the article are satisfied. These requirements ensure that a measure is 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." Protection of public morals provides scope for incorporating ethical considerations and the moral views of the population. There is precedence in WTO case law for prohibiting import and placing on the market based on ethical objections, cf. the decision of the Appellate Body of the WTO in case WT/DS401 challenging EU measures prohibiting the importation and marketing of seal products. Ethical norms and moral views will be influenced by a nation's prevailing social, cultural, ethical and religious values, and will thus differ from country to country. There is also broad international agreement on the need for special permission procedures for GMOs, cf. the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Ethical considerations, sustainability and benefit to society

As mentioned earlier, the Ministry's position is that the provisions of the Gene Technology Act on ethical considerations, sustainability and benefit to society can be used as an independent basis for refusing to authorise GMOs. The reader is referred to the section on the legislative basis above and to section 10, sixth paragraph, of the Gene Technology Act, which reads, "The competent authorities under the present Act may nevertheless prohibit or restrict such placing on the market if in their view it involves a risk to health or the environment or if placing on the market is otherwise in conflict with the purpose of this Act." The legislative history of the Act (Proposition No. 8 (1992-1993) to the Odelsting, page 46) emphasises the importance of taking into consideration the fundamental values of the Norwegian people, and states that to build confidence and a sense of security, it will be necessary to give considerable weight to the moral views of the population. This point is later amplified (page 67) to highlight the need to ensure that people have confidence in the way GMOs are produced and used and to ensure that such activities are in line with the moral views of the Norwegian people.

Moral views of the Norwegian people

A guiding principle is that to the greatest possible extent, decisions should reflect the Norwegian people's moral views and the ethical norms of Norwegian society, as these have been expressed in the responses from consultation bodies, studies and other forms of enquiry. In the public consultations, various sources have expressed moral views that justify the introduction of a prohibition against these products. The Ministry attaches importance to maintaining consumer trust in the ability of the public administration to put the Gene Technology Act into practice in keeping with its intentions.

People consider many topics to be of relevance in questions pertaining to GMOs, e.g. patenting of seeds, solidarity with farmers in developing countries and establishment of sustainable agricultural production systems. Norwegians currently perceive the use of modern biotechnology for advances in medical treatment in a far more positive light than gene technology in connection with production of food and feed, where the technology tends to be viewed as unbeneficial and risky. Many consumers and organisations do not consider the arguments for the benefits of GMOs to be worth the perceived risk. A large consumer segment does not appear to accept GM feed and food products unless they provide a health or environmental benefit, such as reduced use of herbicides. This is evident in statements by the Network for GMO-Free Food and Feed (No GMO Norway) and is supported by several studies from different sources, most recently in March 2017 in a survey from Consumption Research Norway (SIFO). SIFO finds that there is considerable scepticism to the use of biotechnology in food production and that little has changed since a similar survey was conducted in Norway 22 years ago. Large consumer organisations, the agriculture industry, Coop Norge, the Reitan Group (REMA food retail chain) and Norgesgruppen are currently working actively to keep GM goods off the Norwegian market. Thus, market access with GMO labelling would not be satisfactory for a large group of Norwegian consumers. These are ethical considerations and values that are not merely held by a small segment of society. They have a more universal validity, and a

significant proportion of the population believes that safeguarding these values is the responsibility of the government.

According to existing regulations, products consisting of or containing GMOs must be labelled to enable consumers to choose not to purchase them. In most cases, the major groups opposed to the use of GMOs in Norway do not view this free consumer choice as a satisfactory measure. As seen in e.g. the national consultative rounds concerning the GMOs at hand, the organisations that are opposed to GMOs are calling for a complete prohibition on the import of these GMOs into Norway. The introduction of such products with subsequent labelling has not been seen as adequately safeguarding the ethical considerations relating to the matter.

Continuing a restrictive policy

Norway has been restrictive with regard to GMOs over the years. Various governments have received broad support for this policy from the consumer and environmental organisations, the agriculture industry and the Storting, cf. the debate of 28 April 2015 based on Document 8:30 S (2014–2015), most recently confirmed in the Standing Committee on Business and Industry recommendation concerning the white paper on agricultural and food policy of 6 April 2017 (Recommendation 251 S (2016–2017)), in which the committee states that Norway “...must continue to pursue a restrictive GMO policy.”

Although the food industry in Norway seeks to compete on as equal a footing as possible with other European actors, Norway’s food and feed industries still prefer unmodified ingredients to GMOs.

It is in light of the overall assessment of the legislative basis, guidelines and signals from the Storting, the public consultation process, management practice and studies and surveys that the Ministry now recommends that living products from the GM maize line 1507 and oilseed rape lines Ms8, Rf3 and Ms8xRf3 are to be prohibited for use in industrial processing and as feed. The health risk from these GMOs is considered to be minimal, while the environmental risk for relevant uses in Norway is evaluated as being negligible for maize line 1507, and low but not insignificant for the oilseed rape lines Ms8, Rf3 and Ms8xRf3.

Below, the Ministry’s assessments are summarised in more detail for each GMO:

1. Maize line 1507

The Ministry recommends a prohibition against the placing on the Norwegian market of the GM maize line 1507 from DuPont Pioneer and Dow AgroSciences LLC, under the Gene Technology Act, for uses authorised in accordance with the EU’s GMO Directive (2001/18/EC), i.e. for feed and industrial processes. The prohibition applies to living organisms only. The Norwegian Environment Agency has recommended that Norway should not prohibit maize line 1507 under the Gene Technology Act. The Ministry agrees with the Agency’s assessment that the intended uses of maize line 1507 do not represent an increased health or environmental risk in Norway, but has nonetheless come to the

conclusion that a prohibition should be imposed in Norway under section 10, sixth paragraph of the Gene Technology Act, in light of the ethical problems that arise in connection with the intended use.

The Ministry attaches importance to the production regime for cultivating maize line 1507 in the countries that produce it. The maize line has been conferred resistance to the herbicide glufosinate ammonium, which has been classified as having both acute and chronic adverse effects on mammal health, including reproductive health and foetal development. This herbicide was withdrawn from the Norwegian market in 2008 due to adverse effects on health and the environment. Importing maize line 1507 that is produced using glufosinate ammonium in another country is perceived by sizeable user groups in Norway as ethically problematic and unsustainable. The Ministry refers to the discussion above regarding the moral views of the Norwegian people, where factors such as solidarity with farmers in developing countries and establishment of sustainable agricultural production systems are considered important in issues relating to GMOs. In the view of the Ministry, the ethical considerations alone are sufficient grounds for prohibiting maize line 1507 in this case.

The maize line has no special traits that are beneficial to Norwegian users. The Ministry is not aware of any current consumers or food or feed producers in Norway who want fertile maize line 1507 on the market.

The recommendation to prohibit GM maize line 1507 is considered to lie within the latitude for processing cases under EEA and WTO legislation. Please refer to the general discussion above regarding the regulatory framework and the ethical objections involved in this case.

2. *Oilseed rape lines Ms8, Rf3 and Ms8xRf3*

The Ministry recommends a prohibition against the placing on the Norwegian market of the GM oilseed rape lines Ms8, Rf3 and Ms8xRf3 from Bayer CropScience AG, under the Gene Technology Act, for authorised uses in accordance with the EU's GMO Directive (2001/18/EC), i.e. for feed and industrial processes. The Ministry has attached critical importance to the environmental risk posed by the oilseed rape lines. The prohibitions apply only to living organisms and are in accordance with the Norwegian Environment Agency's recommendation.

As regards oilseed rape lines Ms8, Rf3 and Ms8xRf3, the Ministry sees their use as authorised in the EU under GMO Directive (2001/18/EC) as posing a low environmental risk, but considers this risk nevertheless to provide sufficient grounds for prohibition under the Gene Technology Act. The transport, industrial processing and handling and use of these oilseed rape lines for food and feed purposes may lead to unintended spillage of seeds and undesirable spreading. Oilseed rape seeds are capable of surviving in soil for many years. Pollen from established GM plants is easily carried by wind and insects and could pass on the inserted traits to *Brassica rapa ssp. oleifera*, unmodified oilseed rape and related species such as *Brassica rapa ssp. campestris*, *Brassica juncea*, *Raphanus*

raphanistrum, *Brassica nigra* and *Hirschfeldia incana*. The Ministry points out that the spread of GM oilseed rape as a result of seed spillage along transport routes is well documented. In Japan, for example, germinating GM oilseed rape has been found along railways and harbour areas. GM oilseed rape plants have also been found along railways in Switzerland, where a national referendum in 2005 led to a moratorium on cultivating GMOs. Even with only the prescribed use, without cultivation, the Ministry finds that based on available knowledge, there exists a non-negligible risk of the undesired spread of GM oilseed rape.

The Ministry's position is based on the Norwegian Environment Agency's assessment that spread of the inserted genes of oilseed rape lines Ms8, Rf3 and Ms8xRf3, regardless of which variety or species, would have an undesirable effect on biodiversity. Gene flow from GM varieties to wild species would alter the recipient species' gene pools (the sum of a population's genetic material), and the Agency views this as a reduction of biodiversity, even if the inserted traits do not make the recipient organisms more fit for survival or affect their ecological function. Moreover, if the genes were to transfer to non-GM varieties in agriculture, producers would suffer economic losses. Organic agriculture, for example, has zero tolerance for the presence of GMOs. Once the damage has occurred, it may be difficult to reverse or remedy.

The recommendations for prohibition are considered to lie within the latitude for processing cases under EEA and WTO legislation. The arguments pointing to environmental risk in this case are comparable to those made against oilseed rape line GT73, which the Norwegian authorities prohibited in 2012 under the Gene Technology Act. The environmental risk is viewed as sufficient to satisfy EEA legal requirements. Furthermore the recommendations for prohibition are considered to be in keeping with the SPS Agreement. The expert assessments by the Norwegian Environment Agency and the Ministry which form the basis for the prohibitions satisfy the SPS Agreement's requirements for scientific and risk assessment. Alternative measures have been considered and found to be inadequate.

Impacts of prohibiting the placing on the market of the GMOs at hand

The Ministry does not anticipate any significant impacts on Norway's public administration, consumers or trade and industry. National public consultations have shown that there is general scepticism towards GM products. At this time the agriculture industry does not wish to begin using GMOs, and feed producers are avoiding GM raw ingredients. Large consumer groups have clearly expressed their ethical objections regarding the GMOs at hand. For maize line 1507, the Ministry believes it has adequately proven that the Norwegian people's ethical objections are so significant that prohibition is justified on the grounds of protecting public morality. An additional factor is that the Storting supports a restrictive policy with regard to GMOs.

Other uses of the products

The regulations entail prohibitions against the living maize line 1507 and the three oilseed rape lines Ms8, Rf3 and Ms8xRf3 for use as feed and for industrial processing. The prohibitions do not apply to import for e.g. laboratory or field experiments; such cases will be regulated pursuant

to the Gene Technology Act, chapter 2 regarding contained use. Nor do the regulations entail prohibitions against non-living, processed products of maize line 1507 or oilseed rape lines Ms8, Rf3 and Ms8xRf3, as such products are regulated pursuant to the Norwegian Food Act.

Submission

The case has been submitted to all the ministries.

The Ministry of Climate and Environment

recommends:

The Regulations amending the Regulations of 15 December 2000 relating to a prohibition against the placing on the market of certain genetically modified products in Norway shall be adopted in accordance with the attached proposal.

Annex

Regulations amending the Regulations of 15 December 2000 relating to a prohibition against the placing on the market of certain genetically modified products in Norway

*Laid down by Royal Decree of 2 June 2017 under the Act of 2 April 1993 No. 38 relating to the production and use of genetically modified organisms, etc. (Gene Technology Act).
Submitted by the Ministry of Climate and Environment.*

I

The Regulations of 15 December 2000 relating to a prohibition against the placing on the market of certain genetically modified products in Norway shall be amended as follows:

In section 1, new items 10–13 shall read as follows:

10. Living, genetically modified maize line 1507 from DuPont Pioneer and Dow AgroSciences LLC, represented by Dow AgroSciences Europe, authorised in the EU for use as feed and in industrial processes by Commission Decision of 3 November 2005.
11. Living, genetically modified oilseed rape line Ms8 from Bayer CropScience AG, Germany, authorised in the EU for use as feed and in industrial processes by Commission Decision of 26 March 2007.
12. Living, genetically modified oilseed rape line Rf3 from Bayer CropScience AG, Germany, authorised in the EU for use as feed and in industrial processes by Commission Decision of 26 March 2007.
13. Living, genetically modified oilseed rape line Ms8xRf3 from Bayer CropScience AG, Germany, authorised in the EU for use as feed and in industrial processes by Commission Decision of 26 March 2007.

II

These Regulations enter into force immediately.