Third joint Aarhus Convention/Convention on Biological Diversity Round Table on Public Awareness, Access to Information and Public Participation regarding Living Modified Organisms/ Genetically Modified Organisms[1]

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Overview of Implementation of the Aarhus Convention with regards to GMOs

Background paper

Prepared by the Aarhus Convention secretariat

This document contains a compilation of relevant information extracted from reports and documents prepared by the secretariat and information provided by Parties to the Convention. The first section includes extracts from the synthesis report of the 2017 reporting cycle submitted to the sixth session of the Meeting of the Parties to Aarhus Convention held in Budva, Montenegro, 11–14 September 2017.[2] The second section includes extracts from the reports on the implementation of the Aarhus Convention with regards to genetically modified organisms (GMOs), including the amendment on public participation in decisions on deliberate release into the environment and placing on the market of genetically modified organisms (Almaty Amendment on GMOs) provided in the national implementation reports[3] submitted by Parties to the Convention during the 2017 reporting cycle. Status of the ratification of the Almaty Amendment on GMOs is available from: https://treaties.un.org/Pages/ViewDetails.aspx?src=IND&mtdsg_no=XXVII-13-b&chapter=27&clang=_en

[1] This document was not formally edited.
[2] Available at: http://www.unece.org/fileadmin/DAM/env/pp/mop6/English/ECE_MP.PP_2017_6_E.pdf
[3] Available at: https://aarhusclearinghouse.unece.org/national-reports/reports

Section I: Extract from the Synthesis report on the status of implementation of the Convention presented to the Aarhus Convention Meeting of the Parties at its sixth session[4]

Introduction

9. The report consists of four parts: chapter I briefly describes procedural aspects of the fifth reporting cycle; chapter II attempts to identify some regional trends in the implementation of the Convention in three subregions; chapter III provides a thematic analysis of the implementation of articles 3 to 9 of the Convention and the amendment to the Convention on genetically modified organisms (GMO amendment); and chapter IV offers conclusions on implementation trends and on the fifth reporting cycle itself.

II. Some regional trends on implementation

A. Eastern Europe, the Caucasus and Central Asia

Access to justice

39. Parties did not report on any progress made in ratifying the GMO amendment, and their national legislation in this area is still in the process of development. Georgia ratified the GMO amendment on 4 February 2016.

B. European Union, Iceland, Norway and Switzerland

Access to justice

49. According to national implementation reports, the practice of public involvement in decision-making related to genetically modified organisms (GMOs) is supported by the necessary legislative provisions and practical arrangements. Only a few obstacles were mentioned, including the availability of all the necessary and accurate information on GMOs and expert opinions to participate effectively during GMO decision-making.

C. South-Eastern Europe

Access to justice

58. The reporting Parties have not yet ratified the GMO amendment. Nevertheless, they have enacted some legislative provisions on GMO decision-making.

III. Thematic review of implementation

C. Collection and dissemination of environmental information (article 5)

Availability of product information (article 5, paragraph 8)

114. With respect to article 5, paragraph 8, concerning measures taken to develop mechanisms to ensure that sufficient product information is made available to the public, many reporting Parties from the European Union, Iceland, Norway and Switzerland subregion mentioned the operation of eco-labelling schemes, energy labelling for electric goods, organic labelling and other national labels. Georgia reported that requirements on food safety are in place, while Kazakhstan and Kyrgyzstan mentioned requirements

[4] Document (ECE/MP.PP/2017/6) is available from: http://www.unece.org/fileadmin/DAM/env/pp/mop6/English/ECE_MP.PP_2017_6_E.pdf.

on labelling of products containing GMOs. Among the reporting Parties from Eastern Europe, the Caucasus and Central Asia subregion, only Belarus mentioned the existence of eco-labelling and eco-certification systems.

D. Public participation in decisions on specific activities (article 6)

General provisions (article 6)

118. In general, countries from all subregions provided information in their national implementation reports on their continuous efforts to improve legislation with the objective to better implement article 6 and, where relevant, the updated European Union directives. For instance, in Iceland and Cyprus efforts are under way to transpose Directive 2014/52/EU[5] into national environmental assessment legislation. Denmark enacted a new Environmental Assessment Act in 2016. Czechia adopted changes to its Environmental Impact Assessment Act as a result of the recommendations of the Meeting of the Parties to the Aarhus Convention and an infringement procedure at the European Union level. Croatia initiated new environmental impact assessment and strategic environmental assessment regulations to address shortcomings in those procedures, including consultation deficiencies, pointed out by the Information Commissioner. Malta enacted the Environment Protection Act and Development Planning Act in 2016, detailing the public participation provisions of relevant decision-making relating to environment. France amended its Environmental Code by adding new provisions on public participation, the rights of the public and a switch to paperless procedures following the report of the Special Commission on the Democratization of Dialogue on the Environment.

119. Improvements mainly focused on environmental impact assessment, its openness and participatory opportunities. Other types of decisions affecting the environment, where some Parties made efforts to ensure public participation, included building and planning decisions, environmental pollution permits, river basin water management plans, decisions on the environmental protection measures, decisions on the creation of protected areas, GMO-related decisions and environmental licensing and decisions on the lifetime extension of the operation of nuclear reactors (e.g., Croatia, France, Ireland and Lithuania).

Public participation in decision-making on permitting the deliberate release of genetically modified organisms (article 6, paragraph 11)

149. On the implementation of the requirement of article 6, paragraph 11, regarding public participation in decision-making on permitting the deliberate release of GMOs, see section H of this chapter below.

G. Access to justice (article 9)

Challenging decisions, acts or omissions not complying with article 6 provisions (article 9, paragraph 2)

187. Among Parties from the South-Eastern Europe subregion, Montenegro mentioned provisions of those special laws on environmental impact assessment, GMOs, waste and pollution permits that foresee the right to administrative complaint of the respective decisions. An application to the administrative court could be lodged after the administrative review. Serbia specified in its national implementation report the judicial and non-judicial forums which might be approached by the public concerned for the review of decisions taken during environmental impact assessment procedure. Albania mentioned that administrative courts are available to interest groups in cases involving the violation of their legitimate public interest.

[5] Directive 2014/52/EU of the European Parliament and of the Council of 16 April 2014 amending Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment, 2014 O.J. (L 124), pp. 1–18.

H. Genetically modified organisms

201. Decision II/1 on GMOs (i.e., the GMO amendment) was adopted by the Meeting of the Parties at its second session (Almaty, Kazakhstan, 25–27 May 2005). To date, 31 Parties, including the European Union, have ratified, accepted or approved the amendment. However, the GMO amendment will only enter into force when three fourths of the Parties that were Parties at the time the amendment was adopted have ratified, approved or accepted it. A further two ratifications from those Parties are required in order for the GMO amendment to enter into force.

202. Parties that have ratified the amendment are bound to work towards its implementation. At the same time, these Parties are also bound by article 6, paragraph 11, which remains binding and in force until the entry into force of the amendment, including new article 6 bis and annex I bis.

203. By decision IV/4 the revised reporting format was adopted, incorporating the requirement for Parties to report on the implementation of article 6 bis.

Article 6 bis and annex I bis

204. Only a few Parties reported on the implementation of article 6, paragraph 11, while the majority provided information on the implementation of article 6 bis and annex I bis to the Convention.

205. As in previous reports, many European Union member States reported that they transposed relevant European Union instruments into national legislation, including provisions on disclosure of information and notification, and public participation rules and procedures. In addition, a number of European Union member States reported that they had ratified the GMO amendment to the Convention (Finland, France, Germany, Hungary, Latvia, Romania and Slovakia). France and Malta ratified the amendment during the fifth reporting cycle. From the European Union, Iceland, Norway and Switzerland subregion, Croatia and Iceland have not ratified the amendment yet.

206. A few Parties mentioned the consultative bodies especially created for GMO decision-making. They consist, inter alia, of NGO participants (in Lithuania, the GMO Management Supervisory Committee and GMO Expert Committee; in Spain, the Participation Committee under the Interministerial Council on GMOs; in Estonia, the Gene Technology Committee under the Ministry of Environment; in Cyprus, the Scientific Committee; and, in France, the High Council for Biotechnologies). A few Parties from the European Union mentioned web-based informational portals on GMO decision-making to assist in disseminating information and to facilitate public consultations (e.g. Bulgaria, Estonia, Germany, Italy, Latvia and Spain).

207. Some countries in Eastern Europe, the Caucasus and Central Asia reported that the legal framework for decision-making on GMOs is still undeveloped (Azerbaijan, Kyrgyzstan and Tajikistan), while others referred to new legislative acts that were passed (Georgia, Kazakhstan and Turkmenistan). In their national implementation reports, only a few Parties reported on the availability of a set of rules regulating genetic engineering, GMO labelling and GMO registration. From this subregion, only Georgia ratified the amendment in 2016.

208. No reporting Party from the South-Eastern Europe subregion ratified the GMO amendment during the fifth reporting cycle. Nevertheless, Serbia outlined its legislation on the decision-making related to GMOs.

Obstacles encountered in the implementation of article 6 bis and annex I bis

209. In many national implementation reports, Parties did not mention any obstacles encountered in the implementation of article 6 bis and annex I bis. This is mainly due to the absence of cases on GMO decision-making. Several European Union member States reported that if GMO products are placed on the market, the European Commission is responsible for consulting the public in accordance with relevant European Union legislation. Latvia noted the difficulty of finding independent experts to prepare risk assessments related to GMO decision-making. Spain mentioned difficulties in disclosing information considered as confidential. This also includes information on the exact location of GMO fields, as cases

of vandalism were reported in the past. The Finnish Board for Gene Technology has not included an NGO representative during its current term (2010–2015), as it did in previous years.

210. Georgia and Tajikistan pointed out the lack of accredited laboratories and the absence of information on the methodology of risk assessment of GMOs.

IV. Conclusions

Status of implementation

268. As the GMO amendment has not been ratified by most of the Parties from Eastern Europe, the Caucasus and Central Asia and the South-Eastern Europe subregions, these provisions of the Aarhus Convention are not sufficiently implemented. Despite this, Parties to the Convention that have not yet ratified the GMO amendment reported on their efforts to implement measures on biosafety and GMOs. Also, European Union member States demonstrated a rather high level of public involvement in decision-making processes on GMOs. This was facilitated by establishing special multi-sectoral or interministerial bodies (committees, commissions and scientific advisory committees, etc.) in this area.

The way forward

269. Based on the analysis of the synthesis report it is advisable for the Parties to:

(f) Ratify the GMO amendment and the Protocol on Pollutant Release and Transfer Registers as soon as possible, adapt their national legislative framework to the requirements of these instruments and ensure the institutional and technical framework for the implementation of these instruments at the national level.

Section II: Extracts from the national implementation reports 2017[6] with regards to genetically modified organisms

Albania

[no responses provided to questions 33, 34 or 35]

Armenia

[available in Russian only]

35. ДОПОЛНИТЕЛЬНАЯ ИНФОРМАЦИЯ О ПРАКТИЧЕСКОМ ОСУЩЕСТВЛЕНИИ ПОЛОЖЕНИЙ СТАТЬИ 6- БИС И ПРИЛОЖЕНИЯ I-БИС
Предоставьте дополнительную информацию о практическом применении положений статьи 6-бис, касающихся участия общественности в принятии решений о преднамеренном высвобождении в окружающую среду и реализации на рынке генетически измененных организмов, например о том, существуют ли какие-либо статистические данные или иная информация об участии общественности в принятии таких решений или о решениях, рассматриваемых в рамках пункта 2 приложения I-бис в качестве исключений, касающихся процедур участия общественности, устанавливаемых в этом приложении

Год: 2015-2017
Армения еще не ратифицировала Алматинские добавления Орхусской Конвенции. Министерством охраны природы разработан и отправлен в Национальное Собрание РА Проект

[6] Available from: https://aarhusclearinghouse.unece.org/national-reports/reports

закона «О биобезопасности использования генетически измененных организмов», который в основном отражает требования Алматинских добавлений и Картагенского Протокола. Был также разработан законопроект в связи с использованием генетически измененых организмов Министерством Сельского хозяйства и отправлен в Министерство охраны природы, но законопроект был отпралвен обратно в МинСельсХоз. из-за необходимости изменить радикальные регулирования законопроекта.

Austria

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

There are no cases of deliberate releases of GMOs, hence to obstacles could be encountered.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

See above: since there are no cases at the national level, there are no statistics.

Azerbaijan

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

A draft law on ensuring the safety of genetic engineering has been prepared and sent to the Cabinet of Ministers. The Milli Majlis (Parliament) is currently examining a draft law on protecting the genetic resources of cultivated plants and their efficient use that provides the legal basis for the latter law.

The Aarhus Centres, websites and media are used to effectively provide information and involve the public in decisions that fall within the scope of article 6 bis.

In no circumstances is the information detailed in this provision deemed confidential.

The public is allowed to present in any appropriate form any comments, information, results of analyses or opinions it considers relevant to a proposed deliberate release or placing on the market. Measures are taken to ensure that the texts of decisions passed by state authorities that fall within the scope of annex I bis, as well as the reasons and considerations on which they are based, are brought to the attention of the public.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

No obstacles were encountered in the implementation of any of the provisions of article 6 bis and annex I bis.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

A book on biosafety has been published to inform the public. Round tables, surveys and seminars have been held, and articles have been published in the media.

Belarus

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The Genetic Engineering Safety Act (Law No. 96 of the Republic of Belarus of 9 January 2006).

♦ Law No. 200 of the Republic of Belarus of 4 January 2007 amending the Seeds Act.
♦ Law No. 231 of the Republic of Belarus of 18 May 2007 amending and adding to certain Codes of the Republic of Belarus with Respect to Establishing Liability for Contravention of Genetic Engineering Safety Legislation (the Administrative Offences Code of the Republic of Belarus and the Criminal Code of the Republic of Belarus)

Resolutions of the Council of Ministers of the Republic of Belarus

- Resolution No. 608 of 13 May 2006 amending and adding to Council of Ministers' Resolution No. 218 of 18 March 1997 and amending Council of Ministers' Resolution No. 1853 of 29 November 1999.
- Resolution No. 1049 of 16 August 2006 approving Regulations on the Procedure for Permitting the Import, Export and Transit of Opportunistic Pathogenic Genetically Modified Organisms and Genetically Modified Pathogens.
- Resolution No. 1135 of 5 September 2006 on certain issues in the State Regulation of Seed Production and Crop Variety Testing.
- The State Seed Production Compliance Assurance Regulations;
- the Crop Variety Testing Regulations;
- Regulations governing the State Register of Seed Producers and Suppliers;
- Regulations governing the State Register of Varieties and Hardy-Shrub Species.
- Resolution No. 1160 of 8 September 2006 approving Regulations on the Procedure for Conducting State Review of the Safety of Genetically Modified Organisms and on Model Terms and Conditions for Agreements relating to the Conduct of State Review and approving Regulations on the Procedure for Permitting the Release of Non-pathogenic Genetically Modified Organisms into the Environment for Trial Purposes.
- Regulations on the Procedure for Conducting State Review of the Safety of Genetically Modified Organisms and on Model Terms and Conditions for Agreements relating to the Conduct of State Review;
- Regulations on the Procedure for Permitting the Release of Non-pathogenic Genetically Modified Organisms into the Environment for Trial Purposes.
- Resolution No. 1195 of 12 September 2006 approving Regulations on the Procedure for State Registration of Varieties of Genetically Modified Plants, Species of Genetically Modified Animals and Strains of Non-pathogenic Genetically Modified Microorganisms.
- Resolution No. 1222 of 15 September 2006 approving Regulations on the Procedure and Conditions for Providing Information from the Genetically Modified Organisms Databank.

Decisions of the Ministry of Health of the Republic of Belarus

- Decision No. 65 of 25 August 2006 on certain issues in Genetic Engineering Safety
- Instructions on the Safety Requirements for Contained Use Systems in Second-, Third-and Fourth-level Risk Work with Genetically Modified Organisms;
- Instructions on the Procedure for Accreditation of Contained Use Systems in Second-, Third-and Fourth-level Risk Work with Genetically Modified Organisms;
- Instructions on the Safety Requirements for Transport of Opportunistic Pathogenic Genetically Modified Organisms and Genetically Modified Pathogens;
- Instructions on the Procedure for Registration by State Legal Entities of Opportunistic Pathogenic Genetically Modified Organisms and Genetically Modified Pathogens Engineered in the Republic

of Belarus, Imported into the Republic of Belarus, Exported from the Republic of Belarus or Transiting through Its Territory.
- Decision No. 73 of 21 September 2006 approving Forms of Permits for and Declaration of Import, Export and Transit of Opportunistic Pathogenic Genetically Modified Organisms and Genetically Modified Pathogens.
- Decision No. 076-0806 of 25 August 2006, Instructions on Application of the Procedure for Conducting Risk Assessment of Potential Adverse Impacts of Genetically Modified Organisms on Human Health.
- Decision No. 116 of 22 December 2006 approving Forms for the Provision of Information to the Genetically Modified Organisms Databank.

Decisions of the Ministry of Natural Resources and Environmental Protection of the Republic of Belarus
- Decision No. 49 of 17 August 2006 on the Procedure for a Carrier to Notify the Ministry of the Environment of the Transit of Non-pathogenic Genetically Modified Organisms through the Territory of the Republic of Belarus.
- Decision No. 50 of 17 August 2006 on the Safety Requirements for Contained Use Systems in First-level Risk Work with Genetically Modified Organisms.
- Decision No. 51 of 17 August 2006 on the Procedure for Registration by Legal Entities and Individual Entrepreneurs of Non-pathogenic Genetically Modified Organisms Engineered in the Republic of Belarus, Imported into the Republic of Belarus, Exported from the Republic of Belarus or Transiting through Its Territory.
- Decision No. 52 of 17 August 2006 approving Regulations on the Ministry of the Environment's Expert Council on the Safety of Genetically Modified Organisms.
- Decision No. 55 of 29 August 2006 approving Instructions on the Procedure for Conducting Risk Assessment of Potential Adverse Environmental Impacts of Genetically Modified Organisms.
- Decision No. 56 of 29 August 2006 on Safety Requirements for Experimental Fields and Other Facilities Designated for the Conduct of Trials of Non-pathogenic Genetically Modified Organisms on their First-time Release into the Environment.
- Decision No. 57 of 29 August 2006 approving Instructions on the Procedure for Conducting Trials of Non-pathogenic Genetically Modified Organisms on their Release into the Environment.
- Decision No. 37 of 23 April 2007 on the Provision of Information to the Genetically Modified Organisms Databank.

Decisions of the Ministry of Agriculture and Food of the Republic of Belarus
- Decision No. 61 of 19 September 2006 approving Instructions on the Procedure for Permitting Seeds to be Imported into and Exported from the Republic of Belarus.

Decisions of the Ministry of Statistics and Analysis of the Republic of Belarus
- Decision No. 260 of 28 September 2007 approving the form of State Statistical Reporting for Genetic Engineering 1 – 'Report on Genetic Engineering Activities'.
- Decision No. 263 of 14 October 2008 recognizing the loss of force of Decision No. 260 of the Ministry of Statistics and Analysis of 28 September 2007.

Decisions of the State Customs Committee of the Republic of Belarus
● Decision No. 40/38 of 24 May 2006 amending and adding to Decision No. 54/19 of the State Customs Committee and the Ministry of Agriculture of 5 July 2002 and to Decision No. 55/20 of the State Customs Committee and the Ministry of Agriculture of 5 July 2002.
● Decision No. 7 of 16 February 2009 on the Procedure for Providing Information to the Institute for Genetics and Cytology of the National Academy of Sciences of Belarus, a State Scientific Institution.

Additional information about the legislation of the Republic of Belarus may be found on the website of the National Legal Information Centre.

The Law of the Republic of Belarus on Accession to the Cartagena Protocol on Biosafety to the Convention on Biodiversity was passed in 2002.
Council of Ministers' Resolution No. 734 of 5 June 2002 on measures to implement the Cartagena Protocol on Biosafety to the Convention on Biodiversity lists the national government bodies responsible for implementing the Protocol. The Ministry of the Environment is responsible for implementing the Protocol as regards the release of living modified organisms into the environment; the Ministry of Agriculture and the Ministry of Health are responsible as regards the use of living modified organisms for economic purposes.
Council of Ministers' Resolution No. 963 of 19 June 1998 provides that a State scientific institution, the Institute for Genetics and Cytology of the National Academy of Sciences of Belarus, is to fulfil the functions of a National Biosafety Co-ordination Centre. The Centre's site contains a database of legislation on biosafety.
Council of Ministers' Resolution No. 1222 of 15 September 2006 approved Regulations on the Procedure and Conditions for Providing Information from the Genetically Modified Organisms Databank.
Under these Regulations, information may be retrieved from the databank in the form of electronic documents over the Internet, using standard data transfer protocols. Information must be provided free of charge and without restrictions to Belarusian national government bodies, local executive agencies and administrative authorities, legal entities and citizens; biosafety co-ordination centres of other countries; international organizations; foreign legal entities and foreign citizens.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The relevant Belarusian authorities have not received any applications for the deliberate release into the environment and placing on the market of genetically modified organisms.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Because there have been no applications for deliberate release into the environment and placing on the market of genetically modified organisms in Belarus, there has been no involvement of the public in decisions regarding GMOs.

Belgium

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

unchanged compared to the previous report

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

See Federal report

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

www.ogm-ggo.be

Bosnia and Herzegovina

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

(a) With respect to paragraph 1 of article 6 bis and:
(i) Paragraph 1 of annex I bis, arrangements in the Party's regulatory framework to ensure effective information and public participation for decisions subject to the provisions of article 6 bis;

- Law on Genetically Modified Organisms ("Official Gazette of BiH" , No 23/09) (LoGMO BiH)
- Law on Genetically Modified Organisms of Republika Srpska ("Official Gazette of RS", No 41/2009) (LoGMO RS)
- Decision on the Appointment of the Council for Genetically Modified Organisms ("Official Gazette of BiH" No 67/15, 49/16)
- Law on Food ("Official Gazette of BiH", No 50/04) (LoF BiH)
- Law on Administration ("Official Gazette of BiH", No 32/02 and 102/09) (LoA BiH)
- Law on Administrative Procedure of BiH ("Official Gazette of BiH", No 29/02, 12/04, 88/07, 93/09, 41/13) (LoAP BiH)
- Rulebook on Conditions and Procedure of Issuance of Permit to Initially Put Genetically Modified Food and Feed on BiH Market and Monitoring and Marking Conditions ("Official Gazette of BiH", No 78/12 and 62/15) (Day 9)

Pursuant to Article 17 of LoGMO BiH, information on the use of GMO and on the procedures of approval by the relevant body is public. The public call is published in the media and on the web site of BiH FSA, listing the time and place for the documents to be reviewed, as well as the procedure how to provide opinions and comments, for which the deadline is 30 days and it is not counted towards the deadline to issue a decision. The relevant body is obliged to present its view of the public comments and opinions, in the reasons for the adoption of the decision.

It is necessary to conduct a public debate before drafting a report on the assessment of appropriateness of placing GMOs or products containing GMOs on the market (Article 44 of LoGMO BiH) and before the issuance of a permit to place GMO on the market (Article 47 of LoGMO BiH).

Pursuant to LoGMO RS, the use of GMOs or products containing GMOs is forbidden. The use is defined as packaging, handing, placing on the market, transport and transit through the Republika Srpska. The law allows only limited use, in closed systems for research activities, but only upon a special approval of RS MAWMF. The oversight over the implementation of the law is conducted by the Food Inspectorate and the Agriculture Inspectorate.

LoGMO BiH prescribes the procedure and conditions for limited use, cross-boundary transfer, deliberate release into the environment and placement on the market of GMOs and products consisting of, containing or originating from GMOs, with the aim of ensuring a high level of protection of lives and health of people, health and well-being of animals, of the environment, of consumer interests regarding GMOs and products consisting of GMO, as well as live modified organisms with the effective functioning of the market. Pursuant to LoGMO BiH, BiH FSA is the central coordination body for professional tasks in relation to GMOs. Also, upon proposal of BiH FSA, the BiH Council of Ministers adopted the Decision on Appointment of the Council for Genetically Modified Organisms (GMO Council), whose goals are defined by Article 56 of the Law on GMO, for the purpose of monitoring the situation and developments in managing GMOs and of providing expert assistance to the relevant bodies in BiH in the implementation of this law.

In the past, upon proposal of BiH FSA, the BiH Council of Ministers adopted a number of GMO-related regulations.
When it comes to legislative, regulatory and other measures conducted regarding public participation in decision-making on deliberate release of GMOs into the environment, BiH did not transpose EU legislation on deliberate release of GMOs into the environment.

When it comes to legislative, regulatory and other measures conducted regarding public participation in decision-making on placement on the market of GMO food and feed, BiH FSA, upon receiving a Request for Decision on Approval of Placement on the Market of Genetically Modified Feed, sent by feed salespeople, and on the basis of Article 56 of LoF BiH, Article 61 of LoA BiH, Article 193, Paragraph (1) of LoAP BiH, Article 11 of LoGMO BiH, Article 19 of the Rulebook on Conditions and Procedure of Issuance of Permits for Placement for the First Time of Genetically Modified Food Feed on the BiH Market and requests for their Monitoring and Labelling and positive Opinions of the GMO Council per requests, issues the Decision on Approval of Placement on the Market of Genetically Modified Feed.

Opinions of the GMO Council per requests of feed salespeople for Decision on Approval, as well as the issued Decisions on Approval of Placement on the Market of Genetically Modified Feed are available on the official web site of BiH FSA.

The public is not involved in procedures of issuance of the Decision on Approval, and BiH FSA maintains a single register of GMOs, pursuant to Article 58 of LoGMO, and it is also available to the public via the official web site of the Agency.

(ii) Paragraph 2 of Annex I bis, any exceptions provided for in the Party's regulatory framework to the public participation procedure laid down in Annex I bis and the criteria for any such exception;
Pursuant to Article 17 of LoGMO BiH, the public is involved in every permit issuance procedure for deliberate discharge of GMOs into environment.

(iii) Paragraph 3 of Annex I bis, measures taken to make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release or placing on the market of such genetically modified organisms, as well as the assessment report where available;
Pursuant to Article 17 of LoGMO BiH, in the permit issuance procedure for deliberate discharge of GMOs in environment, the competent body is obliged to inform the public on:

- Content of application;
- Content of technical documentation;
- Risk assessment;
- Content of the GMO Council's opinion.

Public call indicating the time and place where the above-mentioned documents can be seen, as well as the proceedings of giving opinion and objections are published via the media and on the FSA BiH web page. The relevant body's deadline for insight and opinion/objections is 30 days.

(iv) Paragraph 4 of Annex I bis, measures taken to ensure that in no case the information listed in that paragraph is considered as confidential;
Pursuant to Article 8 of LoGMO BiH, the requesting party cannot regard the following information as confidential:
a) First name, last name, company name and company seat;
b) Intended manner of use of GMOs and of products consisting of, containing or originating from GMOs, conditions under which the product will be placed on the market and conditions for use;
c) Characteristics of GMOs and products, as well as of their components;
d) Scope and group of dangers stemming from limited use of GMO;

e) Monitoring plan regarding the placement of GMOs onto the market, their use and measures in case of unforeseen risks during the placement of GMOs and of products consisting of, containing or originating from GMOs;
f) Information about health, biodiversity or environmental hazards;
g) Risk assessment
As a result, information contained in Paragraph 4 of Annex I bis cannot be regarded as confidential, pursuant to LoGMO BiH.

(v) Paragraph 5 of Annex I bis, measures taken to ensure the transparency of decision-making procedures and to provide access to the relevant procedural information to the public including, for example:
a. The nature of possible decisions;
b. The public authority responsible for making the decision;
c. Public participation arrangements laid down pursuant to Paragraph 1 of Annex I bis;
d. An indication of the public authority from which relevant information can be obtained;
e. An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments;
Concerning the permit issuance procedure for deliberate release of GMO in the environment, under Article 17, Paragraph 2, Subparagraph (d) of LoGMO BiH, the public is provided access to the GMO Council's opinion, which can be said to have the nature of a possible decision. Also, under Paragraph 3 of this Article, public participation arrangements are presented to the public, while the relevant information can be obtained on the website of the Food Safety Agency of BiH (FSA BiH). Comments can be submitted to the Food Safety Agency (FSA) BiH, Entity Ministries in charge of agriculture, forestry and water management, BiH Administration for the Protection of Plant Health, and BiH Veterinary Office, depending on whether deliberate discharge of GMO in the environment is in question or placing GMOs on the market.

(vi) Paragraph 6 of Annex I bis, measures taken to ensure that the arrangements introduced to implement Paragraph 1 of Annex I bis allow the public to submit, in any appropriate manner, any comments, information, analyses or opinions that it considers relevant to the proposed deliberate release or placing on the market;
Concerning the permit issuance procedure for deliberate discharge of GMO in the environment, the public can submit their opinions and comments. Unfortunately, the LoGMO BiH contains no provisions that would stipulate into more detail the permit issuance procedure for placing GMOs on the market, apart from providing that public hearings need to be organised.

(vii) Paragraph 7 of Annex I bis, measures taken to ensure that due account is taken of the outcome of public participation procedures organized pursuant to Paragraph 1 of Annex I bis;
Pursuant to Article 17, Paragraph (4) LoGMO BiH, the public authority is obliged to address the opinions and comments of the public in the “reasoning” part of the decision.

(viii) Paragraph 8 of Annex I bis, measures taken to ensure that the texts of decisions subject to the provisions on Annex I bis taken by a public authority are made publicly available along with the reasons and the considerations upon which they are based;
Pursuant to Article 48, Paragraph (2) of LoGMO BiH, the permit for placing GMOs on the market has to be made publicly available, except for the information stipulated and designated as confidential, as well as the assessment of risk to human health, biodiversity and the environment.

Pursuant to Article 17, Paragraph (4) of LoGMO BiH, the public authority is obliged to address the opinions and comments of the public in the “reasoning” part of the decision.

(b) With respect to Paragraph 2 of Article 6 bis, how the requirements made in accordance with the provisions of Annex I bis are complementary to and mutually supportive of the Party’s national

biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity..
The relevant Articles are the following: 2, Paragraph (b); 3; 4, Paragraph (4), 10; 13; 19; 32; 34; 38, Paragraph 4; 39; 43; 46 and 49 of LoGMO BiH.

Bulgaria

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Subpoint (k):
Public participation in decisions concerning the deliberate release of genetically modified organisms (GMOs) is regulated in detail the Act on Genetically Modified Organisms (GMO Act).

A GMO or a combination of GMOs shall be released into the environment after obtaining an authorization granted by the Minister of Environment and Water.

An authorization shall be granted for each particular case, acting on an application in writing from a person.
The Advisory Commission on GMOs to the Minister of Environment and Water within 60 days after submission of an application shall prepare an opinion and shall submit the said opinion to the Minister of Environment and Water.
After preparation of the opinion, the Ministry of Environment and Water shall organize a public consultation, which is to be carried out within 45 days after preparation of the opinion.

The summary of the technical dossier, the summary of the risk assessment and the opinion of the Commission shall be presented in the public consultation. No information designated as confidential according to the procedure established by GMO Act may be subject to consultation.

Not later than 30 days prior to the day of the consultation, the subject of public consultation and the place where the necessary information is available to stakeholders shall be announced in one national daily newspaper, through the local mass communication media, through posting notices in the relevant mayoralties in the area of the release of GMOs into the environment, as well as on the Internet site of the Biosafety Clearing-House information system for implementation of obligations under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and for exchange of scientific, technical, environmental and legal information regarding GMOs.. Any such notice shall furthermore announce the date and venue of the public consultation.

Any person may provide an opinion on the subject of the consultation, whether in writing or in an electronic form. The applicant or representatives thereof and the members of the Commission shall likewise be invited to participate in the public consultation.

Minutes shall be taken at the public consultation and shall be attached to the documents on grant of the authorization.

Acting on the basis of the opinion given by the Commission, the economic analysis, the results of the public consultation, the comments from the rest of the Member States of the European Union, and after consultation with the Minister of Agriculture and Food, the Minister of Environment and Water shall prepare a draft of an authorization for the release of a GMO or a combination of GMOs into the environment within 14 days after the date of holding of the public consultation and shall present the said draft for approval by the Council of Ministers.

The following public registers are established and maintained in an electronic form at the Ministry of Environment and Water: a public register of the authorizations for release of GMOs into the environment as granted; a public register of the location and size of the areas wherein the release of GMOs is authorized

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Subpoint (a) (i):

The regulatory framework for effective information and public participation in decision - making process about deliberate release in the environment and placing on the market genetically modified organisms (GMOs) is secured by provisions of the Genetically Modified Organisms Act (GMO Act).

Procedures for informing and public participation regarding the deliberate release of GMOs into the environment, as well as placing on the market GMOs are similar, as for the the first procedure is competent Minister of Environment and Water, and for the second - Minister of Agriculture and Food.

Subpoint (a) (ii):

The Bulgarian legislation does not provide exemptions from the procedure for public participation set out in Annex I bis, paragraph 2.

Subpoint (a) (iii):

After preparation of the position of the Advisory Committee on GMOs on an application, requesting the deliberate release into the environment, MoEW launched a public consultation, which should be held not later than 45 days from the preparation of the opinion. During the public discussion a summary of the technical dossier, the summary of risk assessment and the Commitee's position should be presented.
When considering the placing on the market of GMOs, after preparation of a positive report on the application, to the public are given the report and a summary of the technical dossier. Public consultation is held for 30 days.

Subpoint (a) (iv):

In Chapter 6 of the GMO Act is defined the confidential information related to GMOs. In case of release of GMOs in the environment and in case of placing GMOs on the market, the following information can not be considered as confidential: the general characteristics of the GMOs, name and address of applicant; purpose and location of release; methods and plans for monitoring the GMO and emergency plans; place of storage; ways of transportation, use of GMOs; risk assessment.

Subpoint (a) (v):

Not later than 30 days before the date of the discussion in a national daily newspaper, through the local mass media, by publishing advertisements in the respective municipalities in the area of release of GMOs into the environment, as well as on the website of the MoEW, should be announced 1) subject of public consultation and 2) place where to find all necessary information, available to interested persons. The notice shall announce the date and the place where the public discussion will be held.

Subpoint (a) (vi):

Any person may provide an opinion on the subject of discussion in writing or in electronic form. The applicant or his representatives are invited to participate in public discussion together with committee members. A public consultation record is kept which is attached to the authorization.

Subpoint (a) (vii):

Based on the committee's position, economic analysis, public consultation, the comments made by other countries - members of the European Union, and after consultation with the Minister of Agriculture and Food, the Minister of Environment and Water, prepares a draft permit release of a GMO or combination of GMOs into the environment within 14 days of conducting public consultation and submits it for approval by the Council of Ministers.
Minister of Environment and Water authorizes the placing on the market after the positive decision of the Council of Ministers.

Subpoint (a) (viii):

The website of the Ministry hosts and maintains public registers of:
- Issued permits for release of GMOs into the environment;
- Location and size of the areas authorized for the release of GMOs.

Ministry of Agriculture and Food establishes and maintains electronic registers of:
- permits for placing GMOs on the market;
- information on the genetic information necessary for control and monitoring after placing on the market;
- areas seeded with genetically modified plants that have been authorized for placing on the market in European Union for cultivation.

Subpoint (b):

The Ministry of Environment and Water will create and maintain an information system "Biosafety Clearing House" to meet obligations under the Cartagena Protocol on Biosafety to the Convention on biological diversity and the scientific, technical, environmental and legal information on GMOs. The data in the system is public.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

There is no practice in applying the requirements of article 6 bis and Annex I bis of the Convention. Public electronic registers were created in compliance with the legislation.

Cyprus

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Paragraph 11: Public participation with respect to decisions over GMOs
Projects involving installations where genetically modified organisms are produced or used, or are planned to be produced or used, are included in Annex I of Law 140(I)/2005 and are therefore subject to an EIA and the provisions outlined above regarding public participation. Where the project will involve the storage or use of genetically modified organisms the EIA report must include a scientific description

of the organisms and an assessment of their origin and the necessary means and measures for their containment.

An amendment to the Aarhus Convention was adopted in 2009 which provides that the notification introduced to obtain an authorization for the deliberate release into the environment or the placing on the market of a GMO on its territory, as well as the assessment report where available and in accordance with its national biosafety framework must be available to the public in an adequate, timely and effective manner. It furthermore provides that all the relevant information relating to the decision making process must be made available, including the nature of the possible decision, and the practical arrangements for participation. Account must be taken in the final decision making of the outcome of the public participation procedure and the decision must be made available to the public, together with the reasons and considerations on which it was based.

The Law on the deliberate release of GMOs into the environment (N. 160(I)2003) also includes provisions on public participation, according to which the Scientific Committee evaluating applications submitted for the deliberate release of GMOs must inform the public, including through the internet, of the application and the possibility of issuing a permit. The applicant must notify the public through at least two daily newspapers of the application, inviting the public to submit comments within 30 days from the date of the notification. Furthermore, the Scientific Committee must ensure that the public is appropriately informed through a public hearing process. A register is maintained which includes the applications submitted for the deliberate release of GMOs, the opinions of the Scientific Committee, any permits issued and all additional information submitted in relation to an application or permit.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Law 10(III)/2009 has been passed amending Law 33(III)/2003, which ratifies the Aarhus Convention, to incorporate Articles 6 bis and Annex I bis.

The national legislation regarding the deliberate release into the environment and placing on the market of genetically modified organisms, Law 160(I)/2003, has an established procedure for providing the public with adequate information. Specifically, the Scientific Committee established by Law 160(I)/2003 to review and evaluate the applications for the release or placing on the market of GMOs, is comprised of both government departments and public organizations, including the Cyprus Consumers Association, the Cyprus National Bioethics Committee and the Federation of Environmental Organizations of Cyprus. Furthermore, Part IV of the Law includes provisions for record Keeping and public notification, laying down the practical procedures for public participation. When the Scientific Committee receives an application for the authorization of the release or placement on the market of GMOs, the applicant has to publish a relevant notification in two daily newspapers and the public is given 30 days to provide written comments on the application. Regardless of this provision, the law also states that the Scientific Committee is obligated to carry out a public consultation, in the form of a public hearing. The records kept by the competent authority are available for inspection and include all applications submitted, all authorizations given, the Opinions of the Scientific Committee, the location where the GMOs were released and other relevant information.

Cyprus has so far not authorized the release of any GMOs and has kept a firm negative stance on the matter of GMO authorization.

Czechia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

k) Regarding article 6, paragraph 11
Act No. 78/2004 Coll., on the Management of Genetically Modified Organisms and Genetic Products makes it possible for the public to participate in decision-making on permits to release GMO into the environment.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In the Czech Republic, the GMO area is governed by Act No. 78/2004 Coll., on the disposal of genetically modified organisms and genetic products, as later amended, and by directly applicable EU legislation (Regulation No. 1829/2003 on genetically modified food and feed, and the Regulation No. 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms).

The disposal of the GMO and genetic products can only be only based on permissions, which are determined by the Act No. 78/2004 Coll. The procedure for granting permits for closed disposal, the authorisation for distribution into the environment, and on the registration in the List for distribution is governed by Section 5 of the Act, which determines, together with section 10, the methods and time limits for the publication of information in various stages of adopting decisions. In the case of objections by the public, the public discussion will take place pursuant to Section 6 of the Act.

MOE maintains a registry of permitted GMOs and the registry of persons authorised to dispose of GMOs according to Act No. 78/2004 Coll.; publishes the registries on its website (Section 22 of the Act).

The MoE also publishes on its website the place of cultivation of GMOs (Article 23, paragraph 2 of the Act No. 78/2004 Coll.).

Denmark

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

k)

The Danish regulations on releases of GMOs into the environment are in the Act on the Environment and Gene Technology. The Act contains provisions according to which affected authorities and organisations must be heard in matters of approvals of genetically modified organisms for release.

There are provisions on the procedure for hearing and information for the public in connection with approvals for trial releases and marketing of GMOs, including:

- hearings must be announced on the EPAs website.
- the EPA must set up a register of approvals for trial releases and marketing of GMOs. The register must include information on the name and address of the applicant, a description of the GMO, the objective and location of the release, a summary of the risk assessment, the Minister

for the Environment's assessment of the case, as well as the approval terms. - A great deal of information such as changes to an approval and results of monitoring of GMOs approved for marketing is made public on the EPAs website.

In practice, the hearing takes place by parts of the application, (the Summary Notification Information Format and an overview of the full application), being sent for hearing to about 50 parties, including environmental and consumer organisations. There are announcements on the EPAs website that the public may comment on new applications for trial releases or marketing of GMOs. The full application, except confidential information, can be supplied on request.

The hearing replies received by the EPA are incorporated in a memo to the Minister, and this forms the basis for the Minister's decision. The memo is subsequently made public on the EPAs website.

Under the MEFD, the Statutory Order on the cultivation of GMOs stipulates rules on the duty to provide information on cultivation of genetically modified crops.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

(a)

(i) The Danish regulations on releases of GMOs into the environment are in the Act on the Environment and Gene Technology. The regulatory framework to ensure effective information and public participation are listed in § 9 a

(ii) In the regulation there are no exceptions to the public participation procedure.

(iii) The regulation on public participation is implemented in the statutory order no.37 of 19th January 2012.

(iv) The statutory order no.37 of 19 January 2012 implemented that the information listed in Annex I (bis), paragraph. 4 cannot be disclosed. In § 4 there is regulation on the minimum level of information that a decision on the deliberate release of GMO’s must contain.

Public registers as mentioned under ad iii) must contain the same amount of information. From § 10 it follows that a decision must contain the same amount of information as implied in the in the EU-regulation, that the Danish regulation is implementing. The public register must contain the same amount of information.

(v) In the Danish Act no. 840 of July 3rd 2015 on the Environment and Gene Technology and in the Statutory Order no. 37 of 19th January 2012 on approval of deliberate release of genetically modified organisms it is clearly described which public authorities which is responsible for GMO-matters in Denmark. The legislation also stipulates which public authority the citizens must address to request information concerning GMOs in Denmark.
a. before mentioned legislation describes the character of the decisions which the public authorities can reach on deliberate release as well as on cases of placing on the market.
b. The EPA is responsible for the handling on decision on the deliberate release and marketing of GMO’s as regards to non-food. As regards to the import and cultivation of GM- food and GM-feed the responsible authorities are the Danish Veterinary and Food Administration and the Danish AgriFish Agency
c. In practice the public participation is organised through that the application (the SNIF-part (Summary Notification Information Format) and a summary of the application is sent in a hearing to about 50 organisations etc. Furthermore this information can be found on the webpage

www.mst.dk. The public is given the opportunity to make comments. The application, however without disclosed information, will be handed out upon request.
d. Reference to c)
e. Reference to c)

(vi) Reference to c)

(vii) The comments of the hearing will be a part of the basis on which the Minister is going to take a decision. There will be made note to the minister. The note is published on the website: www.mst.dk

(viii) All decisions and register of decisions are on the website www.mst.dk

(b) The EPA finds that the conditions in annex I complements and supports the Danish legislation as those conditions are already implemented in Danish legislation. Furthermore this is complementary to that the Danish legislation which is in conformity with the aims of the Cartagena- Protocol on Bio-Safety.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

As earlier stated it is implemented in the regulation that there shall be public hearings.

Estonia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Public participation in decisions on the intentional release of genetically modified organisms (GMOs) into the environment is regulated by the Release of Genetically Modified Organisms into the Environment Act (adopted in April 2004). The Act determines that GMOs may be released into the environment only with the written authorisation of the Minister of the Environment. For this purpose, a relevant application is submitted to the Ministry of the Environment, and pursuant to section 10 of the Act the Ministry of the Environment notifies about open proceedings of issuing a permit and subsequent granting of permit in the official publication *Ametlikud Teadaanded* (Official Notice) and at least in one national newspaper within seven days from the receipt of the application and the issuing of the permit. Regarding release of genetically modified organisms (GMOs) into the environment and granting marketing permits open procedure provisions shall be applied.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In Estonia, the release of GMOs into the environment and marketing is subject to the Deliberate Release into the Environment of Genetically Modified Organisms Act that also contains provisions regarding the engagement and participation of the public in the decision process regarding the release of GMOs into the environment, and marketing.

Pursuant to section 5 of the Act, the Gene Technology Committee has been established in the administrative area of the Ministry of the Environment that inter alia revises and provides assessments regarding the applications for licences to release GMOs in the environment and marketing. Besides government agencies and universities, the committee also includes representatives of environmental organisations who have through the committee a direct access to the information contained in the licence

application and the right to submit additional questions and comments. The committee assesses the licence applications submitted both in Estonia and through any other EU Member State (only regarding marketing).

The act comprises several clauses on disclosure related to the licence application. E.g. pursuant to § 8 and § 23 the Ministry of the Environment must notify the public in at least one newspaper of national circulation, if new data have become available during the processing of the licence or after the granting of the licence regarding the hazards to human health or environment related to the release into the environment or marketing. The content of the information to be disclosed is established in the regulation of the Minister of the Environment No. 68 of 8 June 2004 "Information submitted and disclosed for the hazard having become known related to the release of GMO into the environment or marketing of a product containing or composed of genetically modified organisms".

Section 10 of the Act establishes the procedure for the disclosure of the application for the licence to release GMOs into the environment and marketing and the issued licence. Under this article, the Ministry of the Environment must inform the public of the initiative of the proceeding of the licence and later also of the granting of the licence in Ametlikud Teadaanded and at least in one national newspaper. The content of the notice provides information regarding the applicant, the content of the application, the site of release of the GMOs into the environment and examination of the application. In the respective notice, the period of time when the public can give their opinion shall be designated. This period cannot be shorter than 30 days or longer than 60 days. The Ministry of the Environment must respond to the comments of the public within the period of two weeks after their receipt.

Any already marketed GMO must be labelled so that the consumer is able to choose whether he or she wants to buy a product containing or composed of GMOs (§ 24). The labelling obligation stems directly from the Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the labelling of genetically modified organisms.

Any information contained in the application for the licence and the data of the valid licence are public and they are maintained in the Environmental Register (§ 29). Any relevant information regarding the owner of the licence, GMOs, the acceptable environment and allowed manners of use shall be entered into the permit (§ 12 (5) and § 22 (5)).

In case the applicant for the licence wishes to keep some of the data as business secret, the respective decision shall be made by the Minister of the Environment. The following data must not be considered as a business secret: the description of GMOs, the name and address of the applicant, the aim, site and time of release of GMOs into the environment, and the intended method of use, the planned monitoring method and plan, the results of risk analysis and action plan in case of an accident.

The requirements established in the law meet the requirements of the Cartagena Protocol and facilitate the performance of the aims of the Protocol.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

No licences for release into environment or marketing of GMOs have been issued in Estonia. Therefore it is impossible to speak of obstacles or experiences in this area. Still, the representatives of NGOs participate in the Gene Technology Committee where the EU applications for the marketing permits are assessed. Annually, approximately twenty applications for licences are assessed.

European Union

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, paragraph 11

The amendment to the Aarhus Convention on genetically modified organisms (GMOs) was adopted in May 2005. It specifies the obligations of Parties with regard to public participation in decision-making processes concerning GMOs. Any Party whose regulatory framework is consistent with the GMO amendment is also in line with Article 6, paragraph 11, of the Convention. Reference is thus made to part XXXIII and following of the present report.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The EU ratified the Amendment to the Convention related to GMOs on 18 December 2006, by Council Decision 2006/957/EC.

The relevant EU legislation governing GMOs consists in particular of Directive 2001/18/EC on the deliberate release into the environment of GMOs (GMO Directive) and Regulation 1829/2003 on genetically modified food and feed. Their provisions on access to information and public participation in decision-making on GMOs are consistent with the amendment to the Convention.

In cases of notifications for the placing on the market of GMOs, Article 24 of the GMO Directive provides that the Commission shall make available to the public the summary dossier that accompanies those notifications. It also requires the Commission to make available to the public the assessment report issued by the competent Authority of the Member State that received the notification. The public may make comments on the summary dossier and on the assessment reports to the Commission within 30 days. The Commission shall immediately forward the comments to the competent Authorities. Finally, the assessment reports and the opinions of EFSA for all GMOs which have received written consent for placing on the market or whose placing on the market was rejected shall be made available to the public.

Article 9 of the GMO Directive provides that Member States are to consult the public on the proposed deliberate release of GMOs into the environment for any other purpose than for placing on the market. In doing so, Member States must lay down arrangements for this consultation, including a reasonable time period, to give the public the opportunity to express an opinion. Member States are to make available to the public information on all intentional releases of GMOs into the environment in their territory; the Commission is to make available to the public the information contained in the system of exchange of information established in the EU.

In accordance with Article 31(2) of the GMO Directive, information on genetic modifications in authorised GMOs is listed in a public register available on the website of the Joint Research Centre.

Article 25 of the GMO Directive specifies certain information in notifications which may not be considered as confidential.

According to the Regulation on genetically modified food and feed, EFSA is to make available to the public a summary of the application for authorisation of placing on the market of GM food (Article 5(2)(b)(ii)). Similarly, when delivering its opinion, the Authority must make it public, after deletion of any information identified as confidential (Article 6(7)). The public may make comments to the Commission within 30 days of such publication. A similar procedure applies in case of modification, suspension and revocation of authorisations (Article 10(1)). Similar provisions also exist with regard to the authorisation of GM feed (Articles 17(2)(b)(ii), 18(7) and 22(1)). Authorised genetically modified

food and feed is entered into a public register. Article 30 of the Regulation specifies which information may or may not be considered as confidential (Article 28).

Article 30 of the Regulation specifies certain information in applications which may not be considered as confidential.

As regards the right for public access to documents, Article 29 of the Regulation provides that the application for authorisation, supplementary information from the applicant, opinions from the competent Authorities, monitoring reports and information from the authorisation holder are to be made accessible to the public in accordance with the principles of the Access-to-documents Regulation.

Finland

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, paragraph 11 - measures taken to apply the provisions of article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment:

The provisions on hearing the public are incorporated into the Gene Technology Act (377/1995). Pursuant to Section 36b of the Gene Technology Act, the Board for Gene Technology must consult the public on research and development experiments and field experiments. If GMO products are placed on the market, the European Commission is responsible for consulting the public in accordance with the Directive for release of GMOs into the environment (2001/18/EC) or the Community Regulation relating to genetically modified food and feeds (EC No. 1829/2003).

The Finnish and EU legislation cover the amendments approved at the second meeting of the parties to the Aarhus Convention in 2005, specifying the public hearing procedure in deciding on the release of genetically modified organisms into the environment (Decision II/1). Finland approved the amendment to the Convention on June 10, 2008. It has not yet been internationally ratified.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Paragraph 1 of article 6 bis and Paragraph 1 of annex I bis, arrangements in the Party's regulatory framework to ensure effective information and public participation for decisions subject to the provisions of article 6 bis;

Section 36 b of the Gene Technology Act (377/1995 [Several amendments 2013–2016]) provides for public participation in decision-making on the deliberate release into the environment for other purposes than placing on the market (field experiment) of genetically modified organisms (an English version of the Gene Technology Act can be accessed at http://www.finlex.fi/en/laki/kaannokset/1995/19950377). Public participation involving the placing of GMO products on the market takes place at the EU level in accordance with Directive 2001/18/EC or Regulation (EC) 1829/2003.

Article 6 bis paragraph 1, Paragraph 2 of annex I bis, any exceptions provided for in the Party's regulatory framework to the public participation procedure laid down in annex I bis and the criteria for any such exception;

No exception to the public participation procedure is provided for in the Finnish Gene Technology Act.

Article 6 bis paragraph 1, Paragraph 3 of annex I bis, measures taken to make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release or placing on the market of such genetically modified organisms, as well as the assessment report where available;

The Board for Gene Technology provides a forum for public participation for all field experiment applications received. Information on a projected field experiment is published in the Official Bulletin and on the website of the Board for Gene Technology (GTLK). The public participation procedure takes 60 days, and the public is entitled to acquaint themselves with the application documents for the field experiment and to obtain copies thereof, and to submit written opinions on the applications. The application documents are open to public inspection on the Board's website and at the library of the Ministry of Social Affairs and Health. Requests for copies and written comments will be addressed to the Board for Gene Technology.

For product applications in accordance with Regulation EC/1829/2003 (GM food and feed), it is the task of the Finnish Food Safety Authority (Evira) as the Finnish contact authority for GMO applications to see to it that abstracts of the permit applications drafted by an applicant and EFSA's opinions on the applications are made available to the public. Information on new applications is provided on Evira's website under the heading ´Applications´ under ´Latest applications´, and information on the completion of EFSA's opinions is provided at ´Products to be commented on´ and on the front page of Evira's website at EFSA-Focal Point – Current from EFSA. For all applications, an abstract and an assessment report on the application can be accessed at EFSA's website (http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2). When EFSA's opinion is completed, the public can submit their comments in their native language to the Commission within 30 days on a website administered by the Commission for this purpose at: http://ec.europa.eu/food/plant/gmo/authorisation/authorisation_applications_1829-2003_en.htm.
Applications open for commenting are listed under the section 'Open consultations'. After the consultation period has closed, the applications and the comments submitted by the public will be published on the same website under the section 'Closed consultations'.

The public participation process for product applications in accordance with directive 2001/18/EU (for example, GM cut flowers) is the responsibility of the Commission. Further information can be accessed at the website of the Joint Research Centre (JRC): http://gmoinfo.jrc.ec.europa.eu/default.aspx. In addition to product application information, the website offers summaries of all field experiment applications submitted in EU Member States.

Article 6 bis paragraph 1, Paragraph 4 of annex I bis, measures taken to ensure that in no case the information listed in that paragraph is considered as confidential;

Section 32 of the Gene Technology Act provides that the information listed in paragraph 4 of annex I bis is not considered confidential.

Article 6 bis paragraph 1, Paragraph 5 of annex I bis, measures taken to ensure the transparency of decision-making procedures and to provide access to the relevant procedural information to the public including, for example

(a) The nature of possible decisions;
(b) The public authority responsible for making the decision;
(c) Public participation arrangements laid down pursuant to paragraph 1 of annex I bis;
(d) An indication of the public authority from which relevant information can be obtained;
(e) An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments;

In public participation proceedings relating to field experiments, the procedure is carried out in writing. The public notification concerning the start of the hearing details the public's opportunity to submit

comments by post or e-mail to the Board for Gene Technology within a 60-day period and of the possibility of receiving a copy of the application document. Additionally, in some cases informative meetings on field experiments are arranged, where citizens may present questions and comments. Comments to be presented to the Commission in product approval procedures may be forwarded via the Commission website, by e-mail or mail.

Article 6 bis paragraph 1, Paragraph 6 of annex I bis, measures taken to ensure that the arrangements introduced to implement paragraph 1 of annex I bis allow the public to submit, in any appropriate manner, any comments, information, analyses or opinions that it considers relevant to the proposed deliberate release or placing on the market;

Cf. paragraphs 158 and 161.

Article 6 bis paragraph 1, paragraph 7 of annex I bis, measures taken to ensure that due account is taken of the outcome of public participation procedures organized pursuant to paragraph 1 of annex I bis;

Comments gleaned from the public participation events arranged concerning field experiments are handled in connection with processing the permit application. Pursuant to Section 18 of the Gene Technology Act, the Board for Gene Technology shall issue a permit for release into the environment if the risk assessment in accordance with Section 8 has not revealed any hazard to the health of humans or animals or to the environment, and if the technical documents have been drafted in accordance with Section 17 of the Gene Technology Act. Therefore, the public's comments can affect the granting of the permit only if it is revealed on the basis of them that said conditions are not met. The public's comments are also taken into account in deciding on the conditions for the permit, alongside expert opinions. The grounds for the decision are available to the public.

In EU product approval, the Commission will analyse all comments received from the public and consult the EFSA in regard to them in order to determine whether they have any bearing upon EFSA's opinion.

Article 6 bis paragraph 1, paragraph 8 of annex I bis, measures taken to ensure that the texts of decisions subject to the provisions on annex I bis taken by a public authority are made publicly available along with the reasons and the considerations upon which they are based;

Under Directive 2001/18/EC, in Finland decisions concerning deliberate release of GM organisms into the environment are made by the Board for Gene Technology. The minutes of the meetings of the Board can be accessed at the website http://www.geenitekniikanlautakunta.fi. This authority also provides information directly on request either in writing or by telephone.

Article 6 bis paragraph 2, with respect to annex I bis, how the requirements made in accordance with the provisions of annex I bis are complementary to and mutually supportive of the Party's national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity:

The Board for Gene Technology, operating in connection with the Ministry of Social Affairs and Health is the Finnish competent authority in tasks laid out in the Gene Technology Act and the Cartagena Protocol on Biosafety. The Ministry of the Environment, which is responsible for contacts with the Secretariat of the Cartagena Protocol, has a representative on the Board for Gene Technology.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

No significant obstacles have been encountered in the implementation, but the accuracy of publishing the cultivation site data has been discussed at the national and EU level on account of vandalism of field experiments.

During its round of comments in 2013, the Finnish Association for Nature Conservation pointed out that unlike in previous terms, the Board for Gene Technology has not included an NGO representative during its current term (2010–2015).

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Public comments on field experiment applications are stored in the national gene technology register in connection with the applications and they are available to the public. No actual statistical analyses have been made on them. In a product approval procedure at the EU level, public comments are also stored in connection with the applications.

France

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

There are two authorization procedures for the deliberate release of genetically modified organisms (GMOs) into the environment: authorizations for any purpose other than placement on the market (in particular, for field trials) (Article L.533-3 of the Environmental Code) and authorizations for placement on the market (Article L. 533-5 of the Code).

The documents submitted to the competent administrative authority by an applicant for one of the above authorizations must include *inter alia* an assessment of the health and environmental effects and risks of the GMOs. The High Council for Biotechnologies ('the HCB'), which includes an Economic, Ethics and Social Committee made up of civil society representatives, issues an opinion on every application for authorization.

The National Agency for Food, Environmental and Workplace Safety (ANSES) is also authorized to assess the safety of food that consists of or is produced from GMOs. The opinions of these bodies are published on their respective web sites.

For every application for field trials, a public consultation procedure is initiated via the Internet. The application for authorization, the HCB opinion and a public information file are posted online for each trial.

For every application for placement on the market, an EU-wide public consultation procedure is conducted via the Internet. Applications submitted under Regulation (EC) No. 1829/2003 on genetically modified food and feed are subject to consultation online at http://ec.europa.eu/food/plant/gmo/public_consultations_en.

Applications submitted under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms are subject to consultation via the website of the European Commission's Joint Research Centre at http://gmoinfo.jrc.ec.europa.eu/Default.aspx#.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

France ratified the GMO amendment by Act No. 2016-369 of 30 March 2016.

Georgia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k)
Since 2015, the Law of Georgia on Living Modified Organisms has been enacted, which includes the principles of the Aarhus Convention. According to the mentioned law, deliberate release into the environment and placing on the market of LMOs on the territory of Georgia is prohibited (Title II, Chapter II, article 7, first paragraph).

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

According to the Law of Georgia on Living Genetically Modified Organisms (LMOs), that was adopted in 2014, deliberate release into the environment (article 7, paragraph 1), placing on the market (article 7, paragraph 2), import and re-export (article 1, paragraph 1, section "g^1") of LMOs is prohibited on the territory of Georgia. The respective law aims, among others, to ensure public access to information and participation in decision-making with respect to LMOs related issues (Chapter VII, article 26, paragraph 2).

According to the Georgian legislation, it is obligatory to create unified register of LMOs. According to the Georgian Law on LMOs, unified register is a public document. Any person has the right to get acquainted with it without a delay, in the shortest date (article 27, paragraph 3). According to the amendments made on March 2, 2016 to the mentioned law, unified register of permitted, used LMOs in the contained system shall be posted on the special website.

Regulation on Unified Register of LMOs (2014) defines the list of the mandatory information to be existed in the register (article 2, paragraph 2). According to the Law of Georgia on LMOs, the unified register of LMOs will not include the information, which, according to the Georgian legislation is considered as confidential (article 27, paragraph 4).

The Law of Georgia on Labeling of Food/Animal Feed GMOs and Their GMO Production (2014) aims to:

a) inform consumers about labeling of food/animal feed GMO and their GMO production;
b) protect consumers' interests to have a free choice;
c) define labeling rules of food/animal feed GMO and their GMO production and establish State Control on them;
d) support harmonization and approximation of Georgian Legislation with EU acquis and other legislative norms established by international acts in the field of labeling food/animal nutrition GMO and products produced by GMO.

Decree of the Government of Georgia N320 of 2015 on "Approval of Rule of Labeling of Food/Animal Feed GMOs and Their GMO Production" sets the requirements towards labeling of food/animal feed GMOs and their GMO production and regulates the relations between business operators, state control bodies and consumers.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The lack of appropriate accredited testing laboratories and qualified staff; scarcity of information about the methodology of risk assessment related to products and raw food materials containing GMOs.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The Decree #2-231, 2009 of the Minister of Agriculture of Georgia on the Approval of Additional Requirements for Food Labeling (article 9 – labeling of Genetically Modified Food Products) considers only the obligation of informing the public about existence of GMO components in food (putting appropriate information on a label in accordance with defined rules), that enables the public to make a choice.

The Decree of the Government of Georgia (2013) approves the rules of bio production. The document defines labeling of food products for placing on the market as “bio”, “eco”, “organic”, “ecologically clean” product, which provides to the consumers information on healthy food products.

According to the obligations undertaken by the EU-Georgia Association Agreement and chapter 4 of the Deep and Comprehensive Free Trade Area Agreement (DCFTA) on “Sanitary and Phytosanitary Measures”, elaboration of national legislation by considering the following EU regulations is planned in 2018:

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;

European Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003;

Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

Reflection of the requierements of Commission Recommendation 2010/C 200/01 of 13 July 2010 in national legislation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops is planned for 2021.

It should also be noted, that in case of important legislation amendments, the Ministry of Agriculture of Georgia places the drafts for comments on its official websites. The Ministry conducts as well public hearings, which are open for all interested parties.

The non-governmental sector is involved in the process of informing the public. The National Centre for Monitoring and Scientific Research of Manufacturing of GMO Products is established. Representatives of NGO sector participate in conferences and meetings related to the given issues.

Germany

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k)

The public is also consulted on decisions on the deliberate release of genetically modified organisms into the environment: Section 18 (2) of the Genetic Engineering Act (Gentechnikgesetz – GenTG) prescribes a consultation procedure that must essentially satisfy the requirements of Section 10 (3 to 8) of the Federal Immission Control Act, unless a simplified procedure is conducted once the experience gained of releases of genetically modified organisms is sufficient to guarantee protection. The details of the consultation procedure are defined in the Genetic Engineering Consultation Ordinance (Gentechnik-Anhörungsverordnung). The competent authorities must supervise the implementation of the Genetic Engineering Act (Section 25 GenTG) and may, in individual instances, give the orders necessary to eliminate established offences against this act or to prevent future offences of this kind (Section 26 (1) GenTG). Pursuant to Section 28a GenTG, the public must be informed of any enforceable orders. The current German legislation on genetic engineering already complies with the provisions of the first amendment to the Convention (the "Almaty Amendment"). The Federal Republic of Germany adopted the Almaty Amendment with effect under international law on 20 October 2009.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The aim of the amendment to the Aarhus Convention adopted through decision II/1 at the second meeting of the Parties in Almaty (Kazakhstan) on 27 May 2005 (Almaty Amendment) is to supplement the Convention with minimum requirements for public participation in decisions on the release and placing on the market of genetically modified organisms (GMOs). The Federal Republic of Germany approved the Almaty Amendment by means of a ratification act and adopted it, with effect under international law, on 20 October 2009.

European and German law on genetic engineering had already long provided for public participation in decisions on the release and placing on the market of GMOs. Decisions on the placing on the market of GMOs are taken at EU level, decisions on experimental releases are taken by the Member States. The more detailed specification of the participation procedure in relation to GMOs achieved by the amendment to the Aarhus Convention is in line with the relevant legislative provisions of the European Union on GMOs.

The relevant provisions at EU level, especially Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and Regulation (EC) 1829/2003 of 22 September 2003 on genetically modified food and feed, already contain provisions on public participation in decision-making on GMOs which are in line with the amendment to the Aarhus Convention. With regard to placing on the market, Articles 6, 18 and 29 of Regulation (EC) 1829/2003 contain provisions on public participation in decision-making on GMOs. Article 30 of Regulation (EC) 1829/2003 lays down which information is not treated as confidential. Articles 9 and 24 of Directive 2001/18/EC on deliberate release contain provisions on public participation. Articles 7, 8, 16, 19, 20, 23 and 31 of Directive 2001/18/EC contain provisions on public access to information. Furthermore, Article 25 of the Directive lays down which information is not treated as confidential.

These provisions are transposed in Germany primarily by Part Three of the Genetic Engineering Act (Gentechnikgesetz – GenTG). Section 18 (2) GenTG stipulates that a consultation procedure must be conducted before a decision on authorising release is made. The details of the consultation procedure, e.g. when the duty to consult ceases to apply if additional information is submitted under the simplified procedure, are regulated in the Ordinance on Consultation Procedures in Accordance with the Genetic Engineering Act (Gentechnik-Anhörungsverordnung – GenTAnhV). These provisions ensure effective public participation in accordance with the criteria laid down in Annex 1^{bis} of the Aarhus

Convention. It should be noted that the provisions are also compatible with the Cartagena Protocol on Biosafety with regard to the handling of living modified organisms (LMOs).

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Decisions concerning the placing on the market of GMOs are taken in an EU-wide approval procedure and apply for all the EU Member States. In this respect, public participation is governed by Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. The competent authorities of all the EU Member States are involved in the approval procedures. The Federal Office of Consumer Protection and Food Safety (BVL) is the competent German authority. Opinions on applications to place GMOs on the market and decisions concerning experimental releases are issued by the BVL, inter alia in consultation with the Federal Agency for Nature Conservation (BfN), the Federal Institute for Risk Assessment (BfR) and the Robert Koch Institute (RKI). The Julius Kühn Institute – Federal Research Centre for Cultivated Plants (JKI) – and other participating authorities submit their opinions to the BVL.

All releases of GMOs applied for in Germany are recorded in a database and made available in an overview by the BVL. A site register administered by the BVL records the precise locations of sites on which GMOs are released or cultivated. The aim of the site register is to improve the observation of possible undesirable impacts on the environment, as well as human and animal health. At the same time, the public is to be informed in order to guarantee transparency and coexistence.

Greece

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Legislation and Information provided under this Article, remain the same as it is in the Report of the previous reporting cycle.

Hungary

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, section 11 (participation in the permitting procedure of genetically modified organisms)

112. The permitting procedure of genetically modified organisms (GMOs) in Hungary is laid down by Act XXVII. of 1998. on Gene Technological Activities.

Pursuant to relevant legal requirements the representatives of civil organizations aimed environmental health- and consumer protection – elected according to the procedure determined by them - participate in the Gene-technology Advisory Committee (GEVB). The activities of the committee are governed by Ministry decree 128/2003/FVM (XII. 19.). Gene-technology authorities review permit requests for gene-technological activity with respect to the comments made by the GEVB.

The environmental protection, agricultural and industry gene-technology authorities involve the healthcare gene-technology authority as professional authorities during permit processes falling under national jurisdiction. The healthcare gene-technology authority involves the environmental protection,

agricultural and industry grade gene-technology authorities as professional authorities during permit processes falling under national jurisdiction.

In permit processes falling under EU jurisdiction when national authority tasks are carried out by the competent gene-technology authority, it consults with the GEVB during the fulfilment of its tasks, excluding administrative matters.

The gene-technological authority has to publish the draft permit (without transport, export, import) in its official paper and its website for public consultation, excluding data subject to commercial confidentiality, intellectual copyright or patent. Comments on the draft can be made within 30 days from publication. These comments are evaluated by the Gene-technological Advisory Committee within 10 days, and the competent authority has to reach a decision on the authorization within a further five days.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In Hungary, the Amendment to the Aarhus Convention regarding genetically modified organisms (GMOs) has been announced by Act XIX. of 2008. on the declaration of the amendment to the Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters signed on the 25 July 1998. in Aarhus.

National legislation relating to GMOs has been in place since 1998. The authorization procedure for GMOs including rules on public participation in decisions on the deliberate release into the environment and placing on the market of GMOs is laid down in Act XXVII. of 1998. on the gene technological activity as well as in several decrees on the implementing rules.

Act XXVII. of 1998. on the gene technological activity contains the following rules regarding public information and participation in decisions:

Gene technology authorities
Paragraph (1) of Section 4 on the basis of the opinion elaborated in accordance with Section 8 of a Gene Technology Advisory Committee (hereinafter referred to as ”Gene Technology Committee”), gene technology activities shall be authorised
a) in case of gene technology activities related to human health, to the production of human pharmaceutical products and to cosmetics in direct contact with the human body, by the Healthcare Gene Technology Authority,
b) in the case of gene technology activities in the agricultural and food sector (including process additives used in food production) and in contained use, as well as in the case of other industrial gene technology activities, by the Environmental, Agricultural and Industrial Gene Technology Authority – upon taking into account environmental and agricultural considerations – (the Healthcare Gene Technology Authority and the Environmental, Agricultural and Industrial Gene Technology Authority hereinafter collectively referred to as the “Gene Technology Authority”), provided that the authorisation procedure occurs at a national level.
(2) Authorisation procedures belonging to the scope of the EU, the responsibilities of the national authorities are undertaken by the Gene Technology Authority, which shall consult with the Gene Technology Committee in the framework of its operation, except for the administrative tasks. In relation to Union-level authorisation procedures for food and feed products, the Environmental, Agricultural and Industrial Gene Technology Authority shall consult with the Healthcare Gene Technology Authority. In relation to Union-level authorisation procedures, the Healthcare Gene Technology Authority shall consult with the Environmental, Agricultural and Industrial Gene Technology Authority.

(3) In the authorisation procedures in the fields referred to in paragraph (1) item b) and in paragraph (1) item a), the Healthcare Gene Technology Authority and the Environmental, Agricultural and Industrial Gene Technology Authority shall act as the Special Technical Authority, respectively.
(4) The rules of involving the Special Technical Authority in the authorisation procedures referred to in paragraph (1) shall be governed by the relevant law issued under the authorisation of this Act.

Section 9 (4) The Gene Technology Authority shall publish the draft consent in its official journal and website for public consultation with the exception of confidential business information, copyright information and information regarding variety protection. Comments on the draft consent may be submitted to the Gene Technology Authority within 30 days after publication in the official journal and such comments shall be forwarded to the Gene Technology Committee for opinion. The Gene Technology Committee shall assess such comments and forward its opinion to the Gene Technology Authority within 10 days of its receipt. Upon receiving the opinion of the Gene Technology Committee, the Gene Technology Authority shall finalise or amend the draft consent or reject the application.
(5) When calculating the time limit for the procedure, the period during which the Gene Technology Authority conducts the public consultation shall not be considered.

Special rules of the authorisation of the deliberate release of GMOs into the environment for any purpose other than its placing on the market
Paragraph (1) of Section 10/A. § As regards authorisations for releases of genetically modified organisms or products derived therefrom for any other purposes than placing on the market, the Gene Technology Authority shall make a decision within 90 days of the receipt of the application, after conducting the procedure specified in Section 9 (4) and (5).

(2) The final consent for the releases of genetically modified organisms and products derived therefrom for any other purposes than placing on the market – with the exception of confidential business information, copyright information and information regarding patents and plant variety protection – shall also be published in the Official Journal of the Gene Technology Authority and of the Ministry led by the Minister directing the Gene Technology Authority, and the name of the releasing entity and the genetically modified trait should also be indicated.

Special rules of placing on the market of GMOs
Section 11/A (1) The first placing on the market within the territory of the European Economic Area of genetically modified organisms or combinations genetically modified organisms as or in products shall be subject to authorisation; thereafter, they are freely marketable within the territory of the European Economic Area except as specified in Section 11/B.
(3) As regards authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified organisms, for food and feed uses, the provisions of the relevant directly applicable legal act of the European Union with general scope shall apply.

Registers and data management
Section 19 (1) An institution appointed by the Government (hereinafter referred to as "Registering Body") shall maintain registers of the following and shall make them available on its website without limitation and in a searchable format:
a) a general description of the genetically modified organism or organisms, the name and address of the user, the purpose and location of the release, the intended uses, the environmental risk assessment, and the methods and plans for monitoring of genetically modified organisms and for emergency measures among the data of the documentation specified in the relevant law issued under the authorisation of this Act as well as in the applications for authorisation for genetic modification of natural organisms, for the contained uses of genetically modified organisms and products derived therefrom, for releases for any other purposes than placing on the market or for placing on the market,
b) the final consent, and

c) a list of the names of the laboratories performing genetic modifications and the responsible managers thereof.
(2) The members of the Gene Technology Committee shall maintain the confidentiality of the data received in the framework of the operation of the Gene Technology Committee and may only disclose such data to third parties upon obtaining the consent of the applicant. This provision shall apply even if the user withdraws the submitted application.
(3) The Gene Technology Authority shall forward the data specified in paragraph 1 to the Registering Body, and in case of data specified in item a) of paragraph 1, shall publish the draft consent at the same time.
(4) Among the data submitted for registering purposes, those related to user's rights to confidential business information or patents or variety protection shall not be public provided that user requests the Gene Technology Committee or the Gene Technology Authority to treat such data in this manner.
(5) The Registering Body shall maintain the registers for 10 years after the expiry of the time period specified in the consent.
(6) In case of withdrawal of the consent, the Registering Body shall delete the data specified in item a) of paragraph 1 from its registers.
Section 20 (3) The detailed rules relating to the registration and the accessibility of information specified in Section 19 (1) shall be laid down by the relevant law issued under the authorisation of this Act.
Section 21 (2) The chairman and secretary of the Gene Technology Committee shall prepare annual summary reports regarding the discharging of the duties related to its activities and the annual reports specified in paragraph (1) shall be included in the annual summary reports which shall be published by the Ministry led by the Minister responsible for agricultural policies in its official journal and website.

Decree 82/2003 (VII. 16) of the Ministry of Agriculture and Rural Development on the order of the registering and supplying data as well as Decree 82/2003. on the documentation which shall be enclosed in the notification regarding the gene technological activity determines which documents and information shall be enclosed to the notification for the authorization of GMO. It also contains rules on record keeping and official database. Information stipulated in Section 19 (1) of the Gene Technology Act are registered and made available to the public by the Agricultural Biotechnology Research Centre in Gödöllő[7].

Iceland

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k)

Act No. 18/1996 on Genetically Modified Organisms (GMOs) implements EU Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. The Act sets out the administrative process for issuing permits for placing on the market and other deliberate release of GMOs. According to the act the public must be consulted before a permit to place GMO on the market is issued. The Environment Agency, which issues GMO permits, shall draft a summary of the application that shall be introduced to the public. The Environment Agency's Assessment Report shall also be made available to the public. Furthermore the Environment Agency shall hold public meetings or in other way consult the public, as is necessary, before a permit is issued. The public has 30 days from the publishing of the summary to submit its comments.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

[7] http://biosafety.abc.hu/biosafe_eng.html

Iceland has not signed or ratified the GMO amendment. However Iceland has through the EEA Agreement implemented Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

Ireland

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k)
Ireland is a Party to the Cartagena Protocol on Biosafety, which is implemented through a range of legislative measures, including:

- the Genetically Modified Organisms (Deliberate Release) Regulations 2003, S.I. No. 500 of 2003;
- the Genetically Modified Organisms (Contained Use) Regulations 2001, S.I. No. 73 of 2001;
- EU Regulation 1946/2003 on the transboundary movement of GMOs and
- the Genetically Modified Organisms (Transboundary Movement) Regulations 2004 (S.I. No. 54 of 2004).

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The requirements of the GMO Amendment, Article 6bis and Annex I bis, were regulated within the EU by Directive 2001/18/EC and amending Directive 2015/412 and Regulation (EC) 1829/2003 on the Deliberate Release of GMOs and no substantive amendment to the Directive arose as a result of the Aarhus GMO amendment. Therefore existing national legislation, the Genetically Modified Organisms (Deliberate Release) Regulations 2003, (S.I. 500 of 2003), transposes the requirements of the genetically modified organisms' provision of the Aarhus Convention.

Paragraph 1 of Annex I bis is transposed in Article 16 of the Regulations (which sets out the right of people to make written representations to the Environmental Protection Agency about notifications of intent to make a deliberate release and the timeframes involved);

(i) Article 29(4)(n) states that advertisements of notifications of placing a GMO on the market must inform people of their right to make written representations to the European Commission and Article 9 sets out the format of a public register of notifications of intent to deliberately release a GMO or place one on the market.

(ii) Article 14(1), (2) and (5)(a) and (b) of the Regulations outline the cases where exceptions may be made to the public participation procedures. These refer to situations where deliberate releases have already been granted where the site of the test is an issue. The exceptions created in Paragraph 2(b) are transposed in articles 27(1)(c); 29(5); 30(1) and 30(5) of the Regulations. These articles of the regulations allow for exceptions to granting the placing of a GMO on the market where consents have already been granted or where they are requested for research purposes or for culture collections.

(iii) Article 9(4) and (5)(a) and (e). These Articles allow for the publication by the Environmental Protection Agency of a summary of the notifications of intent to place on the market or to deliberately release a GMO as well as the relevant environmental risk assessments associated with each.

(iv) Articles 9(1), (2) and 10(4) of the Regulations set out certain information that must be made available to the public including the name and address of the person applying to deliberately release or place the GMO on the market; a description of the GMO and intended uses; the

location of the release; the related environmental risk assessment; methods and plans for monitoring the GMO and emergency plans.

(v) Articles 15(1) and 29(3) and (4) of the Regulations provide that public advertisements of intentions to deliberately release or place a GMO on the market must be published by anyone using GMO material. Article 9(1)(q) provides that the Environmental Protection Agency must make its decisions on notifications accessible to the public to allow them to participate in decision making.

(vi) This is specifically provided for in Article 16 which outlines the format of and fees for making representations. Article 15(1)(g) of the Regulations provides that notifiers must highlight that written representations can be made to the Environmental Protection Agency within 28 days of the publication of an advertisement of notification relating to deliberate release. Article 29(4)(n) of the Regulations provides that advertisements for notifications of placing a GMO on the market must inform the public that written representations can be made to the European Commission within 30 days of the publication of notification summaries. This allows the public to participate in decision making on this issue.

(vii) Articles 16(4) and 23 oblige the Environmental Protection Agency, as the Irish competent authority, to take public representations into account when deciding on notifications of deliberate release and inform the submitters of their decision. As regards the notification to place a GMO on the market, the taking into consideration of public representations on this issue is a matter for the European Commission and the Environmental Protection Agency under Articles 32(3) (4) ('any other information') and 33 and 39 (taking of decisions on notification and renewal and informing notifier).

(viii) Article 9(1)(o) and (q) and (5) outline the format of the public register of information concerning notifications to release or place GMOs on the market and the publication of decisions on those notifications reached by the Environmental Protection Agency or European Commission.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

In accordance with Article 15 of the Genetically Modified Organisms (Deliberate Release) Regulations 2003 (S.I. No 500 of 2003), an applicant proposing to release a GMO into the environment (for example a GM crop field trial or certain categories of medical trials) is required to place an advertisement in a newspaper 'circulating in the area of the proposed deliberate release' informing the public of the proposed release. This advertisement must invite members of the public to make representations to the EPA in relation to the proposed release.

www.epa.ie/pubs/advice/gmo/Public%20Representations.pdf

The EPA has a policy of publishing details of such licensing applications, including applications details, the advertisement, the consultation process responses, extracts from the deliberations concerned and the decision itself on the Agency website. Recent examples include:
http://www.epa.ie/licensing/gmo/release/hepatitis/
http://www.epa.ie/licensing/gmo/release/fieldtrial/
www.epa.ie/licensing/gmo/fieldtrial/
http://www.epa.ie/licensing/gmo/release/vettrial/
www.epa.ie/licensing/gmo/vettrial/
http://www.epa.ie/licensing/gmo/release/haeb/
www.epa.ie/licensing/gmo/haeb/

Other reports and publications concerning GMOs are publically available free of charge on the Environmental Protection Agency's website.

Italy

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k) With respect to paragraph 11, measures taken to apply the provisions of article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.

In 2005, the MATTM, in cooperation with the Bio-safety Unity of the ICGEB (International Centre for Genetic Engineering and Biology) of Trieste, established the Italian node of the Italian Biosafety Clearing House (BCH) with the objective of:

- implementing the obligations of The Cartagena Protocol on Biosafety;
- implementing the Aarhus Convention and the Almaty amendment on GMOs;
- complying with the EU and Italian legislation for information and public hearings on GMOs.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The procedure for authorisation to deliberately release Genetically Modified Organisms into the environment with experimental and marketing purposes is regulated at EU level by the Directive 2001/18/EC and by the Regulation (EC) 1829/2003 on genetically modified food and animal feed.

In Italy, the Directive 2011/18/EC was implemented by Legislative Decree 224/2003; the National Competent Authority (NCA) for the implementation of Legislative Decree 224/2003 is the Ministry for the Environment Land and Sea.

Under Art. 12 of Legislative Decree 224/2003 the NCA carries out public consultations and ensures access to information on authorisation requests (notifications) for marketing and deliberately releasing GMOs into the environment through a dedicated website.

The Ministry of Environment, in collaboration with the Biosafety Unit, of the International Center for Genetic Engineering and Biotechnology (ICGEB), created a web platform for the Italian Biosafety Clearing House (BCH) to assist the promotion of public awareness and the exchange of information on biosafety. In this platform were implemented two sections on public information and public consultation that are constantly updated.

The public information section provides adequate information to the public on notifications concerning the deliberate release and placing on the market of genetically modified organisms (GMOs).

The Public consultation section gives the opportunity for any physical or juridical person, institution, organisation or association, to put forward observations, or to provide information on any notification for the deliberate release into the environment for experimental purposes via the dedicated section of the Italian BCH.
The following documents and information are subject to public consultation:

- the synthesis of the dossier supplying information necessary to carry out the environmental risk assessment of the deliberate release of a GMO;
- the environmental risk assessment;
- any new information available on risks for human health and the environment.

The BCH website provides the opportunity to become part of a group of subjects qualified to have access to documents and information on every new notification submitted. In order to facilitate the participation in the public consultation procedures, a list that includes central and local institutional authorities, trade associations and non-governmental organizations for environmental and consumer protection has been prepared. Upon request, any natural or legal person, institution, organization or association can be included in the consultation list. At the start of every public consultation and in the case of inclusion of any new information related to the same consultation, the members of the list are advised. Registered subjects have the opportunity to express opinions during the public consultation period of 30 days.

Directive (EU) 2015/412, amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs in their territory after the EU authorization, came into force on 2 April 2015. Directive (EU) 2015/412 provides a two-phase mechanism, during the authorisation procedure of a GMO, pursuant Directive 2001/18/CE or Regulation (EC) no.1829/2003, or during the renewal of the authorisation.

In the first phase, during the authorisation procedure of a GMO or during the renewal of the authorization, a Member State may demand to the notifier to adjust the geographical scope of the authorization of the GMO.
If the notifier adjust the geographical scope of his initial demand, this adjustment shall be implemented in the authorization. Where a Member State wishes all or part of its territory to be reintegrated into the geographical scope of the authorisation from which it was previously excluded, it may make a request to that effect and the geographical scope of the authorization will be amended accordingly.

In the second phase, if no demand for adjustment of the geographical scope was made or where the notifier confirmed the geographical scope of its initial demand, a Member State may adopt measures restricting or prohibiting the cultivation of a GMO in all or part of its territory.

The Directive provides for extensive information to the public through the website of the Ministries (of the Environment, of Agricultural Policies and of Health) and by the Regions.

Kazakhstan

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

With regard to paragraph 11:
In accordance with paragraph 5 of Article 12 of the Law "On food safety" (from July 21, 2007 №301) turnover of genetically modified objects and biologically active food additives shall be permitted only after scientifically sound confirmation of their safety, holding of which is carried out in accordance with the legislation of the Republic of Kazakhstan, and their state registration in accordance with Article 34. Before scientifically sound confirmation of safety of GMOs in food products is established, accepted level of its percentage in food products should not exceed the one established in the countries of the European Union.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Since the genetically modified organisms (GMOs) specifically mentioned in the definition of environmental information in paragraph 3 a) of Article 2 of the Convention, the provisions of Article can be applied in general in this article 4 and 5 of the Convention.

The definition of GMO given in the EC and in the Law "On food safety". Environmental requirements in the production and use of GMOs are installed in st.195, 248, 281, 282 EC. Law "On food safety" established by the legislative requirement to include in the labeling of food products information on their composition, including - on the availability and amount of food, fodder, biologically active food additives and GMOs, which greatly facilitates access to environmental information and implements the requirements under Article 5, paragraphs 6-8 AC.

In Article 282 EC RK sets out the basic requirements for the order of the genetic engineering activity in general terms: section 1.4 requires that the polluter - manufacturers of food and feed derived from GMOs, must inform the customer that the product is produced from GMOs.

Article 17 of the Law "On food safety" and obliges to inform consumers about the availability and amount of GMOs. Article 34 of the same law states that before the establishment of scientifically sound confirmation of safety of GMOs in food products accepted level of their content in food products does not exceed the established in the EU countries (0.9%). GMO production is related to the environmentally dangerous economic activities (Government Resolution dated June 27, 2007 # 543), and is subject to obligatory ecological insurance of civil liability of individuals and (or) legal entities (Law "On Mandatory Environmental Insurance" dated December 13, 2005 №93)
The state registration of GMOs and to review the decision on the state registration is carried out according to the order of the Republic of Kazakhstan from October 19, 2009 №546 (as amended by the Order of the Republic of Kazakhstan from January 17, 2012 №17) «On establishment of state registration of rights and withdrawal of the decision on state registration of the product baby food, food and biologically active food additives, genetically modified objects, dyes, disinfectants, disinfection and disinfestation, materials and articles in contact with water and food, chemicals, certain types of products and substances that have harmful effects on human health ". The processes (steps) the sale (sale or delivery), including import (import) GMOs and related processes of packaging, packaging, labeling, storage and transportation of GMOs defined by the Rules of turnover (Resolution of the Government of Kazakhstan on June 27, 2008 N630). According to claim 8 of these Rules on documents, leaflets (insert sheets), labels, counter koleretkah, labels, decals (stickers), in addition to the information specified by the legislation of Kazakhstan on food safety, the state and Russian languages shall contain information on presence and amount of GMO in the food product.

In accordance with the Rules of work on science-based GMO safety confirmation (the RoK Government dated 16 April 2008 N346) GMO risk assessment is carried out as an integrated risk assessment during laboratory research. Withdrawal of GMOs in the Republic of Kazakhstan is carried out in the presence of the positive conclusions of state ecological and sanitary-epidemiological expertise. The use of these organisms and substances in the absence of such findings is prohibited (Section 6 of the Regulations).

According to the Law of RK "On Seed" from February 8, 2003 sowing seeds of varieties derived from genetically engineered (genetically modified), not included in the State Register of selection achievements, it is not allowed.
Thus, the regulatory framework ensures labeling of products produced using GMOs. June 26, 2008 Kazakhstan ratified the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

In accordance with Article 10 of the claims 3 to claim 4 of the Technical Regulations "Requirements for Safety of food additives, flavorings and processing aids", adopted by Council Decision of the Eurasian Economic Commission dated July 20, 2012 №58 under assessment (confirmation) of compliance of food additives, flavorings and processing aids are provided further details: 3) for use in food additives, flavorings, and processing aids and GMO ingredients derived from GMOs. Registration of products containing GMOs is performed by Ministry of National Economy, Republic of Kazakhstan, Consumer Protection Committee.

Kyrgyzstan

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, paragraph 11

Kyrgyzstan has ratified the Cartagena Protocol [on Biosafety to the Convention on Biological Diversity] and is currently drafting the appropriate legislation.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Kyrgyzstan acceded to the Cartagena Protocol on Biosafety to the Convention on Biodiversity in 2005. It participates in the Biosafety Clearing House.

In 2009, a draft Biosafety Act was prepared and sent to the Government, but it was returned on the grounds that this issue had not been properly explored and so legislation was premature. It was also suggested that the country's laboratory services should be developed and a GMO identification and labelling system introduced before establishing statutory requirements.

In 2013, a Bill to ban the cultivation, production, import and sale of products containing GMOs was drafted on the initiative of members of the Jogorku Kenesh. However, the Government concluded that it should be sent back for revision. An interdepartmental working group was set up to reconsider and revise this draft Act in order to bring it into line with international agreements. Moreover, in its conclusions, the Government noted that, under Article 26 of the Statutes and Regulations Act, legislation that requires central government funding for implementation must not be adopted until a source of funding has been identified.

In 2015, a draft Genetic Engineering Safety Act was sent to the Executive Office of the Government for review. However, it was subsequently withdrawn because of the preparation of the draft Environmental Code.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Kyrgyzstan's technical resources and regulatory framework are insufficient to address the essential aspects of biosafety regulation. These include supervising and regulating bioengineering activities and the creation and transboundary movement of genetically modified organisms.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Kyrgyzstan is currently not undertaking any projects with the Secretariat of the Convention on Biodiversity in relation to implementing the Cartagena Protocol, nor any other official projects relating to GMOs.

Latvia

11. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON THE COLLECTION AND DISSEMINATION OF ENVIRONMENTAL INFORMATION IN ARTICLE 5

Article 5, paragraph 8

Article 26.[1] of the Law on Circulation of Genetically Modified Organisms stipulates that food products containing genetically modified organisms, consisting of them or being produced from them, shall be placed for sale separately from other food products in such a way as to be easily identifiable.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Paragraph 1 of article 6 bis and Paragraph 1 of annex I bis

The Republic of Latvia has acceded to the Convention's amendment on public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms (GMOs) of 27 May 2005 by adopting the law "On Amendment to the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters" of 14 February 2008.

Regulation on access to information and public participation in the domain of GMO circulation has been incorporated into Chapter V of the Law on Circulation of Genetically Modified Organisms (GMO Law), CM Regulation No.457 "Regulations Regarding the Deliberate Release of Genetically Modified Organisms" of 26 May 2009 (CM Regulation No.457), CM Regulation No.1078 "Methodology for the Risk Assessment of Genetically Modified Organisms" of 22 December 2008 and CM Regulation No.784 "Procedures for the Contained Use of Genetically Modified Organisms, as well as Issuance and Annulment of a Permit" of 22 September 2008 (CM Regulation No.784). Article 8 of the EPL provides public participation rights in adoption of decisions regarding release of the GMOs into the environment.

GMO Law, Article 3, Paragraph 4, comprises a principle of public information and participation which provides that authorities promote public education and informing, hear out and evaluate public opinion regarding issues related to the circulation of GMOs. Chapter V of the GMO Law contains provisions on openness and availability of information, public participation in decision-making process, obligation to provide information as well as requirements for circulation of information.

A permit to release a GMO into the environment or place on the market is issued by the Food and Veterinary Service (Service) after examination of the relevant submission.

According to CM Regulation No.457, Section 5, the Service shall post on the website thereof in the State Information System – into the Register of GMO Circulation (GMO Register) - the following information:

(a) environmental risk assessment of the GMOs;
(b) summary information on the release of GMOs into the environment or placing on the market;
(c) other documents submitted by a person, to which the status of restricted access has not been assigned;
(d) the risk assessment report;
(e) the time period by which the public may express its opinion and provide proposals, indicating the place of submission thereof;

(f) the decision, including the conditions referred to in the permit on the release of GMOs into the environment or placing on the market, and the report on the public opinion;
(g) information regarding the locations for the release into the environment of GMOs;
(h) information regarding the locations for the cultivation of GMOs;
(i) report on the results of the release into the environment or placing on the market monitoring.

According to Paragraph 18.5. of the CM Regulation No.784 it is the duty of the Service to inform the public regarding the notified contained use activities and involve it in the process of issuing a permit for contained use.

A person, who performs activities with GMOs is obliged, in conformity with Article 30 of the GMO Law, to inform the relevant competent authorities and the public, without delay, regarding the cases when scientifically substantiated opinions regarding the possible adverse effect of GMOs on human and animal health or the environment have been received, as well as when the harm has already been caused to human and animal health or the environment or there are direct hazards that such harm could be caused, or negative changes in the environment have been observed in connection with the deliberate release of the GMOs. Similarly paragraph 47 of the CM Regulation No.457 provides that if information is received regarding the adverse effects on health or the environment caused by the GMOs to be released into the environment or placed on the market or regarding a prohibited placing on the market of GMOs, the Service shall, within one day after receipt of information, inform the public thereof.

Paragraph 2 of annex I bis

No exceptions have been provided for to the public participation procedure.

Paragraph 3 of annex I bis

According to CM Regulation No.457, Section 5, the Service not later than within three working days after receipt of a submission makes available to the public summary information on the intended release of GMOs into the environment or placing on the market and environmental risk assessment of the GMOs. Not later than within three working days after receipt of a risk assessment report done by the Scientific Expert Commission the Service makes it available to the public.

Paragraph 4 of annex I bis

Paragraph 8 of the CM Regulation No.457 stipulates that the following information shall not be considered as confidential;
(a) the given name, surname, address of the person (for a legal person – the name and legal address);
(b) the description of the GMO, which allows the identification thereof;
(c) the purpose of the release of the GMO, the place and anticipated use thereof;
(d) the monitoring programme and emergency action plan; and
(e) the environmental risk assessment of the GMO.

Paragraph 5 of annex I bis

According to Article 27 of the GMO Law competent authorities provide the public with information regarding the circulation of GMOs in accordance with the requirements of the regulatory enactments regulating the circulation of GMOs. Transparency of decision-making procedures and provision of access to the relevant procedural information to the public is ensured by requirements of the CM Regulation No.457, especially Section 5. (See commentary to Paragraph 1 of annex I bis, *supra*, especially the last paragraph.)

Paragraph 6 of annex I bis

Paragraph 1 of Article 28 of the GMO Law stipulates that the public – any natural person, as well as associations and foundations, have the right to submit recommendations or express an opinion prior to competent authority issuing a permit for the release into the environment or placing on the market of GMOs.

Any person, within 30 days after putting of the risk assessment report into the GMO Register, may express its opinion and submit written proposals to the Service on the release into the environment or placing on the market of the GMOs. (Paragraph 46 of the CM Regulation No.457.)

Paragraph 7 of annex I bis

The competent authority involves the public into the decision-making process prior to taking the decision regarding release into the environment or placing on the market of GMOs. (Paragraph 3 of Article 28 of the GMO Law.)

The Scientific Expert Commission prepares a report on the public opinion. The Service, taking into account the risk assessment report, the report on the public opinion and the proposals of the Supervisory Council of Genetically Modified Organisms, issues a permit or a decision regarding the refusal to issue a permit, indicating the grounds for refusal. (Paras. 10, 13 of the CM Regulation No.457.)

Paragraph 8 of annex I bis

According to CM Regulation No.457, Section 5, the Service not later than within three working days after taking of a decision puts into the GMO Register the following information;

(a) the decision, including the conditions referred to in the permit on the release of GMOs into the environment or placing on the market, and the report on the public opinion;

(b) information regarding the locations for the release into the environment of GMOs;

(c) information regarding the locations for the cultivation of GMOs.

Not later than within three working days after receipt thereof the report on the results of the release into the environment or placing on the market monitoring is put into the GMO Register.

Paragraph 2 of article 6 bis

The requirements are mutually supportive of the Party's national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The public not always is provided with sufficient and easy-to-perceive information on the availability on the market of food products containing GMOs, consisting of or produced from them. For example, the relevant information is difficult to read on the product labelling, not always the products have been placed separately.

Impartial information from independent experts on environmental risks arising from particular GMOs is not available.

Decisions on placing on the market are taken at the EU level, thus hampering effective public participation.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

A local government may set a prohibition by issuing binding rules for the cultivation of genetically modified crops in the relevant administrative territory or in a particular territory thereof upon its own initiative or on the basis of a proposal of the public, duly informing the public and consulting therewith in advance of adoption of the said rules. (GMO Law, Article 22.)

From 1 December 2009 till 1 July 2013 103 administrative territories (of the whole 110) on the basis of public consultation adopted decision on the ban of cultivation of genetically modified crops.

A map and list of local governments which have banned cultivation of genetically modified crops are available at the websites of the MEPRD and the State Plant Protection Service.

The MEPRD has provided organizational and informative support to NGOs in organizing seminars, conferences, press conferences and other events regarding GMOs.

No applications for permits have been received by Latvian authorities regarding release into the environment for experiments and placing on the market of GMOs.

The association “Zemes draugi” (Friends of the Earth) has contributed to public participation in decision-making with the implemented public initiative “GMO Free”.

Lithuania

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The main legislation regulating public information and participation in the sphere of implementation of Article 6 bis and Annex I bis includes:

(a) the Law on Genetically Modified Organisms (the GMO Law);

(b) Order No 602 ‘On the Formation of a GMO Management Supervisory Committee and the Approval of Its Regulations’ of 18 December 2001 of the Minister of Environment;

(c) the Order of the Minister of Environment of 18 October 2004 approving the Regulations on the information system of genetically modified organisms;

(d) the Procedure for the deliberate release into the environment and placing on the market of GMOs approved by Order No D1-225 of the Minister of Environment of 29 April 2004;

(e) the Procedure for public information and participation in decision-making on the deliberate release into the environment and placing on the market of genetically modified organisms approved by Order No 299 of the Minister of Environment of 11 June 2003.

The GMO Law and the implementing regulations transpose into the national law the provisions 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. Lithuania also applies Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Regulation No 1829/2003).

Lithuania has no exceptions of public participation with respect to Annex I bis, paragraph 2.

Article 6 bis, paragraph 1 and Annex I bis, paragraphs1 to 8

Article 12 of the GMO Law provides that the public shall have the right to participate in the making of decisions relating to the use of GMOs and genetically modified products and to receive information thereon, according to the procedure established by law. The state management of activities involving the use of GMOs is performed by the MoE in Lithuania.

Lithuania also has a GMO Management Supervisory Committee and a GMO Expert Committee. The GMO Management Supervisory Committee is structured in accordance with the principle of proportionality and includes representatives of manufacturers, scientists, public servants and NGOs. The key function of the Committee is making proposals for decisions on GMO issues. The Committee reports to the MoE. The GMO Expert Committee prepares conclusions of assessment of risks to the environment and human health with respect for each request submitted for the granting of a permit. The assessment conclusions are submitted to the MoE and also presented at a meeting of the GMO Management Supervisory Committee.

The Procedure for the deliberate release into the environment and placing on the market of GMOs lays down two procedures for the deliberate release of GMOs into the environment: one for not placing on the market (field trials) and the other for placing on the market. These two procedures are based on the assessment of risks to the environment and human health. Prior to submitting a request and a notification for the deliberate release of GMOs into the environment, a notifier assesses the risks to the environment and human health. On receiving a request and a notification, with 10 working days the MoE presents a summary of the request received (a full request where required) by electronic means to the GMO Expert Committee, members of the GMO Management Supervisory Committee, authorities concerned (the Ministry of Agriculture, the Ministry of Health and the State Food and Veterinary Service) and the public (through the GMO information system), with the exception of confidential information. In the event of placing on the market, an assessment report is also provided.

With respect to each application for the deliberate release of GMOs into the environment for not placing on the market, the public consultation procedure begins with publishing the information on the internet through the GMO information system and the website of the Joint Research Centre of the European Commission. The public is entitled to make comments and proposals within the set 30-day period. In the event of placing GMOs on the market, the public information and participation procedures take place in accordance with the provisions of Regulation No 1829/2003. Scientific opinions on the assessment of risk to the environment and human health are published on the website of the European Food Safety Authority.

The Procedure for the deliberate release into the environment and placing on the market of GMOs stipulates that a notifier may indicate the information in the request submitted, the disclosure of which might harm his competitive position. In this case a notifier has to provide a justification as to why the information indicated by him should be treated as confidential, and provide verifiable documents justifying such confidentiality. Prior to deciding whether the information may be kept confidential, the MoE has the duty to consult the notifier on that. The following information is not considered confidential: the description of the GMO, name and address and purpose of the research, location and time and purpose of the release of the GMO, methods and plans for monitoring, assessment of risks to the environment and human health and an action plan for emergency response.

Prior to taking the decision on the release of GMOs into the environment, the proposals received are given a reasoned evaluation and it is determined whether they are justified and should be taken into consideration. The MoE informs the public through the GMO information system about: decisions taken on the contained use of genetically modified materials and GMOs; the deliberate release into the environment and placing on the market; specific use and maintenance conditions; the reasons and motives for rejecting the notification; emergency response plans and safety measures applicable in emergencies; provisionally restricted or prohibited GMOs, the use of which is permitted in the EU under legislation; the opinions and reasoned objections of consultation with the GMO Expert Committee; and updated decisions, monitoring results, etc.

Article 6 bis, paragraph 2

Lithuania has acceded to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The provisions of this Protocol supplement the legal regulation laid down in Article 6 bis, paragraph 1. The national provisions implementing Article 6 bis, paragraph 1 are harmonised with the biosafety system in place in Lithuania and comply with the objectives of the Cartagena Protocol on Biosafety.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

No obstacles have been encountered. These provisions have not yet been applied in practice.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

NEW! With a view to implementing the obligations under European Union law, i.e. in order to transpose the provisions of Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, the preparation of amendments to the GMO Law has begun in 2016. These amendments will specify the permitting procedures in detail, including the rules on public information and participation.

Luxembourg

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In the Grand Duchy, this issue is governed *inter alia* by the Law of 13 January 1997 on Control of the Use and Release of Genetically Modified Organisms. The competent authority is the Minister responsible for health matters. The Law can be consulted at http://www.ms.public.lu/fr/legislation/ogm/index.html.

The Government's 2013 Programme stated that:
"The Government will continue to apply the precautionary principle to genetically modified organisms (GMOs), to promote sustainable GMO-free agriculture and to uphold its critical position on GMOs, not only at the European and international levels, but in Luxembourg itself. It will as far as possible prevent the use of GMOs nationally and will launch information and awareness campaigns on the subject.

The Minister (of Agriculture, Viticulture and Consumer Protection) will also ensure that the import of genetically modified plants for use as animal feed is reduced to the greatest possible extent. To this end, the Minister intends to promote a GMO-free sector within conventional agriculture, as well as the widespread use of a 'Free from GM feed' label, which is intended to guarantee that foods produced in Luxembourg, such as milk, meat and eggs, come from animals reared without the use of GMO-based feeds."

In this context, we should recall that Luxembourg has always had major reservations about GMOs, given the absence of any widespread consensus in the scientific community that these organisms are harmless.

Thus, in line with its preventive and precautionary approach, Luxembourg has already prohibited the marketing of some of these products, with a ban on the cultivation of Mon 810, a transgenic variety of maize, and a ban on placing Amflora, a transgenic variety of potato, on the market with a view to its cultivation.

It should be noted that the marketing of these genetically modified organisms was authorized by the European Commission without the criticisms of several Member States, including Luxembourg, being taken into account.

Luxembourg has always opposed the introduction of GMOs into agriculture at EU level. For a long time, agriculture in Luxembourg has resolutely focused on high-quality production sectors, asserting positive differences from mass-market imported products and aiming to thrive in the face of globalization and the increasingly international nature of trade in agricultural produce.
This approach highlights the virtues of local produce and aims to offer consumers regional premium agricultural products of unimpeachable quality – and so it has no place for GM crops.

Luxembourg has adopted very strict national legislation on the coexistence of GMOs and traditional crops: the Law of 18 March 2008 on the Marketing of Seeds and Plants and on the Coexistence of Genetically Modified, Conventional and Biological Crops (http://www.legilux.public.lu/leg/a/archives/2008/0032/a032.pdf#page=2) aims to ensure absolute transparency and extremely high levels of accountability in relation to GM crops. It sets out measures providing a guarantee and a very high level of protection for producers who do not use GMOs against the unintended release of GMOs on their farms, thus ensuring continued freedom of choice for farmers and consumers.

Luxembourg is currently a GM-crop-free country.

Luxembourg became a Contracting Party to the Nagoya - Kuala Lumpur Supplementary Protocol of 15 October 2010 on Liability and Redress to the Cartagena Protocol on Biosafety.

Malta

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k) With respect to paragraph 11, measures taken to apply the provisions of article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.
As regards the deliberate release of genetically modified organisms, this is regulated by the Deliberate Release into the Environment of Genetically Modified Micro-Organisms Regulations (S.L.549.60), whereby the public is given the opportunity to make representations and comments on any proposed release as per Regulations 9 and 12.

Montenegro

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k) With respect to paragraph 11, measures taken to apply the provisions of Article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.
The Law on Genetically Modified Organisms, Chapter VI, regulates the matter of intentional introduction of GMO into the environment. Also, Article 32 defines that before the intentional introduction of GMOs, products containing, consisting of or deriving from GMOs into the environment, the applicant shall obtain the approval of the administration body competent for environment protection (Environment Protection Agency). Before issuing an approval, the Agency may request the applicant to submit additional data. The applicant may in the application refer to the data or results of intentional introduction of GMOs into the environment from other application that has been submitted to the administration body competent for

environmental protection if such data are not designated as a secret or if it has obtained written consent of the applicant in question. Provision of Article 33 stipulates that the administration body competent for environmental protection shall decide on the application within 90 days from the day the complete application was received. The administration body shall enter the applicant that has been approved for intentional introduction of GMOs, products containing, consisting of or deriving from GMOs into the environment, in the register of issued approvals for intentional introduction into the environment and shall issue a decision on entry in the register to the applicant within eight days from the day of such entry. Article 34 prohibits introduction of GMOs into the environment in the protected areas, in the areas intended for organic production of agricultural products, and in the areas for development of eco-tourism. Also, provision of Article 35 stipulates that the applicant shall, in the course of the procedures for approving introduction of GMOs into the environment, without delay notify the competent body of any change in the requirements that are relevant for risk assessment, unintentional change or new information and it shall provide for more strict measures with the purpose of protecting human health and the environment, which are indicated in the application. When administration body competent for environmental protection gains knowledge of the information which may have significant effect on the assessment of risk to human health and the environment, it shall evaluate such information, make them accessible to the general public, and order the applicant to adjust the conditions of intentional introduction of GMOs into the environment or cancel the intentional introduction of GMOs and products containing, consisting of or deriving from GMOs into the environment. If, in the course of the procedure of introducing GMOs into the environment, the GMO business operator suspects that the level of risk is higher than the one that was estimated, it shall without delay cancel the introduction of GMOs into the environment and notify the administration body (Agency). Article 36 stipulates that the GMO business operator shall submit to the administration body competent for environmental protection the report on the progress of intentional introduction of the GMOs into the environment within 60 days from the day of introduction and, within the deadlines specified in the approval, submit interim reports in written or electronic form.

Netherlands

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

The Dutch Decree on Genetically Modified Organisms Environmental Management 2013 (Besluit ggo 2013) (based on EC Directives 90/219, 90/220, 98/81 and 2001/18) mainly aims to secure the safety of man and the environment. The procedural terms and conditions for decision-making with respect to genetically modified organisms (including public information, participation and access to justice) are regulated partly by the provisions of the General Administrative Law Act and partly by specific regulations in the Decree on Genetically Modified Organisms Environmental Management 2013. This legal system applies to decisions on the contained use of genetically modified organisms and deliberate release into the environment for other purposes. The Dutch system already complies with the guidelines on access to information, public participation and access to justice concerning genetically modified organisms.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Concerning legislative, regulatory and other measures that implement the provisions on public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms in article 6 bis, describe:
(a) With respect to paragraph 1 of article 6 bis and:

(i) Paragraph 1 of annex I bis, arrangements in the Party's regulatory framework to ensure effective information and public participation for decisions subject to the provisions of article 6 bis;

The Dutch regulations on decision-making about genetically modified organisms (GMOs) are based on the relevant EU regulations. Most relevant for this are Directives 2001/18 / EC and 2009/41 / EC, and Regulations (EC) 1829/2003, 1830/2003 and 1946/2003. The Regulations are directly applicable in the Netherlands. The Regulations have been implemented in the Netherlands in the GMO Decree 2013. General provisions of the General Administrative Law Act apply to the Dutch procedure for decisions based on the Decree. This Decree provides for public information provision and citizen participation. Citizens are alerted to draft decisions via the Internet and national and regional newspapers and can submit their views on the draft decision. All views are taken into account in the final decision. The text of this contains reactions to the views. Interested parties can challenge the final decision in court. Regular use is made.of the aforementioned possibilities.

(ii) Paragraph 2 of annex I bis, any exceptions provided for in the Party's regulatory framework to the public participation procedure laid down in annex I bis and the criteria for any such exception;
All Dutch procedures for permits and authorizations of GMOs provide for public participation according to the General Administrative Law Act. There are no exceptions to this. GMOs with an authorization to the EU market may be marketed in the Netherlands on the basis of that authorization. For purposes other than placing on the market, the regulations for the decision-making procedure apply.

(iii) Paragraph 3 of annex I bis, measures taken to make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release or placing on the market of such genetically modified organisms, as well as the assessment report where available;
See the answer under (i).

(iv) Paragraph 4 of annex I bis, measures taken to ensure that in no case the information listed in that paragraph is considered as confidential;
This has been implemented in both EU and Dutch regulations (see Directive 2001/18 / EC, Article 25). If information is kept confidential, there must at least be a summary of the information that contains sufficient information to be able to follow the environmental risk assessment done.

(v) Paragraph 5 of annex I bis, measures taken to ensure the transparency of decision-making procedures and to provide access to the relevant procedural information to the public including, for example: a. The nature of possible decisions; b. The public authority responsible for making the decision; c. Public participation arrangements laid down pursuant to paragraph 1 of annex I bis; d. An indication of the public authority from which relevant information can be obtained; e. An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments;

Websites of the National Institute for Public Health and the Environment (see answer to question 36) contain both general information about the procedures and specific information about individual applications and permits.

(vi) Paragraph 6 of annex I bis, measures taken to ensure that the arrangements introduced to implement paragraph 1 of annex I bis allow the public to submit, in any appropriate manner, any comments, information, analyses or opinions that it considers relevant to the proposed deliberate release or placing on the market;

See the answers under (i) and (v).

(vii) Paragraph 7 of annex I bis, measures taken to ensure that due account is taken of the outcome of public participation procedures organized pursuant to paragraph 1 of annex I bis;

See the answers under (i) and (v)

(viii) Paragraph 8 of annex I bis, measures taken to ensure that the texts of decisions subject to the provisions on annex I bis taken by a public authority are made publicly available along with the reasons and the considerations upon which they are based;

See the answers under (i) and (v).

(b) With respect to paragraph 2 of article 6 bis, how the requirements made in accordance with the provisions of annex I bis are complementary to and mutually supportive of the Party's national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity.

The Cartagena Protocol on Biosafety has been implemented in the Netherlands (via EU llegislation) by the Decree on GMO 2013. This also implements the requirements set out in Annex Ia of the Aarhus Convention, so that the relevant rules together form a whole.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The existing EU and Dutch legislation already provided for the necessary rules and procedures prior to the entry into force of Article 6a. As a result, the implementation of Article 6a and Annex Ia did not lead to any obstacles.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

All steps in the procedure for decisions issued by the Netherlands and the texts thereof are to be found for everyone on the websites mentioned in the answer to question 36.

North Macedonia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

The intentional release of GMO in the environment is regulated by chapter 5.1 intentional release of GMO or combination of GMO in the environment in the Law on genetically modified organisms. In accordance to article 34 from the Law, each notificator before performing intentional release into the environment must submit a notification to the Ministry of environment and physical planning that contains specific technical documentation and information necessary for the implementation of the risk assessment as a result of the intentional release of GMO and risk assessment. The Ministry in the term of five days from the day of the receipt of the complete notification is obligated to publish a short content on the web page and to publish it in two daily newspapers on the territory of the Republic of Macedonia. The stakeholders can submit their opinion in the term of 30 days from the date of publishing. The Ministry is obligated to provide insight to the stakeholders of the data from the notification, risk assessment, the report of GMO assessment as well as other information that accompany the notification. The Ministry is obligated to take into consideration when issuing the permit, the promptly submitted opinions and comments. The Ministry of environment and physical planning in the term of 90 days from the day of receipt of the complete notification issues a permit for intentional release of GMO or with a decision rejects the notification if the conditions are not met for the intentional release of GMO.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

On the basis of article 12 paragraph (6) from the Law on genetically modified organisms (Off. Gazette of the RM no. 35/08 and 163/13) a Rulebook is carried regarding the modality and procedure for the public participation in the issue of permits for limited use of GMO, for intentional release of GMO in the environment, for release of the GMO on the market, as well as other information related to the use of GMO (Off. Gazette of the RM no. 23/14). The same is correlated with paragraphs 1, 3, 7, 8 from article 6 bis and Annex I.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The increase of the number of people responsible of the implementation of the legislation on GMO is necessary.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Practical application is not initiated of the provisions for public participation in the decisions for intentional release into the environment and placement of genetically modified organisms in accordance with article 6.

Norway

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Introduction
Public participation and effective access to information as regards the deliberate release into the environment and placing on the market of genetically modified organisms is regulated by the Gene Technology Act of April 3, 1993 no. 38, as well as the Regulations on Impact Assessment of December 16 2005 no. 1495. EU directive 2001/18/EC as well as the Cartagena Protocol are implemented through the Gene Technology Act with regulations.

a) Paragraph 1of article 6 bis and paragraphs 1-8 of Annex I bis
i) Implementation of article 6 bis and annex I bis paragraph 1
According to section 13 of the Gene Technology Act, a public hearing shall always be conducted before approval is given for the release of genetically modified organisms (GMO) into the environment. This hearing must be carried out in a way that ensures that the general public, and particularly interest groups who will be affected, are given access to relevant information and a real opportunity to make their opinions known. A decision to hold a public consultation shall always be published.

ii) Implementation of article 6 bis and annex I bis paragraph 2
As noted, a public hearing must always be held if the release of GMO into the environment requires approval. According to section 10 of the Gene Technology Act, the release into the environment and placing on the market as defined in the Aarhus Convention always requires approval. There are therefore no exceptions to the duty to conduct public hearings.

iii, iv, v) Implementation of article 6bisand annex I bis paragraph 3, 4 and 5

According to section 13 of the Gene Technology Act, a public hearing shall ensure that the general public is given access to all relevant information, also procedural. The decision to hold a public hearing shall always be published. The decision is therefore always published on the website of the relevant public authority, together with all other relevant information. Letters containing this information are also generally sent to all parties considered affected by the decision. In addition, section 12 of the Gene Technology Act provides that the Public Information Act applies in full as regards the release of GMO into the environment. As previous chapters have demonstrated, the Public Information Act provides a right to all information included in annex I bis paragraph 3 and 5.

In addition the following information shall, according to section 12 of the Gene Technology Act, not be considered confidential and therefore always be available to the public:

a. the description of the genetically modified organism, the user's name and address, the purpose of the use and the location of use
b. methods and plans for monitoring and emergency response
c. assessments of foreseeable effects.

This fully satisfies the requirements of paragraph 4 of annex I bis.

vi) Implementation of article 6bis and annex I bis no. 6

This is satisfied by the requirement to conduct a public hearing, see *i)* above.

vii) Implementation of article 6bis and annex I bis no. 7
According to state practice, all responses to a public hearing are submitted to the public authority making the decision. These responses are thoroughly examined and taken into account before a decision is made.

viii) Implementation of article 6bis annex I bis no. 8
All decisions regarding the deliberate release into the environment and placing on the market of genetically modified organisms are published on the website of the public authority having made the decision. In addition, the Gene Technology Act section 12 states that all decisions made are subject to the conditions of the Public Information Act. The public therefore has a right to access all final decisions, as well as the terms upon which the decision was made.

b) Article 6bis paragraph 2
Section 9 of the Gene Technology Act incorporates import, export and transport in the definition of release into the environment of genetically modified organisms. This means that such actions are subject to the same requirements as regards public access and participation as other decisions under the Convention. In addition, there is also a Regulation on the Labeling, Transport, Import and Export of Genetically Modified Organisms of 2005 no. 1009 that ensures consistency with the objectives of the Cartagena Protocol.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

The Norwegian government does not hold specific statistics as regards public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms. Further, as there is a legal requirement to always conduct a public hearing in such cases, there will be no statistics as regards exceptions to this rule.

Poland

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, paragraph 11, Article 6a, Appendix I a

Provisions included in CAP define the issue of publishing information to parties in connection with the existing proceeding. The provisions of the Act on access to information about the environment with regard to the procedures concerning public participation envisage publishing of information in connection with a proceeding conducted by an authority. According to CAP the use of the aforementioned procedures is required upon issuing certain administrative decisions, namely the integrated permit, decisions issued on the basis of the Act of 22 June 2001 on genetically modified organisms and genetically modified micro-organisms (Journal of Laws of 2015, item 806), hereinafter referred to as "the GMO Act" or with regard to the decision on environmental conditions. Provisions that are included in the Amendment to the Aarhus Convention concerning the genetically modified organisms, are also reflected in the provisions of the GMO Act. At the same time, Article 14a of the GMO Act precisely determines the information regarding GMO that are subject to being published. The public has the right and a possibility to become familiar with the request and the documentation. This takes place by way of GMO registers that operate on the website of the Ministry of the Environment.

Portugal

17. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6

Genetically Modified Organisms

In the period from 2014 to 2016, 3 notifications for deliberate release into the environment of GMOs were submitted to APA under Decree-Law No. 72/2003 of 10 April. The respective public consultations pursuant to Article 11 of the legislation in question had been taken into account. The 3 notifications were submitted in 2016).

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

(a) **Article 6A, paragraph 1**

Annex I A, paragraph 1

Decree-Law No. 72/2003 of 10 April, transposing into national law Directive 2001/18/EC of 12 March on the deliberate release of genetically modified organisms (GMOs), clearly establishes in Article 27 that the competent authority - APA - must provide the public with information concerning the deliberate release into the environment and placing on the market of GMOs, including:

- Information on the permits granted;
- Results of monitoring carried out;
- Register of the location of released GMOs and cultivated GMOs;
- Information on the deliberate release or placing on the market of products containing or consisting of GMOs, done without authorisation.

Annex I A, paragraph 2

Decree-Law No. 72/2003 envisages in article 28 that only information considered confidential can be waived for public disclosure in order to protect intellectual property rights as well as the competitive position of companies.

Annex I A, paragraph 3

The legislative instrument provides for in its article 14 that the competent authority shall send to the European Commission a summary of the notification, within 30 days of the date of its receipt.

Annex I A, paragraph 4

According to Decree-Law No. 72/2003, Article 28, paragraph 3, and in accordance with the provisions of the Aarhus Convention, the following information cannot be declared as confidential:

a) Description of the GMO, name and address of the notifier, purpose and location of release

b) Methods and plans for monitoring the GMO and for the emergency response

c) Assessment of environmental risks.

Annex I A, paragraph 5

APA provides information through its website, in particular with regard to legislation, information on the cultivation of GMOs, environmental monitoring, GMOs authorised for placing on the market, authorised notifications for deliberate release into the GMO environment for experimental purposes, and procedures for notifiers who wish to submit applications for the deliberate release of GMOs into the environment or the placing on the market of GMOs.

It should be noted that, under the authorisation procedures for the deliberate release of GMOs (experimental trials) a public consultation is held prior to decision-making, pursuant to article 11 of the referred Decree-Law. The announcement of the public consultation is done through the written media as well as on the PARTICIPA http://participa.pt website.

On the topic of GMOs, APA also ensures the provision of explanations where necessary, via e-mail or telephone.

Annex I A, paragraph 6

Decree-Law No. 72/2003 of 10 April establishes in its Article 11 that the general public is consulted prior to making a decision on applications for the deliberate release into the environment (experimental trials), ensuring the notification is displayed for a period up to 60 days. The announcement of this information is made through an advertisement in 2 nationwide newspapers, and, if possible, on a regional or local level, which contains the address where the information can be viewed and indication of the start and end date of the public consultation. This information is also made available on the PARTICIPA http://participa.pt website.

Annex I A, paragraph 7

The outcome of the public participation was taken into account when making the decision. Each response received and directly related to the object of the consultation, i.e. with the respective notification, was analysed in all public consultation processes.

Annex I A, paragraph 8

The texts of the decisions taken on the deliberate release of GMOs into the environment, or placing GMOs on the market are published on the APA website at http://www.apambiente.pt/index.php?ref=16&subref=85&sub2ref=429.

(b) **Article 6 A, paragraph 2**

The provisions of article 6 A are included in national legislation since 2003 (see text in **Annex I A, paragraph 6**).

Ratification of the Cartagena Protocol on Biosafety, through Decree No. 7/2004 of 17 April, ensured compliance with the requirement to raise global awareness and public participation in respect of the cross-border movements of GMOs. In Portugal, APA, as the competent authority for the Cartagena Protocol, submits information through the central portal of the Information Interchange Centre - Biosafety Clearing House (BCH).

Thus, national legislation ensures compliance with the provisions of paragraph 2 of article 6 A.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

APA fosters public consultation of applications for the deliberate release of GMOs (experimental trials) prior to decision-making, pursuant to article 11 of Decree-Law No. 72/2003 of 10 April (see text of Annex I A, paragraph 6).

Romania

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

With respect to paragraph 11, measures taken to apply the provisions of article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.

Emergency Government Ordinance No.43/2007 regarding deliberately introduction on the environment and on the market of genetically modified organisms contains provisions on public participation and information, in its Article 6 para.(4) and Article 17.

Emergency Government Ordinance No.44/2007 regarding the isolation conditions of the genetically modified organisms approved by Law No.3/2008, guarantees public information and consultation in the permitting procedure for activities using genetically modified organisms under isolation conditions, in Article 20.

Romania has accepted the GMO amendment of the Aarhus Convention by the adoption of Law No. 24/2008.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Concerning legislative, regulatory and other measures that implement the provisions on public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms in article 6 bis, describe:
The National Environment Protection Agency (NEPA) is the competent authority under EU Directive 2001/18/EC regarding deliberate release into environment of genetically modified organisms (GMO).

NEPA ensures public information and participation in the decision-making process, according with the provision of the Emergency Government Ordinance No. 43/2007 on deliberate release into environment of the genetically modified organism, approved by Law No. 247/2009, transposing Directive 2001/18/EC.

The national legislation includes provisions regarding public consultation and public information in the decision-making process on the deliberate release into the environment of GMOs. All the notifications are published on the internet pages of the JRC (Joint Research Centre - European Commission) and NEPA websites. Public information at the national level is performed in cooperation with the local

environmental protection agencies operating under the NEPA. *All* the risk assessment submitted by the notifiers and the summary of all the decisions taken by the competent authorities are published on the NEPA website: www.anpm.ro. If necessary, public debates are organised during the authorization procedure for deliberate release of GMOs and placing on the market.
NEPA doesn't divulge to the third parties any information which has been accepted to be confidential and protects the intellectual property rights, related to the received data.
In no case the following information may be kept confidential:
The general characteristics of the genetically modified organism, the name and address of the notifier, location of the site;
Measures of containment.
Any harmful effects on human health and on the environment;
The emergency plans.

(a) With respect to paragraph 1 of article 6 bis and:
(i) Paragraph 1 of annex I bis, arrangements in the Party's regulatory framework to ensure effective information and public participation for decisions subject to the provisions of article 6 bis;
The Competent Authority shall consult and inform the public in the decision-making process, in accordance with legislation in force on public access to information and the one regarding confidentiality;
Thus, in the case of cultivations of genetically modified higher plants in scientifically purposes, according to Article 13 (2) g), of OUG 43/2007 any notifier, before the deliberate introduction into the environmental of GMO or a combinations of such organisms in Romania, must submit to the competent authority a notification which include among other things information to the public in electronic and written format, as set out in Annex No. 8 of GEO No.43/2007, in order to obtain an authorization.
For commercial cultivation of genetically modified higher plants, the notification shall also contain information for the public as well as a summary of the notification.

(ii) Paragraph 2 of annex I bis, any exceptions provided for in the Party's regulatory framework to the public participation procedure laid down in annex I bis and the criteria for any such exception;
(iii) Paragraph 3 of annex I bis, measures taken to make available to the public in an adequate, timely and effective manner a summary of the notification introduced to obtain an authorization for the deliberate release or placing on the market of such genetically modified organisms, as well as the assessment report where available;
Within 5 days from the beginning of the authorization procedure, the competent authority shall publish on the internet the summary notification and information to the public.
(iv) Paragraph 4 of annex I bis, measures taken to ensure that in no case the information listed in that paragraph is considered as confidential;
Article 43 of GEO 43/2007 contains provisions on confidentiality;
Article 43 (3) The competent authority shall decide, after consulting with the notifier, which information will be considered confidential and shall inform the notifier, the authorities concerned and the control body, about this decision.
Article 43 (4) The following information is confidential:
general description of the genetically modified organism, the name and address of the notifier, purpose of the deliberate release into environment, the location and intended use;
the monitoring plans of the genetically modified organism and methods of intervention in case of emergency;
risk assessment on human health and the environment;
the opinions of Biosafety Comission and of the authorities involved.
(v) **Paragraph 5** of annex I bis, measures taken to ensure the transparency of decision-making procedures and to provide access to the relevant procedural information to the public including, for example:

a. The nature of possible decisions;

In this case, the decision relates to the issuance of the authorization for deliberate release into the environment, or import agreement, the decision to renew, suspend or revocation of the authorization as appropriate.

b. The public authority responsible for making the decision;
The competent authority for the purposes of GEO 43/2007, i.e. the National Environmental Protection Agency.

c. Public participation arrangements laid down pursuant to paragraph 1 of annex I bis;
GEO 43/2007, provides modalities for public consultation in the authorization procedure for deliberate release into the environment of genetically modified organisms.
Within 5 days from the beginning of the authorization procedure, both for deliberate release into the environment for scientifical purposes and for cultivation, the competent authority shall initiate the public consultation and public participation in decision-making process.

d. An indication of the public authority from which relevant information can be obtained;
The competent authority for the purposes of GEO 43/2007, the National Environmental Protection Agency shall consult and inform the public in decision-making process, in accordance with legislation on public access to information and regarding privacy.
In the authorization procedure for deliberate introduction into environment for scientifically purposes, according to Art. 17 (3) of GEO 43/2007:
The competent authority shall publish on its internet address the summary notification according to Art. 13 para. (2). d) and information to the public as art. 13 para. (2). g). Information to the public shall be published at the local Environmental Protection Agency or local authority where the introduction into the environment is intended to be made.
In the authorization procedure for deliberate release into environment for commercial purposes, according to Art. 32 (2) of GEO 43/2007:

The competent authority shall publish on its internet address:
a) the summary notification according to Art. 29 para. (2). d);
b) information to public according art. 29 para. (2). k)

e. An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments;
According to GEO 43/2007, public comments may be submitted to the competent authority. Public consultation lasts 30 days, begins on the 6th day and ends on the 36th day after the start of the authorization procedure.
(vi) Paragraph 6 of annex I bis, measures taken to ensure that the arrangements introduced to implement paragraph 1 of annex I bis allow the public to submit, in any appropriate manner, any comments, information, analyses or opinions that it considers relevant to the proposed deliberate release or placing on the market;
According to Art. 17 (4) of GEO 43/2007:
The public submits its observations to the competent authority, during the consultation provided in par. (2), by e-mail or by mail with acknowledgment of receipt, and may consult the notification file, excluding confidential data, according to a letter submitted to the competent authority, in compliance with provisions of the article 43.
(vii) Paragraph 7 of annex I bis, measures taken to ensure that due account is taken of the outcome of public participation procedures organized pursuant to paragraph 1 of annex I bis;
Public comments are considered in the authorization procedure for the deliberate release into the environment for scientifical purposes.
Thus, according to art. 17 (5) of GEO 43/2007, within 10 days after completion of the public consultation, the competent authority shall prepare a summary of its observations, which is submitted to the central public authority for environmental protection, authorities involved and the Biosafety Comission.

Within 90 days from the beginning of the authorization procedure, the competent authority shall take a decision based on the scientific opinion of the Biosafety Comission and of the authorities involved, also based on the synthesis of public consultation and the consultation of Member States.
(viii) Paragraph 8 of annex I bis, measures taken to ensure that the texts of decisions subject to the provisions on annex I bis taken by a public authority are made publicly available along with the reasons and the considerations upon which they are based;
Article 21 of OUG 43/2007 :
(1) Without prejudice to Article 43, the competent authority shall inform the public and publishes on its website address, within 30 days after making a decision, the following information:
, decisions and review of the decisions taken pursuant to Articles 16-19 and Article 22;
competent authority report and the control body report, as provided in Article 8.

(b) With respect to paragraph 2 of article 6 bis, how the requirements made in accordance with the provisions of annex I bis are complementary to and mutually supportive of the Party's national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity. Romania accepted the amendment on GMOs to Aarhus Convention by adopting Law nr.24/2008. The provisions are part of the internal law and the rights of the public and can be directly claimed, under this legal basis.
Government Emergency Ordinance nr.43/2007 on the deliberate release into the environment of genetically modified organisms approved with amendments and completions by Law 247/2009, contains provisions on public participation and information in article 6 para. (4) and Article 17, art. 21,. Article. 32, art. 33 (8), Article 74.
The legislation provides that NEPA shall:
- Consult and inform the public in the decision making process, in compliance with the legislation on public access to environmental information and privacy;
- Inform the authorities concerned and the public about the revision, suspension or withdrawal of authorization and about any accidents.

The procedure for authorizing activities regarding the contained use of genetically modified microorganisms is public. Within 10 days of acceptance of the notification the competent authority shall publish it on the website. Proposals and public comments shall be submitted to the competent authority within 30 days of the date of posting of notification. For contained use classes 3 and 4, as appropriate, the competent authority organizes public debates supported by the notifier. After the public debate, the competent authority shall prepare a report which is forwarded to the authorities concerned in the notification procedure.

Information regarding GMOs are environmental information and are available to the public according to GD no. 878/2005. (1) In cases where the information in the notification is in conflict with the provisions of Government Decision no. 878/2005 on public access to environmental information, supporting evidence must be provided.
Can not be considered confidential:
a) general characteristics of the genetically modified organism;
b) name and address of the company;
c) location of the facility and intended use;
d) contained use class and biosecurity measures;
e) risk assessment;
f) emergency plan.

With respect to paragraph 2 of article 6 bis, how the requirements made in accordance with the provisions of annex I bis are complementary to and mutually supportive of the Party's national biosafety framework and consistent with the objectives of the Cartagena Protocol on Biosafety to the Convention on Biodiversity.

Romania accepted the amendment on GMOs to Aarhus Convention by adopting Law nr.24/2008. The provisions are part of the internal law and the rights of the public and can be directly claimed, under this legal basis.
Government Emergency Ordinance nr.43/2007 on the deliberate release into the environment of genetically modified organisms approved with amendments and completions by Law 247/2009, contains provisions on public participation and information in article 6 para. (4) and Article 17, art. 21,. Article. 32, art. 33 (8), Article 74.

The legislation provides that NEPA shall: - Consult and inform the public in the decision making process, in compliance with the legislation on public access to environmental information and privacy;- Inform the authorities concerned and the public about the revision, suspension or withdrawal of authorization and about any accidents.
The procedure for authorizing activities regarding the contained use of genetically modified microorganisms is public. Within 10 days of acceptance of the notification the competent authority shall publish it on the website. Proposals and public comments shall be submitted to the competent authority within 30 days of the date of posting of notification.
For contained use classes 3 and 4, as appropriate, the competent authority organizes public debates supported by the notifier. After the public debate, the competent authority shall prepare a report which is forwarded to the authorities concerned in the notification procedure.

Information regarding GMOs are environmental information and are available to the public according to GD no. 878/2005. (1) In cases where the information in the notification is in conflict with the provisions of Government Decision no. 878/2005 on public access to environmental information, supporting evidence must be provided cannot be considered confidential:
a) general characteristics of the genetically modified organism;
b) name and address of the company;
c) location of the facility and intended use;
d) contained use class and biosecurity measures;
e) risk assessment;
f) emergency plan.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Order No. 1205/2009 for the establishment and functioning of the National Register of locations of the introduction of GMOs into the environment, ensures the public information in an organized manner. Thus, the register, which is in fact a database, created electronically and on paper, which provides the annual locations of the GMOs is published on the NEPA website.

Serbia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

(k) With respect to paragraph 11, measures taken to apply the provisions of article 6 to decisions on whether to permit the deliberate release of genetically modified organisms into the environment.

In accordance with Article 15 of the Law on Genetically Modified Organisms (LGMO) (informing to the public), following the receipt of the application, the MAEP shall make available to the public the contents of the application in at least one daily newspaper distributed on the entire territory of the Republic of Serbia, and through electronic media. The MAEP shall organize and hold a public debate lasting up to 30 days from the day when the application contents were made available to the public.

The opinion of the Expert Council and the final decision with a rationale shall be published by the Ministry in at least one daily newspaper distributed on the entire territory of the Republic of Serbia and through electronic media.
- Please, refer also to Article 63 of the Law on Food Safety specifying that upon placing genetically modified food and genetically modified feed on the market, including quantities in bulk, the business operator concerned shall provide the recipient of such food or feed the with the prescribed data in writing.

17. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6

The Aarhus Centre Subotica has organized a great number of public debates on the environmental impact assessment studies for projects and public consultations on different documents such as the Strategy of Local Sustainable Development of Subotica, Law on GMO, Law on Waste Management, inviting citizens and professional organizations to participate in decision-making process. In cooperation with the TERRA'S association, objections were already filed against a case with the explanation that it is not under the remit of the municipal administration, but the provincial secretariat, since it relates to hazardous waste where the law prescribes the competence of provincial institutions.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The Republic of Serbia has not ratified the GMO amendment, i.e. it is not a signatory to the GMO amendment.

- MAEP is responsible for the implementation of the LGMO
- Directorate of Plant Protection (Group for the Protection of Plant Varieties and biosafety), as an administrative body within the MAEP, is responsible for receiving and reviewing applications for approval the work with GMO (GMO Experiment in laboratory, greenhouse) and deliberate release of GMOs into the environment (experimental work with GMOs in the field).
- LGMO provides the prohibition of commercial cultivation of living modified organisms, as well as the prohibition of placing in the market living modified organisms and products of GMO.
- Concerning information to the public (Article 15 LGMO) please refer to answer given in Chapter XV, item (j).

Slovakia

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

k)

By Council Decision No. 2006/957/EC of 18 December 2006 the European Community approved amendments to the Convention on access to information, public participation in decision – making process, and access to justice in environmental matters on behalf of the European Community (EU OJ L 386/46, 29 December 2006) that were adopted at the second meeting of the Contracting Parties to the Convention (25 to 27 May 2005, Almata, Kazakhstan).

The respective legal regulations of the Community regulating the release of GMO, in particular European Parliament and Council Directive No. 2001/18/EC of 12 March 2001 on deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, and European Parliament and Council Regulation (EC) No. 1829/2003 of 22 September 2003 on genetically modified food and feed contain provisions on public participation in the process of decision-making on GMO that are in compliance with amendments to the Aarhus Convention.

Merely the provision of Sect. 2 of Annex 1a to the Convention was transposed to Act No. 151/2002 Coll. on using genetic technologies and genetically modified organisms as amended which, in our opinion, constitutes a slightly more detailed regulation than the one in the Directive.
This was caused by the need to simplify the repeated introduction into the environment and to accelerate and simplify the proceedings in matters where it is necessary to give repeated consent to the launch of a product to the market while maintaining the public rights to be informed.
The texts of Article 34 (3) and Article 35 (3) of Act No. 151/2002 Coll. constitute an application of Council Decision No. 2006/957/EC approving the amendment to the Convention.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In general to Article 6a of the Aarhus Convention:
At the 2nd meeting of parties to the Aarhus Convention, which took place in Almaty, Kazakhstan, on 25 – 27 May 2005, an agreement on amendments to the Aarhus Convention was reached. The amendments regarding GMO were approved by Council Decision 2006/957/EC of 18 December 2006. The Slovak Republic ratified the amendment about GMO on 1 April 2008.
The amendments resulting from the Council Decision were incorporated in Act No. 151/2002 Coll. on using genetic technologies and genetically modified organisms as amended through Act No. 100/2008 Coll.
Act No. 151/2002 Coll. on using genetic technologies and genetically modified organisms as amended (hereinafter Act No. 151/2002 Coll.) transposed legal regulations of the European Economic Community and European Union - Directive 2001/18/EC (formerly 90/220/EEC), and 2009/41/EU (formerly 90/219/EEC), which are in compliance with the objectives of the Cartagena Protocol on Biosafety.
The procedures pursuant to Act No. 151/2002 Coll. are also covered by the general regulation on administrative procedures (Act No. 71/1967 Coll.) except the cases, when Act No. 151/2002 Coll. determines a special regulation. It is expressly mentioned in Article 31 (1) of Act No. 151/2002 Coll.

Ad (i)
Annex Ia (1) to the Convention
Act No. 151/2002 Coll. regulates the following forms of public participation in the decision-making process:

a) submission of comments on the application published on the internet
The ministry shall confirm application filing to the applicant and immediately publish the data on the filed application on the internet, and if it is expedient, also in another suitable way with a call to the public for submitting comments.

In the procedure regarding the consent to the release into the environment, a 30-day time limit for submitting comments from the date of publishing is determined (Article 34 (4) of the act). In the procedure regarding the consent to the placing on the market of a product, a 60-day time limit for submitting comments is determined (Article 35 (4) (b) of the act).

b) obtaining the status of a party to the procedure
The conditions for obtaining the status of a party to the procedure are identical both in the procedure regarding the consent to the release into the environment (Article 34 (2) of Act No. 151/2002) and in the procedure regarding the consent to the placing on the market of a product (Article 35 (2) of Act No. 151/2002):

A party to the procedure[21)] is the applicant for the consent. A party to the procedure can also be a civil association, whose objective according to the by-laws is environmental protection or protection of consumers provided that

a) it has been registered as a civil association[22)] with the objective pursuant to this section for at least one year as at the date of application filing pursuant to letter b),
b) it asks the ministry in writing for it, within 10 days from the publication of the application for consent pursuant to this act, and
c) the application pursuant to letter b) includes a petition[23)] signed by at least 100 natural persons supporting this application.

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21) Article 14 of Act No. 71/1967 Coll. on administrative procedure as amended
A person is a party to the procedure if their rights, legally protected interests or duties will be the subject of the procedure or if their rights, legally protected interests or duties can be directly affected by the decision; a person is a party to the procedure also if they claim that they can be directly affected in their rights, legally protected interests or duties by the decision until contrary is proved. The person that is granted such position by a special act is also a party to the procedure.

22) Act No. 83/1990 Coll. on association of citizens.

23) Act No. 85/1990 Coll. on the right to petition.

In the way that is not in conflict with law, everybody has the right to call upon other persons to support the petition by signing it. Natural persons shall legibly provide their names, surnames, permanent addresses and they shall attach their signatures to the data. Legal entities shall provide their names and registered offices; the persons authorised to act on behalf of them shall legibly provide their names, surnames, permanent addresses and they shall attach their signatures to the data.
If a special regulation lays down the lowest number of persons supporting the petition or the age of persons supporting the petition, the date of birth shall be attached to the data of the person supporting the petition.
The general government body shall not take into account the support of the petition by a person who provided their data illegibly or falsely.
The petition must be in written form. When the petition is filed by electronic means, the written form shall be considered preserved if it contains data pursuant to Article 4 (1) on the person filing it, and at the same time, when an electronic form is available using electronic means, which can be signed by an advanced electronic signature.

Commentary on the provisions of Article 34 and Article 35 of Act No. 151/2002 Coll.:
The provision is formulated so that a civil association can by a party to the procedure and not so that it is a party to the procedure ex lege.
The civil association can enter the procedure only after it applies for its position of a party to the procedure by filing a written application.
Therefore, it is not the government body's duty to determine all the parties to the procedure based on its official duty in every procedure.
On the other hand, the government body will have to publicly announce that the applicant applied for consent which resulted in the commencement of the administrative procedure. It is in compliance with the basic rule of procedure pursuant to Article 3 (5) of Act No. 71/1967 Coll. on administrative procedure.
The way (form) of publishing results from Article 3 (5) of Act No. 71/1967 Coll. on administrative procedure, and from Article 24 (3) of the act.

Ad (ii)
Annex Ia (2) to the Convention

The procedure regarding the consent to the release into the environment = Article 34 (3) of Act No. 151/2002 Coll.
If the subject of the procedure is to issue a consent to the release of such genetically modified organisms into the environment, for which the consent to release has already been issued in comparable biological and geographic conditions, and there is enough experience in releasing them in comparable ecosystems, the civil association pursuant to Section 2 shall have in the procedure the position of a participating person[23a)].

The procedure regarding the consent to the placing on the market of the product = Article 35 (3) of Act No. 151/2002 Coll.
If the subject of the procedure is to issue a consent to the placing on the market of the product, for which the consent has already been issued or it is determined for research or to the collection of cultures, the civil association pursuant to Section 2 shall have in the procedure the position of a participating person.[23a)]

23a) Article 15a of Act No. 71/1967 Coll. as amended by Act No. 527/2003 Coll.

Act No. 71/1967 Coll. on administrative procedure:
A special act can lay down, under which conditions other person than a party to the procedure (hereinafter the "participating person") can take part in the procedure or in a part of it. The participating person has the right to be notified of the commencement of the procedure and on other filings of parties to the procedure, top take part in the oral proceedings and local inspection, to propose evidence and supplementation of the background documents of the decision. A special act can lay down more rights to the participating person.

Ad (iii)
Annex Ia (3) to the Convention

Article 24 (2) (a) Item 8 of Act No. 151/2002 Coll.
In the matters of genetic technologies and modern biotechnology, the ministry is the national notifier to the Commission competent to inform in particular, within 30 days, on each filed application for consent to the release into the environment (Article 34) and on each consent granted pursuant to Article 35 to 37.

Article 24 (3) (a) of Act No. 151/2002 Coll.
The ministry is obliged to publish the essential content of applications for consents pursuant to Articles 33, 34, and 35, and the consents granted on the internet and if necessary, to inform the public in other suitable way.

Ad (iv)
Annex Ia (4) to the Convention

Article 26 (5) of Act No. 151/2002 Coll.
The following data and information must not be subject to intellectual property rights or business secret:

a) general characteristics (description) of a genetically modified organism and genetically modified micro-organism,
b) the business name and registered office of the notifying entity or applicant for consent,
c) the business name of the user, and if import is concerned, the business name of the foreign producer and importer,
d) classification of using in closed areas in risk classes and the appertaining level of protection,
e) the result of risk assessment and its re-assessment,
f) the evaluation of predictable effects, in particular harmful effects on humans or on the environment,
g) the purpose and place of use and expected application of the genetically modified organism and genetically modified micro-organism,
h) methods of monitoring, monitoring plans and emergency response.

Ad (v)
Annex Ia (5) to the Convention

Article 24 (3) (a) of Act No. 151/2002 Coll.

The ministry is obliged to publish the essential content of applications for consents pursuant to Articles 33, 34, and 35, and the consents granted on the internet and if necessary, to inform the public in other suitable way.

Article 3 (5) of Act No. 71/1967 Coll. on administrative procedure
Government bodies are obliged to provide the public with comprehensible and timely information on the official board of the government body, on the internet, if available, or in any other suitable way, about the commencement, execution and end of procedures in the matters that represent the subject of public interest or that are laid down in a special act. While doing so, they are obliged to protect the rights and legally protected interests of the parties to the procedure and other persons. The official board of the government body must be constantly accessible by the public.

Ad (vi)
Annex Ia (6) to the Convention
The act does not specify precisely the form of submitting comments, however, the way of publishing the received applications and decisions is mentioned. The result is that the ministry receives comments submitted in particular electronically and in writing. The way (form) of submitting comments is mentioned in each notice about the received application.

Ad (vii)
Annex Ia (7) to the Convention
After the expiry of the period for submitting comments on the published application, the ministry will evaluate the comments and allow the party to the procedure and the advisory body of the ministry to provide their opinion on them.
The ministry shall not forward for providing opinion such comments of the public which concern the general issues of GMO usage and only express a personal attitude/opinion and professionally do not regard the particular genetically modified organism or other particular topic included in the application.
In accordance with Act No. 71/1967 Coll. on administrative procedure, the MoE SR shall be obliged to determine exactly and completely the real state of things, and for that purpose, to acquire the necessary background document for the decision.
Consequently, in its decision-making the MoE SR deals only with those public comments, which solve the issues of the particular application, contain professional arguments supported by numerical data obtained from renowned institutions, such as the Robert Koch Institute, and other.

Article 3 of Act No. 71/1967 Coll. on administrative procedure:

(1) In the procedure, the government bodies observe acts and other legal regulations. The are obliged to protect the interests of the state and the company, the rights and interests of natural persons and legal entities, and to consistently require the fulfilment of their duties.
(2) The government bodies are obliged to proceed in the procedure in close cooperation with the parties to the procedure, participating persons and other persons affected by the procedure, and always to provide them with the opportunity to defend effectively their rights and interests, in particular to comment on the background documents of the decision and to apply their proposals. The government bodies shall provide the parties to the procedure, participating persons and other persons affected by the procedure with assistance and instructions so that they do not suffer any harm in the procedure due to ignorance of legal regulations.
(3) The government bodies shall be obliged to deal properly and responsibly with every matter that is the subject of the procedure, to settle it in time and without undue delay and to use the most suitable means leading to the correct settlement of the matter. If the nature of the matter admits it, the government body shall always try to settle it in amicable way. The government bodies shall ensure that the procedure is economical and without undue loading of the parties to the procedure and other persons.

(4) The decision of the government bodies must be based on the reliably found state of the matter. The government bodies shall ensure that no unjustified differences occur in decision-making in identical or similar cases as regards facts.

Ad (viii)
Annex Ia (8) to the Convention
Article 24 (3) (a) of Act No. 151/2002 Coll.
The ministry is obliged to publish the essential content of applications for consents pursuant to Articles 33, 34, and 35, and the consents granted on the internet and if necessary, to inform the public in other suitable way.

Article 46 of Act No. 71/1967 Coll. on administrative procedure
The decision must be in compliance with law and other legal regulations, it must be issued by a body competent for it, it must be based on the reliably found state of matters, and it must contain the prescribed details.

Article 47 of Act No. 71/1967 Coll. on administrative procedure

1. The decision must contain the verdict, substantiation and instruction about appeal (remonstrance). The substantiation is not necessary if all the parties to the procedure are fully accommodated.
2. The verdict contains the decision on the matter showing the provision of the legal regulation, according to which the decision was made, and possibly also the decision on the duty to reimburse the expenditures of the procedure. If a duty of performance is imposed on the party to the procedure in the decision, the government body shall specify the time limit; the time limit must not be shorter than the one laid down by a special act.
3. In the substantiation of the decision, the government body shall mention the facts, based on which the decision was made, which considerations led the body in evaluating evidence, how the body used a correct consideration in using legal regulations, based on which the body made the decision, and how it processed the proposals and objections of the parties to the procedure and their positions to the background data of the decision.
4. The instruction about appeal (remonstrance) contains information whether the decision is final or whether an appeal from the decision (remonstrance) can be filed, within what period, with which body and where the appeal can be filed. The instruction also informs whether the decision can be reviewed by the court.
5. The written copy of the decision shall also contain the body issuing the decision, the date of issue, the name and surname of the natural person and name of the legal entity. The decision must include an official seal and signature with the name, surname and position of the authorised person. Special legal regulations may lay down other requirements for the decision.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

After the effective date of Act No. 151/2002 Coll., the public used the time limit for submitting comments in three procedures, in 2012 and 2013. The subject of the procedure were field trials with GM plants and the assessment of using a human agent with GMO content for clinical trials.

Pursuant to Act No. 151/2002 Coll., the applicant for consent is a party to the procedure. Also a civil association can be a party to the procedure once the conditions stipulated by law have been met. The ministry makes decision on the position of the party - civil association - in the procedure based on an application. After the effective date of Act No. 151/2002 Coll., the ministry received one application from the civil association Greenpeace Slovakia for participating in the decision-making process within a procedure about import and placing on the market of corn and derived products of insect-resistant maize

MON 810 YieldGard® for fodder, food, and technical purposes. The application was received by the ministry in 2003.

The ministry's notification duties to the European Commission result from Directives 2009/41/EU and 2001/18/EC. The ministry registers essentially all important data and information regarding the use of genetic technologies and genetically modified organisms, and public participation in the decision-making process, and it applies the obtained data in submitting regular national reports on implementing the directives or in processing an application from the public for access to information.

Slovenia

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

An essential regulation in the field in question is the Management of Genetically Modified Organisms Act (Official Gazette of the Republic of Slovenia [Uradni list RS], Nos 23/05 – UPB1, 21/10 and 90/12; hereinafter: the ZRGSO). This Act also implements the requirements (related to public participation and others) of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

Paragraph 10 of Article 3 of the ZRGSO stipulates that the public has the right to be informed about GMO management, and to be involved in the procedure for issuing permits in compliance with this Act (public principle). This Act governs the management of genetically modified organisms (hereinafter: GMO's) in a closed system as the intentional release of GMO's into the environment.

Public participation in decision-making concerning the deliberate release of GMO's (procedure for issuing a permit to deliberately release GMO's into the environment) is governed by Article 34 of the ZRGSO. The ministry is obliged to provide for the general public to review the technical documentation and risk assessment referred to in paragraph one of Article 31 of this Act and an opinion of the committee for the release of GMO's on the intended deliberate release and a public hearing on the intended release. The public announcement, with a statement of the place and time when documentation may be viewed and the public hearing referred to in the previous paragraph and the manner of stating opinions and comments, must be published in the public media. The period which the ministry must allow for viewing and tendering opinions and comments must be at least 15 days and at most 30 days and must not be counted in the time limit for issuing the permit referred to in Article 32 of this Act. In the reasoning on the decision on the permit, the ministry should also include a position in regard to the opinions and comments of the general public provided within the framework of the public hearing and in the manner referred to in paragraph two of this Article. The costs of the public hearing referred to in paragraph one of this Article must be paid by the notifier.

Paragraph seven of Article 35 of the ZRGSO stipulates that the ministry should inform the public about new data and changes that have occurred after the issue of a permit for the deliberate release of a GMO into the environment and about decisions on this matter.

In accordance with paragraph two of Article 45 of the ZRGSO, permits for placing a product on the market, except for data that are protected as confidential in compliance with this Act and the risk assessment referred to in Article 39 of the ZRGSO, should be available to the public in accordance with regulations governing environmental protection.

Public participation and informing the public are also governed by Article 46, namely by ensuring that public participation is provided in the procedure for issuing a permit for placing a product on the market

and notifying the public on products and their placement on the market in accordance with the provisions of Article 24 of Directive 2001/18/EC.

In addition to the above provisions, the provisions presented below are also relevant for informing and notifying the public.

Point four of Article 7 of the ZRGSO stipulates that, among other things, it is the duty of the Commission for the Management of GMO's to enlighten and inform the public about conditions and developments in the field of the use of genetic technologies and GMO management, about their positions and opinions and about their work.

Pursuant to paragraph two of Article 10 of the ZRGSO, the scientific committee for the deliberate release of environmental GMO's into the environment and the placement of products on the market must issue annual reports on their work in the preceding year, which they must send to the government, which then publishes these in such a manner that they are accessible to the general public.

According to paragraph three of Article 11.a, the ministry must, within three months of receiving the notification referred to in paragraph one of this Article, draft a report on any accident, details on the circumstances of the accident, the type and quantity of genetically modified organisms, and the measures taken and their success, and the accident analysis, including, where applicable, recommendations for future accidents; this report is received by the Government, which immediately informs the public thereof.

Article 12 of the ZRGSO stipulates that data on contained use, the deliberate release of GMOs into the environment and placing products on the market, and data on procedures and activities of ministries responsible for GMO management under this Act, must be public, in compliance with regulations on environmental protection and regulations governing access to public information.

Furthermore, Article 13 of the ZRGSO governs the subsidiary obligation of the state – in a case in which, in accordance with this Act, the state is responsible for guaranteeing measures for reducing or remedying the consequences of adverse effects caused by contained use, the deliberate release of GMOs into the environment or placing products on the market, the ministry must guarantee the preparation and implementation of such measures. The ministry should inform the general public about the consequences and measures referred to in the previous paragraph, and through the ministry responsible for foreign affairs, also the competent bodies of neighbouring countries if the adverse effects could have consequences for the environment or human health in these countries.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Pursuant to Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, the competent authority in the Republic of Slovenia is the Ministry of Agriculture, Forestry and Food.

In the field of GMO's, there are two public registers in Slovenia:

- the GMO Register pursuant to the Management of Genetically Modified Organisms Act (the ZRGSO), and
- the Register of GMO Producers pursuant to the Act on the Co-existence of Genetically Modified Plants with Other Agricultural Plants (the ZSGSROKR).

Based on national legislation, competence in this field is shared by the Ministry of Agriculture, Forestry and Food, the Ministry of the Environment and Spatial Planning, and the Ministry of Health.

The Ministry of Agriculture, Forestry and Food (the Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection) is competent for genetically modified organisms in food and animal feed.

The Ministry of Health is competent for food supplements and food for special dietary or health purposes.

The Ministry of the Environment and Spatial Planning is competent for other management of genetically modified organisms.

The national legislation on genetically modified organisms is included in multiple acts. In addition to the ZRGSO, it is also included in the Animal Feed Act (Official Gazette of the Republic of Slovenia [Uradni list RS], Nos 127/06 and 90/12), the Co-existence of Genetically Modified Plants with Other Agricultural Plants (Official Gazette of the Republic of Slovenia [Uradni list RS], Nos 41/09 and 69/15), Act Regulating the Sanitary Suitability of Foodstuff, Products and Materials Coming into Contact with Foodstuffs (Official Gazette of the Republic of Slovenia [Uradni list RS], Nos 52/00, 42/02, 47/04), and the Agricultural Seeds and Propagating Material Act (Official Gazette of the Republic of Slovenia [Uradni list RS], Nos 25/05-UPB, 41/09, 32/12 and 90/12).

Pursuant to an option provided in Directive 2001/18/EC, the Restriction or Prohibition of the Cultivation of Genetically Modified Plants Act (Official Gazette of the Republic of Slovenia [Uradni list RS], No 69/15) has also been adopted in Slovenia.

Spain

8. OBSTACLES ENCOUNTERED IN THE APPLICATION OF ANY OF THE PARAGRAPHS OF ARTICLE 4

Besides those indicated in section IV, the difficult should be emphasized to make compatible the intellectual property rights and the right of access to environmental information, as well as some commercial information which relates to elements of the environment and engages competition among enterprises.

In this context, it can be mentioned, by way of example, the obligation to inform the public of the exact location of the fields where GMO's are deliberately released (see paragraph 155).

11. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON THE COLLECTION AND DISSEMINATION OF ENVIRONMENTAL INFORMATION IN ARTICLE 5

Article 5, paragraphs 3 and 5

The MAPAMA website provides information on activities carried out in Spain with GMOs and publishes reports on the results of voluntary release notices and the authorizations granted by the Interdepartmental GMO Council. The website also gives information of the GMOs legal framework at European, National and Autonomous level.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

The provisions in this area are: Law 9 / 2003, (April 25), which establishes the legal regime of the contained use, deliberate release and placing on the market of genetically modified organisms; Royal Decree 178/2004 (30 January), which approves the General Regulation for the development and implementation of the Law; Royal Decree 191/2013, of 15 march, modifying the Royal Decree 367/2010 of 26 March, amending various regulations in the area of Environment for its adaptation to the legislation on freedom of access to service activities (Law 17/2009 and Law 25/2009 and Royal Decree 191/2013) By these standards it has been transposed into Spanish legislation several European directives and regulations aimed at protecting human health and the environment against the potential effects arising

from the use of these organisms. The Order ARM/2616/2010 (5 October), regulating the composition and operation of the Participation Committee under the Inter-ministerial Council of Genetically Modified Organisms.

According to the above-mentioned legislation, the "Competent Authority" at the national level is the Inter-ministerial Council of GMOs and the Biosafety National Commission and at the regional level, each one of the Autonomous Communities in accordance in their respective areas of competence on GMOs.

On releasing GMOs into the environment, the following information is considered non-confidential: description of genetically modified organisms; identification of the owner; purpose, place of activity, emergency systems and control measures; evaluation of the effects on human health and the environment; information on deliberate releases made, authorizations of placing on the market , the list of GMOs whose marketing has been authorized or rejected as a product or part of a product; the evaluation reports; the results of the controls on placing on the market; the opinions of the Scientific Advisory Committee. 156"Public" means any natural or legal person, and "public interested" means any non-governmental organization working on environmental conservation or protection, agricultural unions, labor unions, consumer organizations, human and veterinary pharmaceutical industry, crop and livestock industry.

Stakeholders, professional agricultural organizations nationwide, agribusiness cooperatives, consumer organizations and users are represented at the Participation Committee attached to the Inter-ministerial Council of GMOs.

As regards non-discrimination requirement of article 3, paragraph 9, Spanish Constitution of 1978 is directly applicable, particularly Article 14 which says that the Spanish people are equal before the law without any discrimination on grounds of birth, race, sex, religion, politics or any other condition or personal or social circumstance.

Paragraph 1 of Annex I bis

Article 25 of Royal Decree 178/2004, paragraph 4, provides that the competent body will submit the proposed deliberate release to public information for a period of 30 days. It also describes what information should be available to the public.

Paragraph 2 of Annex I bis

Article 28 of Royal Decree 178/2004 provides for the possibility of establishing separate procedures when sufficient experience in specific ecosystems has been gained and the criteria of Annex VI are fulfilled.
Article 29 of Royal Decree provides for the option of simple procedure when several deliberate releases of plants have been generated from the same host plants cultivated but can differ in any of the sequences added or deleted or inserted sequences.

Paragraph 3 of Annex Ia

In case of deliberate release with no intention of placing on the market, article 25.4 of Royal Decree 178/2004, on the procedure after receiving the request, provides that the competent body will submit the proposed deliberate release project to public information for a period of 30. Public information will include a summary of the dossier, including the environmental assessment report. In case of placing on the market, the second transitional provision concerns the procedure for the renewal of previous authorizations, which is developed in Article 41 of Royal Decree 178/2004.

Paragraph 4 of Annex I bis

Article 20.2 of the Law 9/2003 specifies which parts of the information provided by the notifiers are not confidential and therefore can be supplied to the public without any restriction.

Paragraph 5 of Annex I bis

The MAGRAMA manages a web page that is accessible to the public. Within this website there is a section on Genetically Modified Organisms:

http://www.magrama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia
On this website, users can find information about the structure of Public Administration in the context of GMOs, how decisions are made and who is responsible for taking them, what are the different ways for public participation and the Ministry's contacts who provide any information relating to environmental releases of GMOs, as well as links to other sites of interest.

Paragraph 6 of Annex I bis

Option for access to public participation, both for deliberate release activities and contained use, is available on the Directorate General of Quality and Environmental Assessment website is

http://www.magrama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg- /participacion-publica/

This web page describes the procedure to be followed by a citizen to submit comments, objections or any additional request of information on any of the two procedures.

Paragraph 7 of Annex I bis

Article 16 of Law 27/2006 of 18 July, regulating the rights of access to information, public participation and access to justice in environmental matters, establishes the procedure once a request is made by a citizen through the usual channels.

Paragraph 8 of Annex I bis

The third additional provision of Act 9 / 2003 provides that the competent authorities will create public files to compile the location of genetically modified organisms released for purposes other than placing on the market, as well as the location of which are grown in accordance with the provisions of this law for placing on the market.

Article 27 of Royal Decree 178/2004, deals with the obligation to report on deliberate releases of GMOs into the environment without intention to sell by the owner of releases.

Article 49 of Royal Decree provides that information on authorizations for contained use, deliberate release for purposes other than placing on the market and the placing on the market of genetically modified organisms should be accessible for the public

The GMOs section within the above-mentioned MAPAMA website, contains all the data of the public register and is freely accessible to all citizens.

Paragraph 2 of Article 6 bis

All necessary legislative, regulatory and other measures listed above fall within the national biosafety

framework and are consistent with the objectives of the Cartagena Protocol on Biosafety, in particular Article 23 on public awareness and participation, and 21 on confidential information of that protocol.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF ARTICLE 6 BIS AND ANNEX I BIS

The main difficulty is to establish a clear distinction between information that is confidential and information protected by intellectual property rights. In this sense, the provision of specific data, in particular, exact location of the experimental plots, could jeopardize their own tests with the resulting of economic losses to the company or public institution.

Two reports of the legal services of the State and a decision by the Ministerial Council of GMOs have been made to clarify the level of detail to be provided within the information, always based on the full compliance with the law.

Finally, there have been some cases of vandalism in experimental plots once the geographical coordinates of the position of tests with genetically modified crops have been provided.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

To comply with the Aarhus Convention are performed annually, statistics on the number of requests for information on GMOs, by the different possible ways (phone, email, regular mail).

At the following address:

http://www.magrama.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/preguntasfrecuentesomg2_tcm7-390746.pdf

It is provided with information on the issues that most often concerned citizens in this matter.

Sweden

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Under chapter 13, section 12 of the Environmental Code a permit is required for the deliberate release of genetically modified organisms (GMOs) in the environment or the placing on the market of products containing or consisting of such organisms. An application for a permit has to be made to the supervisory authority that is responsible for the supervisory area. That authority also examines permit matters. What authority is responsible depends on what organism and what use are involved. The Swedish Board of Agriculture is responsible for land-based genetically modified plants and animals and the use of GMO as feed. The Swedish Agency for Marine and Water Management is responsible for the release of fish. The Swedish Chemicals Agency is responsible for biological pesticides. The Swedish Food Agency is responsible for food products. The Swedish Medical Products Agency is responsible for medicinal products. The Swedish Food Agency is responsible for forest trees.

The Ordinance on the release of genetically modified organisms in the environment (2002:1086) contains provisions on public participation in permit examinations. Under these provisions the supervisory authority has to give the public and other interested parties the opportunity to state an opinion before taking a decision on the matter of a permit for deliberate release. The supervisory authority also has to

establish routines for such a consultation procedure. These routines have to give interested parties a reasonable amount of time to make comments (chapter 2, section 10). The Ordinance also contains provisions about information to the public (Chapter 4, Section 5). On its website the Swedish Board of Agriculture gives everyone who is interested the opportunity to make comments on applications for field trials and the commercial use of genetically modified plants before decisions are made.

The gene technology authorities have a common web portal that has information about the regulatory framework that applies to GMOs www.genteknik.nu.

The Swedish Gene Technology Advisory Board has the task of following national and international developments in the area of gene technology, monitoring ethical matters and providing advice to promote ethically justified and safe use of gene technology in order to protect human and animal health and the environment. The Board also has the task of spreading knowledge about the development of gene technology.

Switzerland

11. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON THE COLLECTION AND DISSEMINATION OF ENVIRONMENTAL INFORMATION IN ARTICLE 5

(f, h) Article 5 paragraph 6 and 8

Swiss law contains several regulations relating to market transparency in the environmental sector. According to Article 27 EPA any person who puts environmentally hazardous substances into circulation must inform recipients about their environment-related properties and provide them with instructions so that their use does not endanger human health the environment. Similar provision can also be found in Article 29e EPA for putting organisms into circulation, Article 7 of the Federal Act of 15 December 2000 on Protection against Dangerous Substances and Preparations (ChemA, SR 813.1) for placing dangerous substances or preparations on the market, Article 15 GTA for putting genetically modified organisms into circulation, etc. Detailed rules on the content and extent of the information given to recipients, including the labelling of products, are set out by the Federal Council at the ordinance level.

Consumer goods and services are subject to the declaration requirements of the Federal Act of 5 October 1990 on Consumer Information (ConsumIA, SR SR 944.0).

In compliance with the requirements of Article 5 paragraph 6 of the Convention, Article 43a EPA provides that the Federal Council may issue regulations on the introduction of voluntary systems for environmental labels («eco-label») or voluntary systems for the evaluation and improvement of environmental protection in establishments (environmental management and auditing).

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

In Switzerland, the agricultural cultivation of genetically modified organisms (GMOs) remains prohibited due to a parliamentary decision in 2012.

Experimental releases of GMOs are possible but require a federal licence. The Federal Office for the Environment (FOEN) is responsible for issuing licences to release GMOs for experimental purposes. The legal requirements for this procedure are regulated in the Ordinance of 10 September 2008 on the Handling of Organisms in the Environment (RO, SR 814.911). This Ordinance ensures that the general public is appropriately informed about applications for experimental releases and that it can participate accordingly in the decision-making process.

It should be noted, however, that the provisions on genetically modified organisms pursuant to Article 6 bis and Annex I bis of the Convention have not yet entered into force.

Tajikistan

[available in Russian only]

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

В 2005 году Таджикистан присоединился к Картахенскому протоколу по биобезопасности к Конвенции о биологическом разнообразии.
Таджикистан участвует в Механизме посредничества Картахенского Протокола по биологической безопасности. Важным достижением является подписание Таджикистаном Нагойского протокола 21 сентября 2011 году, который предусматривает регулирование доступа к генетическим ресурсам страны и совместное использование на равной и справедливой основе выгод, получаемых от их использования в соответствии с Конвенцией о биологическом разнообразии.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF ARTICLE 6 BIS AND ANNEX I BIS

В стране нет опыта проведения оценки рисков, и осуществлении контроля за преднамеренным трансграничным перемещением ГМО. поскольку до настоящего времени информации о таких случаях не поступало. Нет средств или оборудования для их обнаружения. В стране не имеется сертифицированной лаборатории, способной выявлять наличие ГМО.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

Таджикистан официально считается страной, свободной от ГМО. Около 50 специалистов таможенной службы прошли базовую подготовку по выявлению ГМО.ОО проводятся семинары и тренинги в рамках проектов.

Turkmenistan

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

According to the Law of Turkmenistan "On ensuring food safety and quality" of August 16, 2014, genetically modified organisms (microorganisms) are organisms, microorganisms whose genotypes have been artificially changed by genetic engineering methods. State registration of genetically modified organisms (microorganisms) and other substances and their compounds that are dangerous to human life and health, its heredity is not allowed. It is not allowed to import food products, food additives, materials and products made using genetically modified organisms (microorganisms) into Turkmenistan.

State registration of genetically modified organisms (microorganisms) and other substances and their compounds, which are dangerous for human life and health, its heredity is not allowed. Import of food, food additives, materials and products produced with using genetically modified organisms (microorganisms) are not allowed in Turkmenistan.

Import of genetically modified products for food purposes is prohibited according to the Law of Turkmenistan "On Seed Production" of May 10, 2010.

Activities in the field of genetics, microbiology, as well as related to the use of genetically modified organisms and pathogens of infectious diseases are not subject to licensing in accordance with the Resolution of the President of Turkmenistan "On the issues of licensing activities in Turkmenistan" №10281 dated February 27, 2009.
Thus, the regulatory and legal framework in the field of GMOs is only being formed in Turkmenistan. Turkmenistan has ratified the Cartagena Protocol on Biosafety and the Convention on Biological Diversity.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF ARTICLE 6 BIS AND ANNEX I BIS

The amendment to the Convention has not been ratified by Turkmenistan.

Ukraine

[available in Russian only]

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Отношения между органами исполнительной власти, производителями, продавцами (поставщиками), разработ чиками , исследователями, учеными и потребителями генетически модифицированных организмов и продукции, произведенной по технологиям, предусматривающим их разработку, создание, испытание, исследование, транспорт ировку , импорт, экспорт, размещение на рынке высвобождение в окружающую среду и использование в Украине (далее - обращение с ГМО) с обеспечением биологической и генетической безопасности определены Законом Украины "О государственной системе биобезопасности при создании, испытании,транспортировке и использовании генетически модифицированных организмов "(далее - Закон) .
Согласно требованиям статьи 9 Закона центральный орган исполнительной власти , реализующим государственную политику в сфере охраны окружающей природной среды:

- осуществляет государственную экологическую экспертизу ГМО, предназначенных для использования в открытой системе;
- осуществляет государственную регистрацию средств защиты растений, полученных с использованием ГМО;
- предоставляет разрешения на высвобождение ГМО в открытой системе .

В связи с подписанием в 2014 году Соглашения об Ассоциации между Украиной, с одной стороны, и Европейским Союзом, Европейским Сообществом по атомной энергии и их государствами-членами, с другой стороны, возник ряд обязанностей об имплементации Директив Европейского Союза в сфере ГМО, которыми
предусматривается участие общественности в принятии решений по обращению с гмо.

В 2015 году на рассмотрение Верховной Рады Украины подан Проект Закона о внесении изменений в Закон Украины "О государственной системе биобезопасности при создании, испытании, транспортировке и использовании генетически модифицированных организмов" (относительно введения упрощенной процедуры регистрации на территории Украины ГМО и продукции, произведенной с их применением, зарегистрированных в Европейском Союзе) .

В связи с этим, было принято решение отложить ратификацию поправки по ГМО до принятия Закона "О государственной системе биобезопасности при создании, испытании , транспортировке и использовании генетически модифицированных организмов " в новой редакции, которая в полной мере обеспечит соответствие требованиям Директивы и поправки по ГМО к Орхусской конвенции.

Согласно требованиям действующего законодательства, главным органом в системе центральных органов исполнительной власти в формировании и обеспечении реализации государственной политики в сфере охраны окружающей природной среды, обращения с отходами, рационального использования, воспроизводства и охраны природных ресурсов является Минприроды Украины.

34. OBSTACLES ENCOUNTERED IN THE IMPLEMENTATION OF ARTICLE 6 BIS AND ANNEX I BIS

Отсутствие регулирования длительности законодательного процесса.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS

На базе Государственного предприятия "Сумыстандартметрология" действует испытательная лаборатория, аккредитованная Национальным органом Украины по аккредитации , который является полным членом ILAC - Международной организации по сотрудничеству в области аккредитации лабораторий, в соответствии со стандартами ISO/IEC 17025, ГОСТ ISO 17025- на техническую компетентность и независимость в соответствии с требованиями ГОСТ ISO/IEC 17025.

Испытательная лаборатория проводит исследования образцов пищевой продукции всех групп, сельскохозяйственного сырья на соответствие государственным и отраслевым стандартам, техническим условиям на продукцию по показателям качества, безопасности иГМО.

Испытательной лабораторией молекулярно-генетических исследований генетически модифицированных организмов ГП «Сумыстандартметрология» в 2014 году проанализированы 2370 образцов продукции на содержание ГМО, выявлено наличие ГМО в 7 образцах; в 2015 году было проведено испытание по определению содержания ГМО в пищевых продуктах и продовольственном сырье в 1274 образцах, содержание ГМО обнаружено в 16 образцах.

United Kingdom

15. LEGISLATIVE, REGULATORY AND OTHER MEASURES THAT IMPLEMENT THE PROVISIONS ON PUBLIC PARTICIPATION IN DECISIONS ON SPECIFIC ACTIVITIES IN ARTICLE 6

Article 6, paragraph 11

In March 2001 the European Union adopted Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) and repealing Council Directive 90/220/EEC (http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=Directive&an_doc=2001&nu_doc=18). The Directive is implemented in the UK by part VI of the Environmental Protection Act 1990 and regulations made under that Act (e.g. in respect of England and Wales,

the GMOs (Deliberate Release) Regulations 2002: (www.opsi.gov.uk/SI/si2002/20022443.htm)). Defra, the Scottish Government, the Northern Ireland Executive and the Welsh Government have functions and responsibilities in relation to the deliberate release of GMOs.

33. LEGISLATIVE, REGULATORY AND OTHER MEASURES IMPLEMENTING THE PROVISIONS ON GENETICALLY MODIFIED ORGANISMS PURSUANT TO ARTICLE 6 BIS AND ANNEX I BIS

Member States and the European Union agreed to the amendment to enhance the obligations placed on parties with regard to public participation in decision-making on GMOs adopted at the second Meeting of the Parties to the Convention 25-27 May 2005 in recognition that some United Nation Economic Commission for Europe (UNECE) countries outside the EU have minimal provisions for public consultation on decisions to approve GMOs in their national legal frameworks, and that some of these countries have been strong supporters of an international framework.

The requirements of the amendment, that is Article 6bis and Annex I bis, were already given effect in the European Union by the main EU instruments governing the deliberate release of genetically modified organisms to the environment: Directive 2001/18/EC and Regulation (EC) 1829/2003. As the UK had fully transposed these instruments, there was no need for additional UK legislation to be introduced in order to implement the requirements of the amendment. Directive 2001/18 is transposed into the law of England, Scotland and Wales by Part VI of the Environmental Protection Act 1990 and in England only by the Genetically Modified Organisms (Deliberate Release) Regulations 2002, in Scotland only by the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002, in Wales only by the Genetically Modified Organisms (Deliberate Release)(Wales) Regulations 2002, and into the law of Northern Ireland by Genetically Modified Organisms (Northern Ireland) Order 1991 and the Genetically Modified Organisms (Deliberate Release) (Northern Ireland) Regulations 2003. EU Regulation 1829/2003, which is directly applicable in Member States, is enforced in England through the Genetically Modified Food (England) Regulations 2004 in Wales through the Genetically Modified Food (Wales) Regulation, in Scotland through the Genetically Modified Food (Scotland) Regulations and in Northern Ireland through the Genetically Modified Food (Northern Ireland) Regulations.

EU Member States therefore recognise the importance and value of participation by stakeholders and the public in consideration of applications for approval of genetically modified crops.

All new applications to market traits for GM feed or food since 2004 have been made under Regulation 1829/2003 which sets out a requirement for a mandatory written 30-day public consultation period that must happen before the GM traits for food or feed use can be approved at EU level for marketing.

Transparency and public participation is a fundamental principle contained within the regulation:

the European Food Safety Authority (EFSA) puts the summary data of application dossiers on their website;
EFSA allows public access to all non-confidential parts of a dossier;
EFSA publishes its scientific opinion on an application on its website for public consultation;
the European Commission offers an e-mail alert service to publicise the start of the consultation period;
the European Commission publishes all resulting public comments on its website and distributes them to Member States before they vote on whether to authorise the product;
the FSA provides details of the EFSA website on its website so that any members of the public who wish to participate in these consultations can do so;
Commission Decisions on applications are published on the Commission website.

In the case of GM research trials, each Member State takes its own decisions in accordance with Directive 2001/18/EC. For applications in the UK, the relevant Competent Authority invites public representations

relating to any risks of damage being caused to the environment by the proposed release. In England, the invitation to make representations to the Defra Secretary of State in relation to England and the Welsh Ministers in relation to Wales, including a full copy of the application (excluding commercial in confidence information), is made on the public register and is repeated on the gov.uk website (https://www.gov.uk/genetically-modified- organisms-applications-and-consents). Applications for research trials in Scotland, Wales and Northern Ireland must be handled by the Devolved Administrations for these countries but will follow the same procedure, with an invitation to make representations to the relevant minister for the territory concerned. The respective websites for the Devolved Administrations are http://www.gov.scot, http://gov.wales/?lang=en and https://www.daera-ni.gov.uk/. The public register maintained by Defra covers all UK applications. The period of each consultation has been set at a mandatory minimum of 48 days (the 48 day period comes from the fact that details of Part B applications must be placed on the public register within 12 days of receipt and that the period of consultation must not end less than 60 days from the date the application was received).

Applicants are also required to advertise their application in a national newspaper. The advertisement must contain information on the GMO, and the location, dates and purpose of the intended release. It should also mention that details of the application will be placed on the public register and that the Secretary of State (or devolved Ministers) will invite representations on safety issues raised by the proposed release. The applicant is also required to inform a number of organisations of the application, including the local authority, the parish (community) council, the Environment Agency, Natural England and their equivalent bodies in Scotland, Wales and Northern Ireland as appropriate.

Upon receipt of representations, they are assessed to identify whether any scientific issues have been raised that have not already been considered by the Advisory Committee on Releases to the Environment (ACRE - the statutory scientific expert committee in the UK). If such issues are raised they would be brought to the Committee's attention to be taken into account alongside other relevant evidence. Among other things, ACRE's advice to the authorities on all research trial applications contains a response to the public representations. ACRE's advice is available on the public register and published on the ACRE website, as are the minutes of every Committee meeting. Details of every site with an active consent are also provided. All respondents are notified of the outcome of applications.

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