Economic Commission for Europe

Fourth Joint Aarhus Convention/
Convention on Biological Diversity
Roundtable on Public Awareness,
Education, Access to Information,
Public Participation and Access to
Justice regarding Living Modified
Organisms/ Genetically Modified Organism

Geneva, 11 and 12 December 2023
Palais des Nations, Salle V

Overview of Implementation of the Aarhus Convention with regards to GMOs[1]

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 2021 reporting cycle submitted to the seventh session of the Meeting of the Parties to Aarhus Convention held in Geneva, Switzerland, 18–21 October 2021.[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 2021 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: https://unece.org/sites/default/files/2021-10/ECE_MP.PP_2021_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 seventh session[4]

Introduction

9. The report consists of four parts: chapter I briefly describes procedural aspects of the sixth reporting cycle; chapter II attempts to identify some 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), as well as an overview of the follow-up on issues of compliance; and chapter IV offers conclusions on implementation trends and on the sixth reporting cycle itself.

II. Some subregional trends on implementation

A. Eastern Europe, the Caucasus and Central Asia

Genetically Modified Organisms

49. Most of the reporting Parties from the subregion mention in their reports that they are working towards the ratification of the GMO amendment, yet their national legislation in this field is still in the process of development. Armenia noted a draft law on GMOs (2018) that went through public consultations and is currently pending final revision. Georgia reported that pursuant to the European Union Association Agreement a series of normative acts related to authorization, safety, identification and labelling of GMOs containing food and feed were adopted in the intersessional period. For more information, see section H on GMOs of chapter III below.

B. European Union, Iceland, Norway, Switzerland and United Kingdom

Public participation in decision-making

55. Parties from the subregion are continuing to sharpen procedures for public participation in decisions on specific activities, as well as widen the scope of decisions and decision-making stages where public involvement is required. For the environmental impact assessment procedure, participation is increasingly ensured by Parties in the screening procedure (e.g., Hungary), at the scoping stage (e.g., Cyprus, Germany and Romania), and at a stage of a draft environmental impact assessment decision prior to its adoption (e.g., Croatia). Parties made efforts to ensure public participation in other types of decisions affecting the environment, including building and planning decisions, integrated environmental permits/authorizations, decisions on the environmental protection measures, decisions on authorization of projects that may have a significant impact on Natura 2000, decisions on nature and landscape protection, decisions on forest management, GMO-related decisions, environmental licensing/decisions on the lifetime extension of the operation of nuclear reactors, and decisions related to management of radioactive waste (e.g., Croatia, Cyprus, Czechia, Finland, France, Germany, Hungary, Lithuania, Slovakia and Spain).

Genetically Modified Organisms

59. 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, see section H on GMOs of chapter III below.

[4] Document (ECE/MP.PP/2021/6) is available from: https://unece.org/sites/default/files/2021-10/ECE_MP.PP_2021_6_E.pdf

C. South-Eastern Europe

Genetically Modified Organisms

65. Albania reported on becoming the first Party from the subregion to become a Party to the GMO amendment. However, as the Party indicates, its legal framework in this regard remains very limited. On the other hand, Bosnia and Herzegovina, Serbia and North Macedonia reported on having a legal framework on public participation in GMOs related decision-making in place, see section H on GMOs of chapter III below.

III. Thematic review of implementation

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

Availability of product information (article 5, paragraph 8)

121. 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. In 2018, the Party reported on introduction of the principles of "green" procurement as well as amendments to the Law on Consumer Protection requiring information on goods to contain information on energy efficiency classes of goods. Kazakhstan and Kyrgyzstan mentioned requirements on labelling of products containing GMOs (see section H in chapter III below).

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

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)

204. 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.

H. Genetically modified organisms

221. Decision II/1 on GMOs (i.e., the amendment to the Convention on public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms, GMO amendment) was adopted by the Meeting of the Parties at its second session (Almaty, Kazakhstan, 25–27 May 2005). With Albania accepting the GMO amendment in 2020, to date, 32 Parties 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. One more Party from among the following list of Parties to the Aarhus Convention must ratify, accept, approve or accede the GMO amendment before it can enter into force: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, North Macedonia, Tajikistan, Turkmenistan or Ukraine.

222. Parties that have ratified the amendment are bound to work towards implementation of the new article 6 bis and annex I bis. 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. 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

223. Some 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.

224. From the European Union, Iceland, Norway, Switzerland and United Kingdom subregion, only Croatia and Iceland have not ratified the amendment yet. As in previous reports, many Parties from the subregion reported that they transposed relevant European Union instruments on GMOs into national legislation, including provisions on disclosure of information and notification, and public participation rules and procedures.

225. A few Parties mentioned consultative bodies especially created for GMO decision- making. They consist, inter alia, of NGO participants. The majority of Parties from the European Union, Iceland, Norway, Switzerland and United Kingdom subregion mentioned web-based informational portals on GMO decision-making to assist in disseminating information and to facilitate public consultations (e.g., Bulgaria, Czechia, Denmark, the European Union, Latvia, Lithuania, Norway, Romania, Spain and the United Kingdom). Portugal reported on using the general portal facilitating public participation (including digital) for GMO related decision-making.

226. Some Parties in Eastern Europe, the Caucasus and Central Asia reported that their legal frameworks for decision-making on GMOs are still undeveloped (e.g., Armenia, Turkmenistan), while others referred to legislative acts that are in place (e.g., Georgia, Kazakhstan). In its national implementation report, only Georgia reported on the availability of a set of rules regulating release into the environment, placing on the market, import/re- export of living GMOs and public access to information and participation in respective decision-making.

227. Likewise, Albania is the only Party from South-Eastern Europe and overall, the only Party that accepted the GMO amendment during the sixth reporting cycle. Nevertheless, the Party reported that its legislation on GMO products remains yet very limited. Serbia, Bosnia and Herzegovina and North Macedonia reported on having a public participation procedure (including provisions on public notification, access to information, collection and consideration of comments and informing of the decision etc.) in decisions on the deliberate release of GMOs into the environment.

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

228. 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 explained by the absence of cases on GMO decision-making. Several European Union member States reported that if GMO products were placed on the market, the European Commission was responsible for consulting the public in accordance with relevant European Union legislation.

210. Belgium and North Macedonia noted a lack of human and financial resources as an obstacle. Latvia noted the difficulty of finding independent experts to prepare risk assessments related to GMO decision-making. Spain mentioned difficulties in differentiating between non-confidential information and data protected by intellectual property rights. Finland pointed out the adverse effect of the long consultation period (60 days) on the authorisation process for clinical trials and scientific studies on GMOs. Georgia mentioned the lack of accredited laboratories and the absence of information on the methodology of GMO risk assessment.

IV. Conclusions

Status of implementation

262. Parties from the European Union, Iceland, Norway, Switzerland and United Kingdom subregion demonstrated a rather high level of public involvement in decision-making processes on GMOs. Parties from Eastern Europe, the Caucasus and Central Asia and the South-Eastern Europe subregions reported on their efforts to implement measures on biosafety and GMOs.

263. With the most recent ratifications of the GMO amendment by Albania (2020), only one further ratification is required from those Parties who were Party to the Convention at the time the amendment was adopted in order for the amendment to enter into force. In their reports, a couple of Parties whose ratification of the amendment would count towards its entry into force indicated plans to adopt the necessary legislative provisions for public involvement in decision-making related to GMOs (e.g., Armenia, Kazakhstan and North Macedonia). Belarus reported on the launch of the ratification procedure for the GMO amendment.

The way forward

269. Based on the analysis of the synthesis report it is advisable for those Parties that did not do so, to:

(g) Promote implementation of the Convention in the context of GMOs, in particular by:

(i) Ratifying the GMO Amendment, especially those Parties to the Aarhus Convention who were Parties at the time the GMO Amendment was adopted (i.e., Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, North Macedonia, Tajikistan, Turkmenistan or Ukraine) as soon as possible to ensure its entry into force;

(ii) Adapting Parties' national legislative framework to the requirements of the GMO Amendment and ensuring the institutional and technical framework for its implementation at the national level;

(iii) Strengthening the capacity of authorities and relevant institutions to effectively handle access to information and public participation in decision-making on GMO related matters;

Section II: Extracts from the national implementation reports 2021[5] with regards to genetically modified organisms

Albania

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

Albania it's party of the main international Convention and protocol according of biosafety and GMO-issues, is as follows:

- Cartagena Protocol on Biosafety (BSP) to the Convention on Biological Diversity (CBD) is the main international instrument for regulation of biosafety and GMOs.
- Albania ratified this Protocol in 2004.Albania had ratified Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety by March 2013.
- Albania accepted the amendment on genetically modified organisms (GMO amendment) to the Aarhus Convention, on 3 September 2020.

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

The Albanian legislation about GMO products remains yet very limited, referring briefly and generally to GMOs products in various articles. The main laws that are currently regulating GMO products are the "Food Law" (Nr.9863, dated 28.1.2008) and the Law (No. 9199 dated 26.02.2004) "On the production, processing, certification, and marketing of "Bio" products". However, this last law, although mentions the GMOs, it does not focus much on them, as the object of the law – as can be noted from the title – is the "Bio" or organic products. In addition, in the context of EU legislation approximation, a large package of environmental laws were approved by the Albanian parliament since 2002, some of which include here and there some clauses on various biosafety elements and might be closely linked with the biosafety legal framework (e.g. the law "for protection of environmental", the law "For protected areas", the law "For environmental impact assessment", etc.). In Albania, the key legal act that tends to regulate the use of GMOs in food and feed products is the Food Law. This law consists of a general framework. Review of the regulatory framework on genetically modified food and feed in Albania: a policy perspective act and defines the main regulatory elements related to food and feed products. This law provides a framework for Food Safety and Consumer protection. Major issues regulated within this law include: the handling of risks; import and export issues, particularly the control of imported food; approval and registration of establishments; obligations of the food business operators; issues of novel food and also feed; labelling and advertising of food; food control and authorization of control laboratories; crisis and emergency management; and organizes the State bodies on consumer protection. The attempts to initiate regulation of GMOs mostly within articles related to placing of new products in the market and labelling. However, it treats GMO food and feed in very general terms and almost equivalently to non-GMO products.

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

The Albanian legislation about GMO products remains yet very limited, consisting mainly of ratified international conventions and protocols and limited number national laws.

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

N/A

Armenia

[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 2018г. Министерство Сельского хозяйства Армении разработало законопроект «О генетически измененных организмов РА». Над законопроектом работали соответствующие специалисты из Министерства окружающей среды, Министерства здравоохранения, представители НПО и т.д.. Законопроект размещен на сайте https://www.e-draft.am/projects/1178/justification, где обычно публикуются все законопроекты до представления в Национальное собрание Армении. Представители НПО и научных кругов, эксперты публикуют свои мнения и замечания на счет того или иного проекта закона, которые, если они обоснованы, учитываются уполномоченным органом. Вышеназванный проект закона дорабатывался в соответствии с предложениями и замечаниями в рамках рабочей группы и предложений, сделанных на сайте www.e-draft.

В данное время проект закона "О генетически измененных организмов РА" находится на стадии финальной доработки.

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

Отсутствие правового регулирования и закона о ГМО

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

На сайте е-драфт размещен проект закона, что дает возможность для комментариев представителей НПО и предполагается принятие закона до следующего года

Austria

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 Genetic Engineering Act (Federal Law Gazette I No. 510/1994, last amended by Federal Law Gazette I No. 13/2006) transposes into national law, inter alia, the EU Deliberate Release Directive 2001/18/EC and aims at the prevention of harmful impact of genetically modified organisms (GMO) on the environment. According to Decision II/1 the Genetic Engineering Act includes provisions on the announcement to and the hearing of the general public in the case of GMO release (paras. 43 and 44) and on the information of the general public on permits granted for bringing the respective substances into circulation (para. 58(a)).

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

As mentioned under Article 6, paragraph 11, the Genetic Engineering Act (Federal Law Gazette I No. 510/1994, last amended by Federal Law Gazette I No 114/2012) transposes into national law, inter alia, the EU Deliberate Release Directive 2001/18/EC and aims at the prevention of harmful impact of genetically modified organisms (GMO) on the environment.

According to Decision II/1, the Genetic Engineering Act includes provisions on the announcement to and hearing of the general public in the case of GMO release (Articles 43 and 44) and on the information of the general public on permits granted for bringing the respective substances into circulation (Article 58(a)).

There are no exceptions to the public participation procedure concerning the deliberate release of GMOs in the national regulatory framework. Some exceptions exist for the placing on the market. These are, however, in accordance with exceptions granted at the EU level and in compliance with the EU regulatory framework on GMOs.

In order 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, there are provisions in the Genetic Engineering Act (see its Article 43) as well as in the Ordinance on Public Hearings (Federal Law Gazette I No 61/1997 as amended by Federal Law Gazette I No 164/1998).

Provisions to ensure the transparency of decision-making procedures and to provide access to the relevant procedural information to the public including the nature of possible decisions, the public authority responsible for taking the decision, public participation arrangements laid down pursuant to paragraph 1 annex I bis, an indication of the public authority from which relevant information can be obtained and an indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments are reflected in the Genetic Engineering Act as well as the Ordinance on Public Hearings (see above).

Provisions 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 are also reflected in the Genetic Engineering Act as well as the Ordinance on Public Hearings (see above).

Concerning measures to ensure that due account is taken of the outcome of public participation procedures organized pursuant to paragraph 1 of annex I bis, it can be said that results of public hearings are reflected in the decision document by the competent authority.

Austria is a Party to the Aarhus Convention as well as to the Cartagena Protocol on Biosafety to the Convention on Biodiversity. The legal implementation as described above ensures a complementary as well as mutually supportive approach. 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.

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 safety during the implementation of genetic engineering activities" was prepared and sent for approval to other government agencies.

Belgium

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

Walloon Region:

(k) See Federal report (http:/www.health.fgov.be).

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

Federal authority: The most important obstacle in the implementation of these provisions is the lack of human and financial resources in an unstable and unpredictable context.

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

See http://www.ogm-ggo.be

Bosnia and Herzegovina

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 undertaken with the view of application of the provisions of Paragraph 6 to decisions on whether to permit deliberate release of genetically modified organisms into the environment.

Food Safety Agency

Article 6 Annex I 19 Other Activities (b) and (c)

Food Safety Agency of Bosnia and Herzegovina, within the scope of its competence, as defined under the Law on Food (Official Gazette of BiH: 50/04), participates in development and adoption of food regulations.

In line with the Law on Food, Food Safety Agency of Bosnia and Herzegovina, in cooperation with relevant institutions of BiH, its entities and Brčko District of BiH, prepared and developed the Rulebook on Food Hygiene (Official Gazette of BiH: 4/13), Rulebook on Hygiene of Animal Source Food (Official Gazette of BiH: 103/12), Rulebook on Control Measures Implemented for the Purpose of Verification of Compliance with Food and Animal Feed Regulations and Regulations on Health and Wellbeing of Animals (Official Gazette of BiH: 5/13, 62/17), Rulebook on Raw Milk (Official Gazette of BiH: 21/11, 62/14, 17/19) Rulebook on minced meat, semi-finished and finished meat products (Official Gazette of BiH: 82/13, 84/17).

In the Department for Spatial Planning and Property Affairs of the Government of Brčko District, issuance of environmental permits includes public participation from the very beginning of the process, as mandated under the Law on Protection of the Environment of Brčko District of BiH as well as the Rulebook on Facilities and Machinery that Require Environmental Impact Assessment, and Facilities and Machinery that may only be Built and Out into Operation upon Issuance of the Environmental Permit.

Once the application is submitted for issuance of environmental permit, the documents which represent the ground for issuance of the permit are posted on the official website of the Government of Brčko District of BiH to ensure public is informed of initiation of the proceedings and of possibilities for public participation in the process.

The interested public has 30 days to submit views, comments and suggestions pertinent to the content of the documents and participate in public discussion. After having received comments and suggestions from interested members of the public, the relevant department reviews them and decides whether to reject or accept them. Once comments and suggestions that are deemed relevant are accepted, the relevant body proceeds with making necessary changes and informing the interested parties of its final decision, in accordance with the appropriate procedures which ensures that the outcome of public participation is taken into account.

BiH Ministry of Justice improved its transparency by introducing a web platform: e-konsultacije (e-consultation), developed as a part of the project under the title: “Institutional Capacity Building to Initiate Dialogue with Civil Society”

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)

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 and 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.

BiH Food Safety Agency - http://www.fsa.gov.ba/

BiH Food Safety Agency: Legal framework in the field of genetically modified organisms in Bosnia and Herzegovina:

- Law on Food ("Official Gazette of BiH", No 50/04);
- Law on Genetically Modified Organisms ("Official Gazette of BiH", No 23/09);
- Rulebook on the Manner of Maintenance of the Unified Registry of Genetically Modified Organisms ("Official Gazette of BiH", No 17/12);
- Rulebook on the Establishment of the System for the Development and Assignment of Unified Codes for Genetically Modified Organisms ("Official Gazette of BiH", No 68/12);
- Rulebook on the Conditions for and Procedure of Issuance of Approval for the First-time Placement of Genetically Modified Food and Feed on the Market of Bosnia and Herzegovina and Requirements for Their Traceability and Labelling ("Official Gazette of BiH", No 78/12 and 62/15);

- Rulebook on the Content of Application and Technical Documentation for Placement on the Market, Conditions for Labelling and Packaging of Genetically Modified Organisms or Products which Contain and/or Consist of or Originate from Genetically Modified Organisms ("Official Gazette of BiH", No 78/12);
- Rulebook on the Content and Scope of Risk Assessment Regarding Placement on the Market of Genetically Modified Organisms or Products which Contain and/or Consist of or Originate from Genetically Modified Organisms and Risk Assessment Methodologies ("Official Gazette of BiH", No 79/12);
- Rulebook on the Conditions of Monitoring Plan Regarding the Impact of Genetically Modified Organisms or Products which Contain and/or Consist of or Originate from Genetically Modified Organisms and of Their Use ("Official Gazette of BiH", No 64/14),
- Decision on the Amount of Special Fee for the Issuance of Approval of Placement of Genetically Modified Food and Feed on the Market ("Official Gazette of BiH", No 61/14) and
- Rulebook on the Procedure of Assessment and Authorisation of Laboratories to Test, Control and Monitor Genetically Modified Organisms or Products which Contain and/or Consist of or Originate from Genetically Modified Organisms ("Official Gazette of BiH", No 73/17)

Council for Genetically Modified Organisms

For the purpose of monitoring the situation and developments in the field of GMO management and the provision of expertise in the implementation of the Law on GMO, the Council of Ministers of Bosnia and Herzegovina (hereinafter: BiH Council of Ministers), upon proposal of the Food Safety Agency of Bosnia and Herzegovina (hereinafter: Agency), appoints members of the Council for Genetically Modified Organisms (hereinafter: GMO Council).

The GMO Council provides opinions on the use of GMO as part of administrative proceedings and other procedures upon request of relevant authorities, provides opinions and proposals in the preparation of regulations on the use of GMO, provides opinions and proposals to relevant authorities on the issues of utilisation of GMO, monitors the situation and developments in the field of use of genetic technology and use of GMO, monitors scientific achievements and provides opinions on the use of genetic technology and use of GMO, provides opinions on social, ethical, technical and technological, scientific and other conditions of use of GMO, provides advice to relevant authorities on the issues of utilisation of GMO and of genetic technology, informs the public through the media and scientific conferences on the situation and developments in the field of use of genetic technology and use of GMO, as well as on their own stances and opinions, conducts other professional tasks prescribed by the Law on GMO by subsequent regulations. Until now, the GMO Council has adopted 36 opinions on laboratories for testing, control and monitoring of genetically modified organisms and products which contain or consist of or originate from genetically modified organisms.
Pursuant to Article 16 of the Law on Genetically Modified Organisms ("Official Gazette of BiH", No 23/09), the Council of Ministers of Bosnia and Herzegovina, upon proposal of the Food Safety Agency of Bosnia and Herzegovina and upon the opinion of the Accreditation Institute of Bosnia and Herzegovina, adopted the Rulebook on the Procedure of Assessment and Authorisation of Laboratories to Test, Control and Monitor Genetically Modified Organisms or Products which Contain and/or Consist of or Originate from Genetically Modified Organisms ("Official Gazette of BiH", No 73/17). According to the provisions of the Rulebook, the Ministry of Agriculture, Forestry and Water Management of the Republika Srpska, the FBiH Ministry of Agriculture, Water Management and Forestry and the Brčko District Department of Agriculture conduct the procedure and authorise testing laboratories for control, testing and monitoring of GMO and of products which contain or consist of or originate from GMO. Following the authorisation, the Decision on Authorisation of Laboratories is sent to the BiH Food Safety Agency, which registers them in the unified list of testing laboratories in BiH for GMO. The list will be published in the "Official Gazette of BiH" and on the web site of the Agency.

Co-operation Protocol

Pursuant to the Conclusions of the BiH Council of Ministers, from its 134th Session held on 05 October 2010, and with the aim of providing support to authorised testing laboratories and to the improvement of the GMO control system in Bosnia and Herzegovina, the Agency signed the Co-operation Protocol for the Development of Authorised Testing Laboratories for Genetically Modified Organisms in BiH with the "Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana" (IZSLT), which will serve as the reference laboratory for the area of Bosnia and Herzegovina until such time when an authorised laboratory from Bosnia and Herzegovina reaches the necessary level of reference.

Approval Decision Issuance Procedure

The BiH Council of Ministers, upon proposal of the Agency and in accordance with the Law on Genetically Modified Organisms, adopted the Rulebook on the Conditions for and Procedure of Issuance of Approval for the First-time Placement of Genetically Modified Food and Feed on the Market of Bosnia and Herzegovina and Requirements for Their Traceability and Labelling. Among other things, the Rulebook regulates the procedure how to file a request to place on the market GM food and feed, as well as the issuance of a decision on approval of the placement of GM food and feed, taking into account the opinion of the GMO Council, all the regulations in force and other facts important to make an approval decision for which the Agency is in charge, pursuant to Article 3, Paragraph (2), Subparagraph c) of the Law on GMO.

In order to be issued with a Decision on Approval, a written request should be delivered in writing to the Agency either by registered mail or in person. The applicant requesting to be issued with a Decision on Approval, or the applicant's representative, must have a registered head office in Bosnia and Herzegovina. The Agency confirms to the applicant that it received the application, in a written form, not later than 14 days following the receipt of the application. The confirmation shall state the date of receipt of the application.

All the accompanying official documents must be written in one of the languages and scripts in official use in Bosnia and Herzegovina. Requests to issue decisions on approval of placing feed on the market, received from feed sales companies, shall be discussed by the GMO Council and shall adopt an opinion, pursuant to Article 56 of the Law on GMO, the Rulebook on the Conditions for and Procedure of Issuance of Approval for the First-time Placement of Genetically Modified Food and Feed on the Market of Bosnia and Herzegovina and Requirements for Their Traceability and Labelling and Article 2 of the Rules of Procedure of the GMO Council. In case the GMO Council issues a positive opinion, the Agency issues a Decision on Approval to place on the market genetically modified feed which will be used solely as feed, to the feed sales company which filed a request to be issued with the Decision on Approval to place on the market feed which contains GMO. To date, 36 Decisions have been issued.

Acting in accordance with its scope of authority, the Agency gave its contribution in the preparation and adoption of the legal framework which regulates the procedure to issue approval to place GM feed on the market of Bosnia and Herzegovina. Feed sales companies in Bosnia and Herzegovina which are in need of a Decision on Approval to place GM feed on the market and which wish to place such feed on the BiH market can do that. Of course, the entire process of issuance of the Decision on Approval to place GM food and feed on the market shall be conducted with strict measures of control and in a transparent manner, with continual professional oversight by the GMO Council.

35. FURTHER INFORMATION ON THE PRACTICAL APPLICATION OF THE PROVISIONS OF ARTICLE 6 BIS AND ANNEX I BIS
BiH Food Safety Agency - http://www.fsa.gov.ba/

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 stipulated in the Act on Genetically Modified Organisms (GMO Act), and in particular in artitcle 50 of that 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 MoEW 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 authorization dossier.

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, Food and Forestry, 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. Council of the Ministers adopts decision within 14 days.

The Minister of Environment and Water may issue permit for release of GMO or combination of GMOs into the environment if the decision of the Council of the Ministers is positive and taking into consideration all other documents, incl. the results of the public consultation.

The MoEW maintains in an electronic form:

- public register of the authorizations for deliberate release of GMOs into the environment

- 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, but for the the first procedure the Minister of Environment and Water is competent authority, and for the second – the Minister of Agriculture, Food and Forestry.

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):

Public participation in decisions on the placing on the market of GMO is stipulate in detail the Act on Genetically Modified Organisms (GMO Act), and in particular in Artitcle 66a of that Act.

A GMO or a combination of GMOs shall be placed on the market after obtaining an authorization granted by the Minister of Agriculture, Food and Forestry.

An authorization shall be granted for each particular case, acting on an application in writing from a person.

The Minister of Agriculture, Food and Forestry publishes as soon as they become available the summary of the application; the evaluation report on the application (see below); and information regarding the possibility for public participation in the public discussion, which is conducted at the level of the European Union.

The Advisory Commission on GMOs to the Minister of Environment and Water within 60 days of receiving the application shall prepare an opinion and shall submit the said opinion to the Minister of Agriculture, Food and Forestry.

Based on the opinion of the Commission and in coordination with the Minister of Environment and Water, the Minister of Agriculture, Food and Forestry within 90 days of receiving the application shall prepare and send to the applicant evaluation report on the application. When the report proposes that the GMO can be placed on the market, it, along with any information taken into account in its preparation, is send to European Commission.

Public consultation for 30 days is then conducted based on the published summary of the application and evaluation report. The Minister of Agriculture, Food and Forestry summarizes the comments and proposals made and sends them to the European Commission.

The Minister of Agriculture, Food and Forestry shall issue authorization for placing on the market when:

1. no reasoned objections or open issues have been raised by the European Commission or the EU Member States within 60 days of the submission of the report;

2. reasoned objections or open issues raised have been resolved within 105 days of the submission of the report;

3. the European Commission has issued decision in favour of placing on the market of the GMO.

The Ministry of Agriculture, Food and Forestry maintains in an electronic form:
- public register of the permits for placing GMOs on the market;
- information on genetic modification(s) to facilitate control and monitoring of GMOs as products or ingredient of products after placing on the market;
- public register of the areas planted with genetically modified plants that have been authorized for placing on the market in European Union for cultivation.

Subpoint (a) (iv):

Chapter 6 of the GMO Act regulates the confidentiality of information related to GMOs. In case of deliberate release of GMOs into 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 notifier; 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. The rules regulating the confidentiality of information will be changed after Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain enters into force from 27 March 2021.

Subpoint (a) (v):

The procedural aspects of authorization of deliberate release into the environment and placing on the market of GMOs are stipulated by the provisions of the Bulgarian GMO act and Ordinance on the deliberate release and placing on the market of GMOs. That includes the nature of possible decisions; the public authorities responsible for making the decision; the arrangements for public participation in the decision making process. Those documents are public as they are part of the national legislation. In addition the profile of Bulgaria in the Biosafety Clearing House contains copies of all national legal acts with relevance to GMOs (in Bulgarian and in most cases unofficial translation in English) https://bch.cbd.int/about/countryprofile.shtml?country=bg

Subpoint (a) (vi):

Any person may provide an opinion or any other information that they consider relevant to the authorization procedures, both in writing or in electronic form. Record of all information received from the public or other statkeholders is kept in the authorization dossier. This information is public and can be received upon request subject to protection of personal data. For more details see answers to Question XV (k) and Question XXXIII (a) (iii).

Subpoint (a) (vii):

As described above (see answer to Question XV (k) and Question XXXIII (a) (iii)) results of public consultation are part of the authorization dossiers for the deliberate release into the environment and placing on the market of GMOs and as such they have to be taken into consideration when the final decision by the Competent Authorities is reached.

Subpoint (a) (viii):

The MoEW maintains in an electronic form:

- public register of the authorizations for deliberate release of GMOs into the environment;

- public register of the location and size of the areas wherein the release of GMOs is authorized. The Ministry of Agriculture, Food and Forestry maintains in an electronic form:

- public register of the permits for placing GMOs on the market;

- information on genetic modification(s) to facilitate control and monitoring of GMOs as products or ingredient of products after placing on the market;

- public register of the areas planted with genetically modified plants that have been authorized for placing on the market in European Union for cultivation.

The actual decisions authorizing deliberate release into the environment and placing on the market of GMO will be publically available, but at present no such decisions have been taken in Bulgaria.

In addition the information Joint Research Center (JRC) to the European Commission maintaince public website containing information on notifications submitted from the applicants to the Member States Competent Authorities about deliberate release into the environment and placing on the market of genetically modified organisms https://gmoinfo.jrc.ec.europa.eu/ At present it contains no data from Bulgaria as no notifications have been submitted, but it will be uploaded if such notifications are received.

Subpoint (b):

Requirements of the Cartagena Protocol on Biosafety and of Annex I bis are stipulated in the Bulgarian GMO Act or in the EU legislation that is directly applicable in Bulgaria. They are implemented in an integrated and

mutually supportive manner. For more details see the answers above and the Fouth Bulgarian National Report under the Cartagena Protocol on Biosafety.

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

None.

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

So far no deliberate releases into the environment and placing on the market of GMOs has been authorized in Bulgarian and there is no practical experience 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.

Croatia

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 their approval procedures, state administration bodies are obliged to provide the public with access to information from applications, the content of technical documentation and conducted risk assessments, as well as to state a statement of objections and public opinion in the explanations of their approval decisions. (Article 24, paragraphs 1 and 4 and Article 39, paragraphs 1 and 4 of the AGMO). In the event of any modifications, new data and unplanned changes in the deliberate release into the environment that could adversely affect biodiversity, the environment or human health, the state administration body responsible for environmental protection and nature is obliged to inform the public in accordance with Article 40. .paragraph 3. ZGMO. In case of unplanned release of GMOs into the environment, the state administration body responsible for environmental and nature protection is obliged to inform the Croatian Government of and the public about the event and the preparation and implementation of the program for eliminating the consequences of uncontrolled spread of GMOs in the environment. 4. ZGMO. Pursuant to Article 63, paragraph 4 of the Ordinance on GMO, updated information on the restriction or prohibition of the cultivation of certain GMOs and / or groups of GMOs must also be made available to the public.

Croatia has not ratified the GMO Amendment to the Aarhus Convention. However, the provisions of the Aarhus Convention regarding public access to information and public participation have been fully integrated into the AGMO as in other regulations.

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 127(I)/2018 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, 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) with respect to Article 6 paragraph 11
The Czech legislation does not explicitly allow the public to become a participant in the procedure for permitting the release of GMOs into the environment. Act No. 78//2004 Coll., On the handling of genetically modified organisms and genetic products, provides exclusively for consultative public participation, unlike the older regulation (Act No. 153/2000 Coll.), which allowed the full participation of environmental associations in decision-making. The scope of participants in the proceedings pursuant to Act No. 78//2004 Coll. it is not regulated, so the general regulation in the Administrative Procedure Code applies, according to which other persons whose rights are concerned can become participants in addition to the applicant. However, it is not clear whether they may be representatives of the public concerned.

Consultative participation in decision-making pursuant to Act No. 78//2004 Coll. consists of participating in a public hearing and making a statement. Following the submission of an application for a permit for contained use and for placing on the market, the Ministry of the Environment will publish information on the official

notice board, on the internet and in at least one other appropriate manner in the municipality and region in whose territory the contained use or release takes place, or where such action is, given all circumstances, expected. The public (any person) may send their written statement to the Ministry within 30 days from the date of publication of the application. If the Ministry thus receives a dissenting statement with the release of the GMO into the environment, it will call a public hearing of the submitted application before deciding on the application. It will publish a notice of the public hearing at least five days in advance in the same manner as above. The decision on the submitted application always includes a summary settlement of statements.

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 field of GMOs is governed by Act No. 78/2004 Coll., On the handling of genetically modified organisms and genetic products, as amended, and directly applicable EU regulations (Regulation No. 1829/2003 on genetically modified food and feed, and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms).

GMOs and genetic products may be handled only on the basis of an authorization granted on the basis of Act No. 78/2004 Coll. The procedure for granting a permit for contained use, permit for release into the environment and for entry in the list for placing on the market is governed by Section 5 of the Act, which together with Section 10 sets out the manner and deadlines for publishing information at various stages of the decision-making.

The Czech legislation does not explicitly allow the public to become a participant in the procedure for permitting the release of GMOs into the environment. Only consultative public participation is allowed. The scope of participants in the proceedings pursuant to Act No. 78//2004 Coll. is not regulated, so the general regulation in the Administrative Procedure Code applies, according to which other persons whose rights are affected may become participants, in addition to the applicant.

Consultative participation in decision-making pursuant to Act No. 78//2004 Coll. consists in participating in a public hearing and making a statement. The public (any person) can send their written statement to the Ministry of the Environment within 30 days from the date of publication of the application. If the Ministry thus receives a dissenting statement on the release of the GMO into the environment, it will order a public hearing of the submitted application before deciding on the application. It will publish information on the public hearing at least five days in advance in the same manner as above. The decision on the submitted application always includes a summary settlement of statements.

The Ministry of the Environment maintains a register of permitted GMOs and a register of persons authorized to handle GMOs pursuant to Act No. 78/2004 Coll. and publishes these registers on its website (Section 22 of the Act).

The Ministry of the Environment also publishes a list of GMO cultivation sites on its website (Section 23 (2) of Act No. 78/2004 Coll.).

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

The current legislation allows only for consultative participation of the public (apart from the general regulation of the Administrative Procedure Code).

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 MIM, 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 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. 9 of January 4th 2017 on the Environment and Gene Technology and in the Statutory Order no. 37of 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)

(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.mim.dk

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

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

N/A

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.

Pursuant to section 28 of the General Part of the Environment Code Act, it is provided expressly that everyone has the right to participate in procedure of granting permit for activity with significant environmental impact and in planning an activity with significant environmental impact. In case of the decision-making procedure

related to significant environmental impact, public shall be informed with efficiency that does not cause unreasonable expenses, but ensures that the information shall reach those persons, who have significant connection to the affected environment. Pursuant to the same section public has to be involved in decision-making processes of significant environmental impact effectively and in early phase, before the final solutions have been chosen. In case of public involvement the procedural time-limit must be such that having regard to scope and complexity of the case, it should allow public to participate effectively, including possibility for sufficient preparation time. Pursuant to section 28 the important materials regarding to a case must be easily accessible for public in Internet or in other manner.

The General Part of the Environment Code Act also regulates in detail the procedure of open proceeding regarding the review of environmental permit application.

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.

In 2021, it is planned to bring the Release into Environment of Genetically Modified Organisms Act into line with Regulation (EC) 2019/1381 of the European Parliament and of the Council. The purpose of the regulation is to ensure greater transparency by giving citizens and researchers access to all food safety information provided by the operator during the risk assessment process, with the exception of information classifies as confidential business information.

Subsection 29 (4) of the Act will be amended. The applicable law lists information which may not be treated as confidential business information, but the amendment provides for information which may be treated as confidential business information. In accordance with the amendment, the following may be treated as confidential business information: 1) manufacturing and production processes, except for information that is relevant for the safety assessment; 2) business information and, where appropriate, business relations between the manufacturer or importer and the applicant; 3) breeding schemes and breeding strategies; and 4) DNA sequence information that is not used to determine whether a genetically modified organism is involved.

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.

[1] COM(2017) 198 final, http://ec.europa.eu/environment/nature/legislation/fitness_check/action_plan/communication_en.pdf and SWD(2017) 139 final, http://ec.europa.eu/environment/nature/legislation/fitness_check/action_plan/factsheets_en.pdf.

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 confidential (Article 28).

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

On 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

With respect to 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:

Provisions concerning consulting the public are included in the Gene Technology Act (377/1995) and EU legislation discussed below in section XXXIII.

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

With respect to 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:

Under section 36b of the Gene Technology Act (377/1995), the Board for Gene Technology shall consult the public in regard to a planned deliberate release into the environment for any other purpose than for placing on the market. In practice, this means field trials for research purposes. The Board shall inform about having received the above-mentioned application at least in the Official Gazette, but in practice the information is also published on the website of the Board. The time limit for consulting is 60 days, and the public has the right of access to the application documents concerning the field trial and to copies of them as well as the right to submit written comments on them. The application documents are available for viewing on the website of the Board and at the Ministry of Social Affairs and Health.

The content requirements of applications were amended recently by the Decree of the Ministry of Social Affairs and Health on the deliberate release of genetically modified organisms (1105/2019). The Decree implements Commission Directive (EU) 2018/350 as regards the environmental risk assessment of genetically modified organisms.

As regards placing on the market of GMO products, the consultation of the public takes place at the EU level in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003 (genetically modified food and feed).

There is a separate Government Decree on Chargeable Performances under the Gene Technology Act (1255/2018).

With respect to paragraph 1 of article 6 bis and 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 exceptions are provided for.

With respect to paragraph 1 of article 6 bis and 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 authorisation 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 publishes information on all field trial applications received as provided in section 36b of the Gene Technology Act.

As regards product applications (GM feed and food) under EU Regulation (EC) No 1829/2003, the website of the Finnish Food Authority provides a link to the EFSA website with the summaries of the latest authorisation applications and the EFSA opinions on the applications. In force from 27 March 2021, Regulation (EU) 2019/1381 amending Regulation (EC) No 178/2002 on general food law will increase the transparency of the scientific activities of the EFSA. Once the opinions of the EFSA are completed, members of the public may make comments on them to the Commission in their native language for 30 days.

Consultations relating to product applications (such as GM cut flowers) under Directive 2001/18/EC are ensured by the Commission. Before the approval of a GMO, the public is allowed 30 days to make comments to the Commission on the application summary and the EFSA opinion under the Directive. Further information is available on the website of the Joint Research Centre (JRC) of the Commission. In addition to information on product applications, the website also contains summaries of all the field trial applications submitted in EU Member States.

With respect to paragraph 1 of article 6 bis and 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 lays down provisions on which information is not considered as confidential.

With respect to paragraph 1 of article 6 bis and 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:

1. **The nature of possible decisions;**
2. **The public authority responsible for making the decision;**
3. **Public participation arrangements laid down pursuant to paragraph 1 of annex I bis;**
4. **An indication of the public authority from which relevant information can be obtained;**

An indication of the public authority to which comments can be submitted and of the time schedule for the transmittal of comments:

The Gene Technology Act lays down provisions on decision-making and availability of information concerning field trials and on consultation of the public as presented above. Correspondingly, provisions on the decision-making process concerning products are laid down in EU legislation, and information is easily available online.

Section 32 of the Gene Technology Act will be amended by 27 March 2021 due to the amendments of the confidentiality provisions of Directive 2001/18/EC in conjunction with the amendment of EU General Food Law (GFL) (Regulation 178/2002). The amendments of the GFL Regulation and Directive 2001/18/EC took into account not only the Aarhus Convention but also the General Data Protection Regulation (GDPR) of the EU.

With respect to paragraph 1 of article 6 bis and 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:

Comments may be submitted e.g. by post, email or via the Commission website. In some cases, information events are also organised about field trials where the public may make oral questions and comments.

With respect to paragraph 1 of article 6 bis and paragraph 7 of annex I bis, measures taken to ensure that due account is taken of the outcome of public participation procedures organised pursuant to paragraph 1 of annex I bis:

The duty to state the reason for an administrative decision (section 45 of APA) and public access to the results of consultation procedures promote due account to comments in decision-making.

Public comments made on field trial applications arefiled with the applications in the national gene technology register and are available to the public.

In the EU product authorisation procedure, the Commission sends the comments received for analysis either to the competent authority or the EFSA to establish whether they have an impact on the EFSA opinion. Comments made by the public are also filed with the applications.

With respect to paragraph 1 of article 6 bis and 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:

Decisions concerning the deliberate release into the environment of genetically modified organisms are, under Directive 2001/18/EC, made in Finland by the Board for Gene Technology, whose decisions are available e.g. on the website of the Board.

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 Board for Gene Technology operating in conjunction with the Ministry of Social Affairs and Health is the Finnish competent authority in duties laid down in the Gene Technology Act as well as 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 in the Board for Gene Technology.

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

The time limit (60 days) provided for consulting the public under section 36b of the Gene Technology Act has proved to be challenging as the operating environment is changing. The effect of the long consultation period on the authorisation process for clinical trials has resulted in Finland not being an attractive target country of multicentre trials that allow patients in multiple countries to participate in clinical trials. In the context of compassionate use under a special permit, the long authorisation process may result in a delay in medical treatment, which, in certain situations, may pose a risk to human life or health. The effect of the long consultation period of the public on the application process has also been observed in scientific studies conducted on genetically modified plants. Harmonising implementation with Finland's short growing season, thesis projects and the project funding of university research groups has proved to be challenging in terms of schedules for the authorities and research groups alike.

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 procedures for authorizing the deliberate release of genetically modified organisms (GMOs) into the environment: authorizations for any purpose other than placing them on the market, in particular field trials (article L. 533-3 CE) and marketing authorizations (article L. 533-5 CE).

The file sent by the applicant to the competent administrative authority includes in particular an assessment of the effects and risks of GMOs for health and the environment. Each authorization request is subject to an opinion from the High Council for Biotechnologies (HCB), which notably includes an Economic, Ethical and Social Committee made up of representatives of civil society.

The national agency for food, environmental and occupational health safety (ANSES) is also competent to assess the health safety risks of foods consisting of GMOs or produced from GMOs. The opinions of these bodies are published on their respective websites.

For each field experiment request, a public consultation procedure is set up via the Internet. The authorization application file, the HCB opinion and a public information sheet are posted online for each trial.

For each marketing application, a public consultation procedure is carried out at Community level via the Internet. The files presented within the framework of Regulation (EC) No. 1829/2003 concerning genetically modified foodstuffs and animal feed are subject to consultation on the following website: http://ec.europa.eu/food /plant/gmo/public_consultations_en.
Those filed under Directive 2001/18/EC relating to the deliberate release of genetically modified organisms into the environment are subject to consultation on the website of the Joint Research Center of the European Commission 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 Law No. 2016-369 of March 30, 2016.

Georgia

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

(k) Release into the environment and placing on the market of Living Genetically Modified Organisms on the territory of Georgia is prohibited[234].

[225] Environmental Impact Assessment.
[226] During the reporting period, such information was sent to over 6000 subscribers.
[227] According to EAC.
[228] Pursuant to EAC.
[229] By the Order (N2-94, 22.02.2018) of the Minister of Environmental Protection and Agriculture of Georgia on the Approval of the Rules for Public Hearings.
[230] According to the Resolution N181, 23/03/2020 of the GoG on the Approval of Measures for the Prevention of New Corona Virus in Georgia.
[231] Pursuant to the Law of Georgia on Aquaculture (2020).
[232] Monitoring is conducted in accordance to the Law of Georgia on Agriculture.
[233] According to EAC.
[234] Pursuant to the Law of Georgia on Living Genetically Modified Organisms (2014), which considers the principles of the Convention.

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

Release into the environment, placing on the market[304], import/re-export[305] of living GMOs[306] is prohibited on the territory of Georgia; public access to information and participation in respective decision-making is ensured[307]; it's obligatory to create living GMOs unified register, which shall be placed on special webpage excluding legally defined confidential information[308]. List of the mandatory information for the register is defined[309].

Legislation[310] aims to:

- inform consumers about food/animal nutrition GMO, their GMO production;
- protect consumers' interests to have a free choice;
- define labeling rules of food/animal nutrition GMO and their GMO production, establish state control;
- support approximation/harmonization of national legislation with EU acquis and other international legislative norms in this field.

Respective government decrees[311] set requirements towards labeling on existence of GMO-components, enabling consumers to make his/her choice when selecting-purchasing products; regulate relations between business operators, state control bodies and consumers.

[304] According to the Law of Georgia on Living Genetically Modified Organisms (2014), Article 7.
[305] Article 4.
[306] Genetically Modified Organisms.
[307] Article 26.
[308] Article 27.
[309] Under the Regulation on Unified Register of Living GMOs approved by the Order N165, 2014 of the Minister of Environmental Protection and Natural Resources.
[310] The Law of Georgia on Labeling of Food/Animal Feed GMOs and Their GMO Production (2014).
[311] Decree of the GoG N301, 2016 on the "Approval of Technical Regulation – Provision of Information to the Constomers about Food Products", and Decree of the GoG N320 of 2015 on "Approval of Rule of Labeling of Food/Animal Feed GMOs and Their GMO Production".

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

Lack of accredited testing-laboratories, qualified staff; information scarcity about the risk assessment methodology related to GMO-containing products and raw food materials.

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

Bio-production rules[312] provide information to the consumers on healthy food products.

Pursuant to the DCFTA[313] obligations, and in accordance with the EU Regulations[314] and Recommendation[315], GoG approved the following normative acts:

- Requirements for Genetically Modified Food Products and Animal Feed[316];
- Technical Regulation on Identification and Labeling of GMOs, Identification of GMO Produced Food/Animal feed[317];
- Amendments to the Decree N548,16/10/2018[318] on authorization of new GMO food/feed, risk assessment, notification, etc.

MEPA uploads the draft legislative amendments to the given issues for comments on its webpage, conducts public hearings. NGO sector is involved in the public informing process, participates in related conferences/meetings. National Center for Monitoring and Scientific Research of Manufacturing of GMO-containing products is established.

[312] The Rules on bio-production, approved by the Decree of the GoG (N198, 30/072013), provide rules for labeling of food products for placing on the market, defining as “bio”, “eco”, “organic”, “ecologically clean”.
[313] EU-Georgia Association Agreement, Deep and Comprehensive Free Trade Agreement (chapter 4 - Sanitary and Phytosanitary Measures).
[314] 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, and Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
[315] EC 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.
[316] N549, 16/10/2018.
[317] N548, 16/10/2018.
[318] Amendments to the Decree N 548, 16/10/2018, made in 2020, pursuant to the Regulation (EC) No 641/2004, relating to the rules of usage of Regulation (EC)No829/2003, in connection with authorization of new genetically modified food and animal feed, notification about accidental or technically unavoidable existence of genetically modified substance identified during existing product and risk assessment.

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 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.

[42] For example, Section 1 of the Berlin Environmental Impact Assessment Act (UVPG Bln); Section 3 BgbUVPG; Section 4 of the Bremen Environmental Impact Assessment Act (BremUVPG); Section 1 (1) of the Hamburg Environmental Impact Assessment Act (HmbUVPG); Section 5 (1) of the Mecklenburg-Western Pomerania Land Environmental Impact Assessment Act (LUVPG M-V); Section 2 (1) of the

Lower Saxony Environmental Impact Assessment Act (NUVPG); Section 1 (1) of the North Rhine-Westphalia Environmental Impact Assessment Act (UVPG NW); Sections 5 and 18 ff. of the Saarland Environmental Impact Assessment Act (SUVPG); Section 1 of the Saxony Environmental Impact Assessment Act (SächsUVPG); Sections 3 and 4 of the Saxony-Anhalt Environmental Impact Assessment Act (LUVPG SH); Section 4 of the Thuringia Environmental Impact Assessment Act (ThürUVPG).
[43] www.uvp-portal.de (Federation), https://www.uvp-verbund.de/startseite (Länder).
[44] https://www.base.bund.de/SiteGlobals/Forms/Suche/BfE/DE/SOA-Suche_Formular.html

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, 29 and 30 of Regulation (EC) 1829/2003 contain provisions on public participation in decision-making on GMOs and the confidentiality of information. In order to further improve transparency, these provisions were amended by Article 2 of Regulation (EU) 2019/1381. 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 1bis 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 6.11 (participation in the permitting procedure of genetically modified organisms)

101. 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 NGOs aimed environmental health- and consumer protection – elected according to the procedure determined by them - participate in the Gene-technology Advisory Committee (hereinafter: GEVB). The activities of the committee are governed by Decree 128/2003 (19 December) of the Minister of Agriculture and Rural Development. Gene-technology authorities review permit requests for gene-technological activity with respect to the comments made by the GEVB. The gene-technology authority is not bound by the opinion of 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 website for public consultation, excluding data subject to commercial confidentiality, intellectual copyright or patent. Comments on the draft permit may be submitted within 30 days of 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.

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.

As is said in (h) above, the deciding authority must take due consideration of all information gathered including the comments (information, analysis or opinions) put forward in the public participation process and this has been confirmed in administrative rulings. Public consultation is extremely important in decisions making regarding the environment, not only to ensure the public's right to express their views, but also to ensure that all relevant information has been gathered before a final decision is made. Public authorities are in many cases bound by deadlines described by law when making decisions but in other cases the authorities decide in each case what is a sufficient time for the public to be able to participate. In many cases extra time is given if requested. It is also up to public authorities to follow the law and take due account of the public consultation, but the general rule is that administrative decisions can be appealed and reviewed if necessary.

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

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, and EU law including:

Directive 98/81/EC on the contained use of genetically modified micro-organisms which was transposed into Irish law under the Genetically Modified (Contained Use) Regulations 2001 (S.I. No. 73 of 2001).

Directive 2001/18/EC, as amended, on the deliberate release into the environment of genetically modified organisms which was transposed into Irish Law as the GMO (Deliberate Release) Regulations (S.I. No 500 of 2003), as amended.

Regulation 1946/2003 on the transboundary movement of GMOs which is regulated in Ireland under 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 6 bis and Annex I bis, were regulated within the EU by Directive 2001/18/EC and amending Directive 2015/412 and Commission Directive (EU) 2018/350 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), as amended, 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. EU regulation 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19) provides for further exemptions.

(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:

GMO Register No: G0726-01 - Gene therapy administration under managed access programme

GMO Register No: G0667-01 - Clinical Trial to test gene therapy treatment for Haemophilia B

Other reports and publications concerning GMOs are available 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 regard to paragraph 11, measures taken to apply the provisions of Article 6 to decisions concerning the release of Genetically Modified Organisms (GMOs) into the environment

In 2005, MiTE established the web platform called Italian Biosafety Clearing House (BCH) with the following goals:

- Implement the obligations set out in the Cartagena Protocol on Biosafety, ratified by Italian Law no. 27 of 14 January 2004 on public awareness and participation (Article 20 of the Cartagena Protocol).
- **Implement the Aarhus Convention and the Almaty Amendment on GMOs; comply with European Union legislation (Directive 2001/18/EC) and Italian legislation (Legislative Decree no. 224 of 8 July 2003) on information and public consultation 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 authorisation procedures for the deliberate release of genetically modified organisms (GMOs) into the environment for experimental purposes and for placement on the market are regulated at the level of the European Union by Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and by Regulation (EC) No 1829/2003 on genetically modified food and feed.

Directive 2001/18/EC was transposed into Italian law by Legislative Decree no. 224 of 8 July 2003.

The competent national authority (CNA) for the implementation of the provisions of Italian Legislative Decree no. 224/2003 is the Minister of Ecological Transition.

Article 12 of Italian Legislative Decree no. 224/2003 assigns the CNA the task of organising the public consultation and ensuring access to information through a specially created website listing applications for authorisation (notifications) to place GMOs on the market and for the deliberate release of GMOs into the environment for experimental purposes.

To comply with the obligations envisaged by current legislation on information and public participation in decision-making processes regarding GMOs, MiTE has created a web platform called Biosafety Clearing

House (BCH). The Italian BCH contains sections relating to public information and public consultation that are constantly being updated.

The section on public information describes the authorisation procedures at the European Union and national level for the deliberate release of GMOs into the environment for experimental purposes and for placement on the market. Moreover, all authorisation measures that have been issued are made available.

The section dedicated to public consultation. The following are subject to public consultation for each notification:

A summary of the technical file containing the information necessary for the assessment of the environmental risk associated with the deliberate release of the GMO into the environment.
An environmental risk assessment.
Any new information on risks to human, animal and environmental health.

To facilitate participation in public consultation procedures, a consultation list has been drawn up (Italian Legislative Decree no. 224/203) that includes the competent institutional entities at the central and local levels, trade associations, non-governmental environmental and consumer protection organisations and the competent departments of Italian public universities. The subjects on the list are notified at the start of each public consultation. Any natural or legal person, institution, organisation or association that so requests may be added to the list by entering the required data in the appropriate registration form, thus becoming entitled to access the documents and information regarding each new notification received. Registered entities may submit comments on the notification during the 30-day public consultation phase.

Directive (EU) 2015/412, amending Directive 2001/18/EC, provides for a two-step mechanism through which Member States may limit or prohibit the cultivation of GMOs on their territory. At the first stage, during the authorisation procedure for a GMO, the Member State which intends to restrict or prohibit its cultivation may request the applicant to restrict the geographical scope of the cultivation of the GMO. In the second stage, after the authorisation of the GMO at the level of the European Union, if the adaptation of the geographical scope has not been agreed to or has not been requested, the Member State can still adopt measures to limit or prohibit the cultivation of the GMO on grounds that must not conflict with the risk assessment for the environment and human health performed during the authorisation procedure. Directive (EU) 2015/412 was transposed into Italian law by Legislative Decree no. 227 of 14 November 2016. Public information on the measures to limit or prohibit the cultivation of GMOs on the national territory is provided through the institutional websites of the Ministries (Ecological Transition, Agricultural Policies and Health) and the Regions and Autonomous Provinces of Trento and Bolzano.

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" (dated July 21, 2007 No. 301), the turnover of GMOs and biologically active food additives is allowed only after a scientifically based confirmation of their safety, which is carried out in accordance with the procedure established by law, and their state registration, in accordance with Article 34, before the establishment of a scientifically based confirmation of the safety of GMOs in food products, the level of their content in food products is not higher than that established in the European Union states. The domestic procedure for the ratification of the amendments to the AC with regard to genetically modified organisms is being carried out. The ratification is scheduled for 2021 in accordance with the plan for the ratification of international treaties and agreements.

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

For the first time, GMO issues were included in the legislation of Kazakhstan in the mid-2000s. The start of this process was facilitated by the campaign "For Kazakhstan Free of GMOs", organized by non-governmental organizations. As part of this campaign, work was done to draw the attention of the general public to the problem of GMOs. Seminars, media coverage, cooperation with academia, consumer societies, appeals to the President, the Prime Minister, monitoring of the Kazakh market, organizing public opinion research, lawsuits against a transnational corporation using GMOs in products - all this undoubtedly influenced attitude to the problem of GMOs on the part of decision-makers. It was during this period that the beginning of the development of legislation was observed.

Thus, active public participation in the regulation of GMOs in Kazakhstan contributed to the beginning of the development of the legislative base of the Republic of Kazakhstan, which is based on the norms of the Constitution of the country, which proclaimed human rights, his life, rights and freedoms as the highest value of the state (Article 1), his right to health protection (Article 29).

The following legal acts regulate GMOs in Kazakhstan.

- Environmental Code;
- Code “On public health and health care system”;
- Law “On Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity”;
- Law "On food safety";
- Law on Consumer Protection";
- Law "On state regulation of the development of the agro-industrial complex and rural areas";
- Law "On seed production";
- Rules for carrying out work on scientifically grounded confirmation of the safety of genetically modified objects. Government Decree of April 16, 2008 N 346;
- Rules for the circulation of genetically modified objects. Government Decree of June 27, 2008 N 630;
- Technical regulation "Requirements for the safety of food products obtained from genetically modified (transgenic) plants and animals". Government Decree of September 21, 2010 No. 969;
- On the adoption of the technical regulation of the Customs Union "On food safety". Decision of the Customs Union Commission dated December 9, 2011 No. 880;
- On approval of the List of environmentally hazardous types of economic and other activities. Order of the Minister of Energy of January 21, 2015 No. 27;
- On approval of the Rules for the circulation of biologically active food additives. Order of the Minister of National Economy of June 30, 2016 No. 297.
- On the approval of the Sanitary Rules "Sanitary and Epidemiological Requirements for the Objects of Preschool Education and Training of Children". Order of the Minister of National Economy of March 17, 2015 No. 217.
- On the approval of the Sanitary Rules "Sanitary and Epidemiological Requirements for Educational Objects". Order of the Minister of Health dated August 16, 2017 No. 611.

From the above documents, the following key points of the regulation of GMO turnover in Kazakhstan can be distinguished, which form the foundations of the biosafety system:

- GMO and GM-products are classified as products that pose a threat to public health:
- Ban on the sale and sowing of genetically modified seeds;
- Ban on GMOs in fish raw materials;
- Ban on the sale of GMOs in educational institutions, in organizations of preschool education and training of children;
- Mandatory labeling and informing the buyer about the presence of GMOs in food;
- GMO production is classified as environmentally hazardous economic activity;
- Creation, breeding and production of GMO requires conclusions of scientific substantiation, state ecological and sanitary-epidemiological expertise;
- Compulsory environmental insurance in the production of GMOs;
- Mandatory registration of GMOs and maintenance of the state register of GMOs;
- Risk assessment of food products obtained by GMOs in the course of laboratory research;

- Implementation of a post-market monitoring system for agricultural producers, providing traceability to where and from where food products were sold;
- Confirmation and ensuring the safety of GMOs in the course of GMO circulation.

Activities related to the ratification of the Almaty Amendment on GMOs have been ongoing since 2015. In accordance with the terms of reference, the IAC EP provides technical support for the ratification of the Amendment. During the specified period, general procedures of coordination with specialized organizations and departmental structures were carried out, scientific expertise and expert opinions were obtained. Ratification of the amendment is scheduled for 2020-2022.

Kyrgyzstan

[available in Russian only]

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

Статья 6, пункт 11
Кыргызстан ратифицировал Картахенский протокол, ведется подготовка соответствующих нормативных актов.

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 Кыргызстан присоединился к Картахенскому протоколу по биобезопасности к Конвенции о биологическом разнообразии принимает участие в Механизме посредничества Картахенского Протокола по биологической безопасности.

В 2009 году подготовлен проект Закона «О биологической безопасности» и направлен в ПКР, но возращен на основании не изученности и преждевременности данного вопроса. Кроме этого, было предложено до введения обязательных к исполнению законодательных требований, развить национальную лабораторную базу и внедрить систему идентификации и маркировки ГИО.

В 2013 году разработан проект Закона КР «О запрете выращивания, производства, ввоза и реализации в КР продукции, содержащей генно-модифицированные организмы», инициированный депутатами ЖК КР. Однако, на основании заключения Правительства КР, проект данного Закона направлен на доработку. Создана Межведомственная рабочая группы в целях пересмотра, доработки и гармонизации положения законопроекта в соответствии с международными соглашениями. Кроме того, в заключении отмечено, что согласно статье 26 Закона КР «О нормативных правовых актах Кыргызской Республики», нормативные правовые акты, реализация которых влечет финансирование из государственного бюджета, не подлежат принятию до определения по ним источника финансирования.

В 2015 году разработан проект Закона КР «О безопасности генно-инженерной деятельности» и направлен на рассмотрение в АПКР. Отозван из АПКР в связи с разработкой проекта Экологического Кодекса КР.

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

Существующая в стране техническая основа и нормативная база не отражает необходимые аспекты регулирования биологической безопасности, в том числе контроль и регулирование биоинженерной деятельности по генетическим манипуляциям, созданию, трансграничному перемещению генетически модифицированных организмов.

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

В настоящее время в Кыргызстане не реализуются проекты с секретариатом Конвенции о биологическом разнообразии, касающиеся осуществления Картахенского протокола по биобезопасности, а также другие официальные проекты, связанные с обращением ГИО.

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 report of risk assessment;
(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 opinion of the public;

(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. In addition, 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.

264. 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:
(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's 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 in accordance with a proposal of the public, duly informing the public and consulting therewith in advance of adoption of the said rules. (GMO Law, Article 22.)

Till 1 July 2016 104 administrative territories (of the whole 110) adopted based on public consultation 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 on the website of 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.

Lithuania

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 information on the implementation of the Convention in the field of GMOs is provided at the implementation of Article 6 bis and Annex I bis.

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

In 2019, in order to fulfil obligations under the European Union law, i.e. in transposing 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 amendments of the Law on GMOs have been adopted (part of the amendments entered into force on 1 November 2020, others on 1 May 2021). These amendments detail the procedures for issuing permits and prohibiting the cultivation of GMOs in the territory of the Republic of Lithuania, including public involvement 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

Au Grand-Duché, la matière est notamment régie par la loi du 13 janvier 1997 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés. L'autorité compétente est le ministre ayant dans ses compétences la santé. La loi est consultable sur le site http://www.ms.public.lu/fr/legislation/ogm/index.html.

Il est à noter que dans le programme gouvernementale de 2013, il est dit que : «Le Gouvernement continuera à appliquer le principe de précaution en matière d'organismes génétiquement modifiés (OGM), à promouvoir une agriculture durable « sans OGM » et à défendre sa position critique face aux OGM aussi bien au Luxembourg qu'aux niveaux européen et international. Il interdira dans la mesure du possible l'utilisation d'OGM au niveau national et lancera des actions d'information et de sensibilisation en la matière.

Le Ministère (de l'Agriculture, de la Viticulture et de la Protection des consommateurs) veillera également à réduire autant que possible les importations de plantes génétiquement modifiées servant d'aliments pour animaux. A cet effet, le Ministère entend promouvoir une filière « sans OGM » au sein de l'agriculture conventionnelle de même qu'une large utilisation du label « nourri sans OGM » qui vise à garantir que des produits luxembourgeois tel s que le lait, la viande et les œufs proviennent d'animaux nourris sans aliments à base d'OGM.»

Rappelons dans ce contexte que le Luxembourg a toujours eu une position très réservée par rapport aux O.G.M., étant donné que l'innocuité de ces organismes ne fait pas l'objet d'un consensus généralisé dans la communauté scientifique.

Conformément à son approche dictée par des objectifs de prévention et de précaution, le Luxembourg a ainsi déjà dans le passé interdit la commercialisation de tels produits (Interdiction de la mise en culture du mais transgénique «Mon 810» et mise sur le marché en vue la mise en culture des pommes de terre transgéniques «Amflora» »).

Il est à relever que la commercialisation de ces organisme génétiquement modifié avait été autorisée par la Commission européenne, sans que les critiques de plusieurs États membres, dont notamment le Luxembourg, n'avaient été prises en compte.

Le Luxembourg s'est toujours opposé au niveau communautaire à l'introduction des OGM en agriculture. Depuis longtemps, l'agriculture luxembourgeoise a résolument opté pour des filières de production de qualité, afin de se démarquer positivement des produits de masse en provenance d'outre-mer et de survivre face à la globalisation et à la mondialisation croissante des échanges des produits agricoles.

Dans ce concept, visant à valoriser les atouts du terroir et offrir aux consommateurs des produits agricoles régionaux haut de gamme d'une qualité irréprochable, il n'y a actuellement pas de place pour la culture des OGM.

Le Luxembourg s'est doté d'une législation nationale très stricte en matière de coexistence entre OGM et cultures traditionnelles. Il s'agit de la loi du 18 mars 2008 sur la commercialisation des semences et plants ainsi que sur la coexistence des cultures génétiquement modifiées, conventionnelles et biologiques. (http://www.legilux.public.lu/leg/a/archives/2008/0032/a032.pdf#page=2) L'objectif est d'assurer une transparence absolue et une responsabilisation sévère concernant les cultures d'OGM. Les mesures en question confèrent une garantie et une protection maximale aux producteurs n'ayant pas recours aux OGM, vis-à-vis d'une dissémination involontaire d'OGM sur leur exploitation agricole, et continuent ainsi à garantir la liberté de choix des agriculteurs et des consommateurs.

Le Luxembourg est actuellement un pays libre de cultures d'OGM.

Le Luxembourg est devenu partie contractante au Protocole additionnel de Nagoya, Kuala Lumpur du 15 octobre 2010sur la responsabilité et la répartition relatif au Protocol de Cartagena sur la prévention des risques biotechnologiques.

Malta

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.
As regards the deliberate release of genetically modified organisms, this is regulated by the Deliberate Release into the Environment of Genetically Modified 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 (Nature and 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.

North Macedonia

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

Genetically modified organisms (GMOs)

- Rulebook on content on information for realization of risk assessment since of intentional release of GMOs. (Official Gazzete on RNM, Nb. 148/09).

The EIA Procedure is defined in Law on Environment and relevant bylaws. Subject of environmental impact assessment are the projects which due to their nature, scope, or location of their implementation, could have a significant impact on the environment. The assessment is performed compulsorily, based on criteria that determine the need to assess the environmental impact, as well as on other generally specified projects that could have a significant impact on the environment. The need to assess the environmental impact is determined by examining each specific case based on the nature, the size and the location in accordance with the stipulated criteria and considering the latest scientific and technical knowledge and decisions in the regulations that specify the lowest limits of emissions in the environment.

The state administration body competent for issues in the field of environment is obliged:

- to publish the notice on the investor's intent to perform a project, in two national daily newspapers and on the website of the state administration body competent for issues in the field of environment.
- to publish the decision on determination of the need of environmental impact assessment in two national daily newspapers, on the website and on the board in the state administration body competent for issues in the field of environment.
- to announce that the EIA study is prepared and available to the public in two national daily newspapers, on the local radio and TV station, while the non-technical report is published on the website of the state administration body competent for issues in the field of environment.
- to publish the report on the adequacy of the EIA study, in two national newspapers and on the website of the state administration body competent for issues in the field of environment.
- to publish the decision on approval or disapproval of the project realization in two national daily newspapers, on the website, as well as on the board in the state administration body competent for issues in the field of environment.
- to announce the time and place of the public hearing regarding the EIA study and to ensure availability of information that is required for the public to participate in the public hearing, in two national daily newspapers and on the local radio and TV stations.

At the request of a foreign country, the information listed above are available to the competent authorities of the foreign country, in accordance with the Espoo Convention.

The Law on Environment provides that within seven days from the day of receipt of the request for issuance of an integrated environmental permit, the Ministry of Environment and Physical Planning is obliged to publish the request in two daily newspapers that are available on the entire territory of the RNM and on its website, as well as within 15 days from the publishing of the request, to provide to the public an access to the available information required for formation of opinions and attitudes, in accordance with the provisions of this law. Any person, the state authorities, as well as the municipalities, the City of Skopje, and the municipalities in the city of Skopje, can submit their opinion in writing, to the Ministry of Environment and Physical Planning within 30 days from the day of publication of the application of integrated environmental permit. The Ministry of Environment and Physical Planning is obliged to consider the opinions when issuing the permit.

The units of the local self-government provide public participation and access to all relevant information, in the procedure for issuance of B integrated environmental permits. Within 30 days from the publication of the request for issuance of an integrated permit, the affected public can submit their opinions and attitudes in writing.

In process of issuing the A-integrated environmental permit, the Ministry of Environment and Physical Planning is obliged, within the A integrated environmental permit, to indicate which of the opinions and the attitudes that are delivered by the public have been considered, and which have not been considered, and the reasons for this. At the request of the affected public, the investor is obliged to organize a public hearing.

Among other things, the law is based on the principle of non-discrimination. According to the Constitution of the Republic of North Macedonia, the citizens are equal in their freedoms and rights regardless of sex, race, skin color, national and social origin, political and religious beliefs, property, and social status.

The intentional release of genetically modified organisms (GMOs) in the environment is regulated in chapter 5.1 Intentional release of GMOs or a combination of GMOs in the environment in the Law on Genetically Modified Organisms. According to Article 34 of the Law, any notifier, before performing intentional release into the environment must submit a notification to the Ministry of Environment and Physical Planning, which specifically contains technical documentation that includes information required for assessing the risk because of the intentional release of GMOs and risk assessment.

Within five days from the day of receipt of the complete notification, the Ministry of Environment and Physical Planning is obliged to publish a short summary on the website and to publish it in two daily newspapers on the territory of the Republic of North Macedonia. The public can deliver its opinion within 30 days from the day of publication. The Ministry is obliged to provide public access in the data of the notification, the risk assessment, the report on assessment of GMOs and other information accompanying the notification. When issuing the permit, the Ministry is obliged to consider the timely submitted opinions and comments. Within 90 days from the day of receipt of the complete notification, the Ministry of Environment and Physical Planning issues a permit for intentional release of GMOs or with a decision it rejects the notification if the requirements for intentional release of GMOs have not been met.

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

Law on genetically modified organisms

Article 12, Public consultations, and notifications. The state administration body competent for issues in the field of environment shall be obliged, within five days after receiving the complete notification, to announce short contents of the notification on receiving a license for limited application of GMO, the notification on receiving a license for intentional release of GMO in the environment, and the notification on receiving a license for releasing GMO products on the market on its web site and in two newspapers available throughout the territory of the Republic of North Macedonia, on account of the user, that is the notifier.

Data regarding the place where insight in the notification data is enabled shall be indicated in the announcement.

The public and the citizens' associations can submit their opinion on the notifications referred to in paragraph to the state administration body competent for issues in the field of environment within 30 days from the day of publication.

The state administration body competent for issues in the field of environment shall be obliged to enable the public and the citizens' associations to insight into the notification data, including the emergency cases plan, the report on GMO product assessment, the opinion received from the Scientific Committee on GMO, opinions received by other competent bodies, as well as other information following the notification.

The form and content of the announcement shall be prescribed by the minister of the state administration body competent for for issues in the field of environment.

The manner and procedure for public participation in issuing licenses for limited application of GMO, its intentional release in the environment, placement of GMO products on the market as well as other information related to GMO application shall be prescribed by the minister heading the state administration body competent for issues in the field of environment.

In the process of issuing a license for limited application of GMO, license for intentional release of GMO in the environment and/or license for releasing GMO products on the market, the state administration body shall take into consideration only promptly submitted opinions and comments.

In the process of issuing the licenses, the time necessary for the public consultation shall not be calculated into the deadline determined for license issuance.

Based to Article 12 of the Law on Genetically Modified Organisms (Official Gazette of RSM no. 35/08 and 163/13), the following bylaws were adopted:

- Rulebook on the form and content of the form of the license for export of GMO and / or GMO products (Official Gazette of RSM no. 23/14)
- Rulebook on the manner and procedure for public participation in the issuance of permits for limited use of GMOs, for intentional release of GMOs in the environment, for placing GMOs on the market, as well as other information related to the use of GMOs (Official Gazette of RSM No. 23/14).

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

There is a need to increase the number of people responsible for implementing GMO legislation.

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

The practical application of the provisions on public participation in decisions on intentional release into the environment and placement of genetically modified organisms in accordance with Article 6 has not been initiated.

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 2, 1993 no. 38, as well as the Regulations on Impact Assessment of December 16 2005 no. 1495. EU directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms has been incorporated into the EEA Agreement and the Directive as well as the Cartagena Protocol on biosafety 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 Freedom of 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:

the description of the genetically modified organism, the user's name and address, the purpose of the use and the location of use methods and plans for monitoring and emergency response 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 Freedom of 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.

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

No obstacles have been encountered in the implementation of any of the paragraphs of article 6bis and annex I bis.

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, Annex I a.
The provisions of the CAP determine the issue of making information available to parties in connection with the pending proceedings. The provisions of the Act on Provision of Information about the Environment concerning the public participation procedure provide for making information available in connection with the

proceedings conducted by the authority. Pursuant to the CAP, the application of the above- mentioned procedure is required when issuing certain administrative decisions, such as the integrated permit, decisions issued under the Act of 22 June 2001 on Microorganisms and Genetically Modified Organisms (Journal of Laws of 2020, item 322), hereinafter referred to as the "GMO Act", or with respect to decisions on environmental conditions. The provisions that the Amendment to the Aarhus Convention on Genetically Modified Organisms contains are also reflected in the provisions of the GMO Act. At the same time, Article 14a of the GMO Act precisely defines the information on GMOs that shall be made available. The public has the right and opportunity to become acquainted with the application and documentation. This is done through the GMO registers that operate on the website of the Ministry of Climate and Environment.

Portugal

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

With regard to Genetically Modified Organisms (GMOs), no notifications were submitted to APA in the period between 2017 and 2019-2020, for deliberate release of GMOs into the environment under Decree-Law No. 72/2003 of 10 April.

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

(a) **Article 6 bis, paragraph 1**
Annex I bis, 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 its 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 bis, 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 bis, 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 bis, 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:

1. Description of the GMO, name and address of the notifier, purpose and location of release
2. Methods and plans for monitoring the GMO and for the emergency response
3. Assessment of environmental risks.

Annex I bis, 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 bis, paragraph 6

Decree-Law No. 72/2003 of 10 April establishes in its article 11 that the general public is to be consulted prior to a decision being made 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 by means of an advertisement in 2 national newspapers, and, if possible, on a regional or local level, showing the exact location where the information can be viewed and indication of the start and end dates of the public consultation. This information is also made available on the PARTICIPA http://participa.pt website.

Annex I bis, paragraph 7
The outcome of the public participation was taken into account when making the decision. Each response received which is directly related to the object of the consultation, i.e. with the respective notification, was analysed in all public consultation processes.

Annex I bis, paragraph 8
Texts of the decisions made with regard to the deliberate release of GMOs into the environment, or with their being placed on the market, are published on the APA website at https://apambiente.pt/prevencao-e-gestao-de-riscos/organismos-geneticamente-modificados.

(b) **Article 6 bis, paragraph 2**
The provisions of article 6 bis have been included in national legislation since 2003 (see text in Annex I bis, paragraph 6).

Ratification of the Cartagena Protocol on Biosafety, through Decree No. 7/2004 of 17 April, has 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 bis.

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

APA encourages 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 bis, paragraph 6).

Republic of Moldova

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.

According to provisions of letter (a), para. (1) art.20 of Law No. 755/2001 on biological security after receipt of notification , on the basis of the information contained in the notification, the National Commission for Biological security is obliged to inform and consult the public about the notification received.

Para. (2) of art. 39 of Law 755/2001 provides that the public shall be informed within 10 days since the notification is received, and the public is entitled to give an opinion within 30 days and follows to be taken into account by the National Commission when making the decision of authorizing the activity proposed. Depending on the comments received, there could be held public debates on any biosecurity issues.

During the years 2017-2020 the National Commission for Biological Security had examined 31 applications and notifications from economic operators related to authorization of importing genetically modified cake from soya beans. The applications and notifications have been placed on the website of the Ministry of Agriculture, Regional Development and Environment for public information and consultation.

In order to harmonise the national legislation with Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, a new draft law on genetically modified organisms has been drafted. The draft law contains mandatory provisions on transparency, information and consultation of the public in the process of making decisions on introduction of GMOs and products resulting from them.

The draft law was consulted with the institutions involved and civil society by publishing it on the website of MARDE www.madrm.gov.md upon the decisional transparency Directory and on the government portal www.particip.gov.md

(https://www.madrm.gov.md/ro/content/anun%C8%9B-privind-ini%C8%9Bierea-elabor%C4%83rii-proiectului-legii-privind-organismele-modificate-genetic

https://cancelaria.gov.md/sites/default/files/document/attachments/proiectul_515.pdf

https://particip.gov.md/ro/document/stages/anunt-despre-consultari-publice-la-proiectul-legii-privind-organismele-modificate-genetic-numar-unic-515madrm2020/7542

At the same time, the draft law was presented to civil society in the framework of two seminars organized within the project "Increasing the competitiveness of the agro-food sector by integrating it into domestic and global value chains, especially in the soybean sector"

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

Law no. 755/2001 on on biosecurity regulates the activities related to the obtaining, testing, production, use and trade of genetically modified organisms through modern biotechnology techniques. The human organism is not subjected to genetic modification.

According to provisions of letter (a), para. (1) art.20 of Law No. 755/2001 on biological security after receipt of notification , on the basis of the information contained in the notification, the National Commission for Biological security is obliged to inform and consult the public about the notification received.

Para. (2) of art. 39 of Law 755/2001 provides that the public shall be informed within 10 days since the notification is received, and the public is entitled to give an opinion within 30 days and follows to be taken into account by the National Commission when making the decision of authorizing the activity proposed. Depending on the comments received, there could be held public debates on any biosecurity issues.

The applications and notifications have been published on the website of the Ministry of Environment for public information and consultation.

In order to harmonise the national legislation with Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, a new draft law on genetically modified organisms has been drafted. The draft Law contains mandatory provisions on transparency, information and consultation of the public in the process of making decisions on introduction of GMOs and products resulting from them.

Another normative act is the Regulation on the authorization of activities related to obtaining, testing, use and trading of genetically modified organisms, approved by GD no. 1153 as of 25-09-2003, which establishes the procedure of issuing the authorizations for the activities of obtaining, testing, use and trading of genetically modified organisms through the modern biotechnology techniques and products resulting from them.

(a) With respect to paragraph 1 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;

Thus, in the case of deliberate introduction into the environment of genetically modified organisms according to the provisions of art.19, para. (1) any natural or legal person, before introducing into the environment a genetically modified organism or a combination of such organisms, for the purpose of research, testing, development and/or for any other purpose, except production for placing on the market, shall submit a notification to the National Commission.

According to point 18 of the Regulation on the authorisation of activities related to the acquisition, testing, use and trading of genetically modified organisms for authorizing the activities that view the deliberate introduction of genetically modified organisms in the environment, it shall be taken into account that:

a) the genetically modified organisms appear by using the techniques indicated in point.8 lit.(a) of this Regulation;

b) the techniques that are not considered to generate genetic changes are indicated in point 8 lit.(b) this Regulation.

Point 22 sets out the list of documents submitted by economic operators to the National Commission for authorisation of activities that view the deliberate introduction on the market of genetically modified organisms and products resulted from them.

(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;

Art. 39, para.(1) of Law No. 755/2001 stipulates that within 10 days from the date of receipt of the notification, the National Commission shall inform the public about it, specifying the ways in which the information may be obtained.

(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;

The Competent Authority shall consult and inform the public in the decision-making process, in compliance with the legislation in force on public access to information and on confidentiality.

Art.11 (1) of Law No. 755/2001 on biological safety in the notification sent to the National Commission, the notifier may indicate the information that will be considered confidential, also providing the necessary justifications, and according to para. (2) of this article, the decision on the information that will be deemed as

confidential, shall be taken by the National Commission, after consultations with the notifier and shall bring it to his attention.

According to art. 11 para. (2) the following information cannot be considered confidential:

(a) general characteristics of genetically micro-organisms/genetically modified organisms, name and address of the notifier, purpose and place of use;
(b) the risk class where the use in isolated conditions and containment measures are included;
(c) conclusions of human health and environmental risk assessment studies;
(d) monitoring methods and plans, as well as measures that may be taken in the event of an accident.

If, for any reason, the notifier withdraws his notification, the National Commission shall respect the confidentiality of the information received, a regulation established in art. 11 paragraph (5) of the same Law.

(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 such case the decision shall refer to the issuance of authorisation of deliberate introduction in the environment or to the agreement of import, of the decision to renew the authorisation or suspend or cancel as appropriate.

b. The public authority responsible for making the decision;
Competent National Authority - National Commission for Biological Security.

c. Public participation arrangements laid down pursuant to paragraph 1 of annex I bis;
Law no. 755/2001 on Biological Safety lays down the procedure of public consultation in case of the procedure of authorising the deliberate introduction of genetically modified organisms into the environment.

Within 10 days from the date of receipt of the notification, the National Commission shall inform the public about it, specifying the ways in which the information may be obtained. The comments of the public shall be received within 30 days from the date of their notification and are taken into account by the National Commission when making the decision to authorize the proposed activity. Depending on the comments received, there could be held public debates on any biosecurity issues.

d. An indication of the public authority from which relevant information can be obtained;
National Commission for Biological security-the Competent Authority has the task to consult and inform the public in the decision-making process, in compliance with the legislation in force on public access to information.

Thus, the Competent Authority shall publish on the website of the Ministry of the environment under the heading ”National Commission for Biological Security " the notification and the set attached to the application.

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 the provisions of art. 39 para. (3) of Law No. 755/2001 the comments of the public shall be received within 30 days from the date of their notification and are taken into account by the National Commission when making the decision of authorizing the proposed activity. Depending on the comments received, there could be held public debates on any biosecurity issues.

(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;

(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;

During the authorization procedure of deliberate introduction in the environment, for testing purposes, the observations of the public are taken into account.

Thus, according to the provisions of art. 39 para. (3) of Law No. 755/2001 the comments of the public shall be received within 30 days from the date of their notification and shall be taken into account by the National Commission when making the decision of authorizing the proposed activity. Depending on the comments received, there could be held public debates on any biosecurity issues.

At the same time, according to the provisions of point. 29 of the Regulation on the authorisation of activities related to the obtaining, testing, use and trading of genetically modified organisms, the National Commission shall inform the notifier within maximum 90 days about the receipt of the notification, noting that:
(a) the notification received is in accordance with the provisions of the legislation in force;
(b) the notifier shall submit additional information;
(c) the proposed activity does not meet the requirements of the Biosafety Law and this Regulation and the notification is rejected; or
(d) the proposed activity is not subjected to the provisions of the Law on biological security and this Regulation.

According to the provisions of art. 39 Law No. 755/2001, the National Commission shall inform the public, specifying the ways in which the information can be obtained. During the consultation, the public shall forward its comments to the National Commission.

(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;

Art. 39 para. (4) of Law No. 755/2001, the National Commission shall ensure the public participation in the decision-making process related to the authorization of activities regulated by this law in accordance with the provisions of national legislation and international legal acts to which the Republic of Moldova is a party.

(b) Regarding paragraph 2 of article 6 bis, the manner in which the the requirements made in accordance with the provisions of Annex 1 bis are complementary and support mutually the national framework on biosecurity of the Party and are consistent with the objectives of the Cartagena Protocol on biosecurity to the Convention on biodiversity

The Republic of Moldova has ratified the Cartagena Protocol on biosecurity at the Convention on Biological Diversity by Law no. 1381 as of 11-10-2002.

Thus, the Republic of Moldova, as a party, by provisions of the normative acts provides that the production, handling, transportation, use, transfer and introduction of any genetically modified organism shall be carried out in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.

The legislation provides that the National Commission for Biological Safety - the Competent Authority has the task to consult and inform the public in the decision-making process, in compliance with the legislation in force on public access to information.

The procedure of authorisation of activities related to the acquisition, testing, use and trading of genetically modified organisms is governed by the Regulation on the authorisation of activities related to the acquisition, testing, use and trading of genetically modified organisms, approved by GD no.1153 as of September 25, 2003.

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

Public perception on the import and use of genetically modified organisms or products is negative, but usually the public rarely reacts to notifications filed by economic operators for the import of genetically modified fodder.

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

According to point 21 of the Regulation on the authorisation of activities related to obtaining, testing, use and trading of genetically modified organisms for the approval of activities related to the deliberate introduction into the environment of genetically modified organisms, the National Commission may apply, as appropriate, the rules and criteria of simplified procedures, provided that:

- the taxonomic position and biology of genetically modified organisms is well known and has information on risk assessment involving plant species and other organisms in the experimental ecosystem;
- there is scientific data resulting from the experimental introduction into the environment of genetically modified plants belonging to the same species of receiving plants;
- the inserted sequences with the result of their expression are safe for human health and environment under the conditions of experimental introduction;
- the inserted sequences are well characterized and integrated into the nuclear genome of the plant.

And in point 27, (e) it is established that, when taking decisions on the activity requested in the notification, the National Commission shall take into account the comments of the public, which are of an advisory nature and are received within 30 days from the date of its information. Depending on the comments received, may hold public hearings on all aspects of the issues examined.

Romania

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.

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:

1. 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;

2. the monitoring plans of the genetically modified organism and methods of intervention in case of emergency;
3. risk assessment on human health and the environment;
4. the opinions of Biosafety Commission 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 Commission.

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 Commission 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, Article 21. Article. 32, Article 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.

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 Ministry of Agriculture, Forestry and Water Management (hereinafter: MAFWM)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 MAFWM 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.

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.

- Ministry of Agriculture, Forestry and Water Management 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 Ministry of Agriculture, Forestry and Water Management, 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

Ad 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 the 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 ZRGSO governs the management of genetically modified organisms (hereinafter: GMOs) in a closed system, the deliberate release of GMOs into the environment and the placing of products on the market.

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 preceding 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 is required to 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 is required to issue annual reports on their work in the preceding year, which are to be sent 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 11a, 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 to limit its effects and prevent similar accidents in the future; 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 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, last amended in 2008, 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, Nos. 127/06 and 90/12 – ZdZPVHVVR), the Co-existence of Genetically Modified Plants with Other Agricultural Plants (Official Gazette of the Republic of Slovenia, 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, Nos. 52/00, 42/02, 47/04 – ZdZPZ), and the Agricultural Seeds and Propagating Material Act (Official Gazette of the Republic of Slovenia, Nos. 25/05-UPB, 41/09, 32/12 and 90/12 – ZdZPVHVVR and 22/18).

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, 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).

Some difficulties have been detected in applicants for information accessing certain databases referred to on the website itself. With the implementation of the Re-use Plan, access to data generated by the Public Authorities in exercising its functions has been simplified.

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

MITERD's website makes available to the public information related to the activities that are carried out in Spain with GMOs and reports are published setting out the results of the voluntary release notices, as well as the authorizations granted by the Interministerial Council on GMOs. It also gives information about current EU, national and regional legislation concerning GMOs. For example, in the Autonomous Community of Madrid, the information is available at http://www.comunidad.madrid/servicios/medio-rural/organismos-modificados-geneticamente

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

The provisions approved in this area are as follows: Law 9/2003, of 25 April, setting out the legal regime for contained used, voluntary release and commercialization of genetically-modified organisms, Royal Decree 178/2004, of 30 January, passing the general Regulation for the implementation and execution of the aforementioned Law, amended by Royal Decree 191/2013, of 15 March, and by Royal Decree 452/2019, of 19 July,

Royal Decree 367/2010, of 26 March, amending various regulations concerning the Environment to bring them in line with legislation on free access the service activities (Law 17/2009 and Law 25/2009) and Royal Decree 191/2013. These rules have been transposed into Spanish legislation various EU Directives and Regulations whose purpose is to protect human health and the environment from the possible effects derived from the use of these organisms.

Order ARM/2616/2010, of 5 October, setting out the composition and operation of the Participation Committee in the framework of the Interministerial Council on Genetically-Modified Organisms.

Order APA/1083/2018, of 8 October, setting out measures to prevent cross-border pollution derived from the cultivation of genetically-modified corn towards neighboring member states in which the cultivation of said genetically-modified organisms is prohibited.

In the aforementioned legislation, the Interministerial Council on GMOs and the National Biosafety Commission are described as the Competent Authority at the national level, and, at regional level, each of the Autonomous Communities is so described according to the competences they hold in GMO matters.

Regarding release of GMOs into the environment, information is not considered confidential where it is a description of genetically-modified organisms, the identification of the owners, the purpose, the location of the activity, the emergency and control measure systems, the assessment of the effects for human health and the environment, information about voluntary releases made, commercial authorizations granted, a list of the genetically-modified organisms who commercialization has been authorized or rejected as products or product components, the assessment reports, the results of the controls on commercialization, the reports of the scientific committees consulted.

In this context, public means any natural or legal person, public concerned means non-governmental organizations that work on the conservation or protection of the environment, the seed industry, agricultural trades unions, workers' trades unions, consumer organizations, the human and veterinary pharmaceutical industry, and the agricultural and livestock production industry.

The sectors concerned, national professional agricultural organizations, agri-food cooperatives and consumer and user organizations are represented on the Participation Committee attached to the Interministerial Council on Genetically-Modified Organisms.

As regards the non-discrimination requirement set out in article 3, paragraph 9, the Spanish Constitution of 1978 is directly applicable, specifically article 14, which provides that Spaniards are equal before the law and that there may be no discrimination on account of birth, race, sex, religion, opinion or any other personal or social condition or circumstance.

Paragraph 1 of annex I bis
Article 25 of the aforementioned Royal Decree 178/2004 indicates at point 4 that the competent body shall subject the voluntary release project to public information for a period of 30 days. It also describes what information must be made available to the public.

Paragraph 2 of annex I bis
Article 28 of Royal Decree 178/2004 sets out the possibility of establishing differentiated procedures when sufficient experience has been acquired in specific ecosystems and when the criteria in annex VI of the aforementioned Royal Decree are met.

Article 29 of the same Royal Decree sets out the option of a simplified procedure when several voluntary releases of vegetables that have been generated from the same cultivated recipient plants but which may differ in any of the sequences inserted or deleted or have the same sequence inserted or deleted, but differ in their phenotypes.

Paragraph 3 of annex I bis
In the event of voluntary release without the intention to commercialize, article 25.4 of Royal Decree 178/2004, on the procedure to follow once the request has been received, provides that the competent body shall subject the voluntary release project to public information for 30 days. The information given to the public must include a summary of the file, which shall include the environmental assessment report.

In the event of commercialization, Transitional Provision Two refers to the procedure for renewing previously-granted commercialization authorizations, which is implemented in article 41 of Royal Decree 178/2004.

Paragraph 4 of annex I bis
Article 20.2 of Law 9/2003 specifies what part of the information provided by those responsible for activities regulated by the law, is not confidential and therefore can be supplied to citizen without any kind of restriction.

Paragraph 5 of annex I bis
MITERD has a website that is accessible to everyone. Within this website, there is a section dedicated to Genetically-Modified Organisms:
https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/.

On this website, the user can find information about the structure of the Administration in the context of GMOs, how decisions are made and who is responsible for making them, the channels for public participation and the contacts at the Ministry who can provide any information related to the releases of GMOs into the environment, besides links to other pages of interest.

Paragraph 6 of annex I bis

The website of the Directorate-General of Quality and Environmental Assessment includes the option to engage in public participation, for both voluntary release activities and contained activity. https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/participacion-publica/

This website describes the procedure that a citizen must follow to submit observations or objections or to request further information about either of the procedures.

Paragraph 7 of annex I bis

Article 16 of Law 27/2006, of 18 July, regulating the rights of access to information, of public participation and of access to justice in environmental matters, sets out the procedure to follow, once a contribution has been received from a citizen through the channels provided for doing so.

Paragraph 8 of annex I bis

Further Provision three of law 9/2003 provides that the competent authorities shall create public registers which shall record the location of the genetically-modified organisms released for purposes other than commercialization, as well as the location of those that are cultivated according to this law for commercialization.

Article 27 of the aforementioned Royal Decree 178/2004 concerns the obligation to give information about voluntary releases of GMOs into the environment without the party responsible for the releases having any intention of commercializing.

Article 49 of the same Royal Decree concerns information for the public and states that information must be made available to the public that related to contained use authorizations, voluntary release for purposes other than commercialization and the commercialization of genetically-modified organisms.

The GMO website within the aforementioned MITERD website, as well as the MAPA website contain all the data included in the public Register and it is freely accessible to all citizens.

Paragraph 2 of article 6 bis

All the foregoing legislative, regulatory and other measures lie within our national biosafety framework and are consistent with the aims of the Cartagena Protocol on Biosafety, specifically articles 23, on Public Awareness and Participation, and 21, on confidential information in said protocol.

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

The main difficulty has been clearly differentiating between information that is not confidential and that which is protected by intellectual property rights. In this regard, providing certain data, specifically, the exact location of experimental plot, could put the tests themselves at risk, with the resultant financial losses for the company or the public institution responsible for them. Two reports from the Government legal services and a decision by the Interministerial Council on GMOs to clarify the level of detail in which the information must be supplied, always in the strictest compliance with the law.

Finally, some isolated cases of vandalism have been recorded on experimental plots once the location coordinates of the genetically-modified crop trials had 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, statistics are prepared annually about the number of requests for information, related to GMOs, through the various channels (telephone, email, postal mail).

At the following address:

https://www.miteco.gob.es/es/ministerio/servicios/informacion/informenacionaldecumplimientoespanol2016_tcm30-378874.pdf
citizens are given information about the topics that most often concern the citizenry 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 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 summary of applications for field trials before decisions are made.

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 and has a web portal with information on gene technology and the regulatory framework that applies to GMOs (www.genteknik.se).

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 their use does not endanger human health or 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 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.

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 the safety and quality of food” (2014), state registration of GMOs is not allowed (Article 9, Part 4); the use of GMOs in the production of food products, materials and products (Article 19, Part 9) and the import into the territory of Turkmenistan of food products, food additives, materials and goods produced using GMOs (Article 27, Part 5).

The Law of Turkmenistan “On seed production” (2010) prohibits the import of genetically modified products for food purposes.

In accordance with the Decree of the President of Turkmenistan of February 27, 2009 “On the organisation of licensing activities in Turkmenistan” (with amendments on June 23, 2014 No. 13722), it was established that activities in the field of genetics, microbiology and the ones associated with the use of genetically modified organisms and pathogens of infectious diseases are not subject to licensing and can only be carried out by authorised government agencies.

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

1. Turkmenistan has not yet ratified the Aarhus Convention’s GMO Amendment.

2. At the Centre of Technologies of the Academy of Sciences of Turkmenistan, a Laboratory for the identification and analysis of products containing GMOs was established and started functioning in 2014. At the same time, in order to improve the efficiency of this laboratory, it is important to take the necessary measures to train and attract the necessary personnel for it. The issue of capacity building in branches related to the monitoring of GMO products, work related to the use of biotechnologies that can have an adverse effect on biodiversity and research into GMOs and food products from them remains open.

Ukraine

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.

Article 13 Part 3 of Law of Ukraine No. 1103-V "On implementation of state biosafety system during creation, testing, transportation and use of genetically modified organisms" of 31 May 2007 (the "Biosafety Law") prohibits the release of genetically modified organisms (GMOs) into the environment before they have been duly registered.

The state environmental expert conclusion should be attached to the registration application pursuant to Paragraph 4 of the Procedure for State Registration of Cosmetics and Medications Containing or Derived from Genetically Modified Organisms adopted by the Cabinet of Ministers of Ukraine on 18 February 2009, Decree No. 114. The conclusion is prepared with due account taken to public opinion (Article 1 1 Part 3 of Law of Ukraine "On Ecological Expert Evaluation").

Paragraph 2 of the Procedure for State Registration of Genetically Modified Organisms of

Agricultural Plant Varieties in Open Systems adopted by the Cabinet of Ministers of Ukraine on 23 July 2009, Decree No. 808, requires that state environmental expert conclusions are attached to applications for state registration of genetically modified organisms of agricultural plant varieties in open systems. The conclusion is prepared with due account taken to public opinion (Article 11 Part 3 of Law of Ukraine "On Ecological Expert Evaluation").

Prior to state registration, GMOs may only be released into the environment for state approbation (testing) purposes. Such release of GMOs is only allowed with the permission of the Ministry of

Ecology and Natural Resources of Ukraine (the "Ministry of Environment") (Article 13 Part 4 of the Biosafety Law). Paragraph 5 of the Procedure for Issuing Authorizations for State Approbation (Testing) of Genetically Modified Organisms in Open System adopted by the Cabinet of Ministers of

Ukraine on 02 April 2009, Decree No. 308, (Procedure 308) states that the applicant must apply to the Ministry of Environment as described in Annex 2 to Procedure 308. Paragraph 5 of the Authorization Application Form requires that the applicant also provides copies of the minutes of public hearings.

This means that the aforesaid authorisation may not be obtained without public hearings.

Law of Ukraine "On Environmental Protection", Law of Ukraine "On Ecological Expert Evaluation" and Law of Ukraine "On Fauna" introduce the ecological expert evaluation procedure for modem biotechnology products.

Paragraph I .4.4 of Regulations for Public Participation in Environmental Protection Decision-making Process, in addition to the types of decisions on the issues that affect or may affect the state of the environment and require public participation, includes the obligation to issue documents for the deliberate release of genetically modified organisms into the environment.

After the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, was signed in 2014, a number of obligations became effective as to the implementation of EU's GMO Directives which require public participation in making decisions associated with GMOs management.

In pursuance of Decree No. 847-r "On implementation of the Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part" issued by the Cabinet of Ministers on 17 September 2014, working groups were established to implement Directive 2001/18/EC on the deliberate release of GMOs into the environment, Directive 2009/41/EC on the contained use of GMOs and the Regulation on Transboundary Movement of GMOs.

In 2015, the Verkhovna Rada of Ukraine received a draft law on amendments to Law of Ukraine "On implementation of state biosafety system during creation, testing, transportation and use of genetically modified organisms" (pertaining to the introduction of a simplified procedure for the registration of EU-registered GMOs and GMO-derived products in Ukraine).

The Parliament decided to postpone the ratification of the GMO amendment until the adoption of the new version of Law of Ukraine "On implementation of state biosafety system during creation, testing, transportation and use of genetically modified organisms", which will ensure compliance with the Directive and the GMO amendment to the Aarhus Convention.

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

The relations among executive authorities, producers, sellers (suppliers), developers, researchers, scientists and consumers of genetically modified organisms and products produced using technologies that involve GMO development, creation, testing, studying, transportation, import, export, marketing, release into the environment and use in Ukraine (hereinafter referred to as "GMO Handling") while guaranteeing biological and genetic safety are defined by Law of Ukraine "On implementation of state biosafety system during creation, testing, transportation and use of genetically modified organisms" (hereinafter referred to as "Law"). Pursuant to the provisions of Article 9 of the Law, the central executive agency implementing the national environmental protection policy:

- carries out state ecological expert evaluation of GMOs intended for use in an open system; - carries out state registration of plant protection products manufactured with the use of GMOs; - issues authorisations for the release of GMOs in an open system.

After the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part,

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In accordance with the applicable legislation, the Ministry of Environment is the main body in the central executive agencies system responsible for the formulation and implementation of the national environmental protection policy, waste management, sustainable use, recovery and protection of natural resources.

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

The duration of the policy-making process is not regulated.

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

A testing laboratory accredited by the National Accreditation Body of Ukraine, a full member of the International Laboratory Accreditation Cooperation (ILAC), operates at "Sumystandartmetrologiia" State-owned Enterprise in accordance with ISO/IEC 17025, State Standard ISO 17025, and State Standard ISO/IEC 17025 — for technical competence and independence.

The testing laboratory conducts research of food samples of all groups of agricultural materials for compliance with the state and sectoral standards and product specifications such as quality, safety and GMOs.

The testing laboratory of molecular genetic research of genetically modified organisms operating at "Sumystandartmetrologiia" State-owned Enterprise analysed 2,370 product samples for GMOs and detected GMOs in 7 samples in 2014. GMO testing in 2015 was conducted using 1,274 samples of food products and food materials, and GMOs were detected in 16 samples.

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://eurlex.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.

[1] References to legislation are as amended.

[2] DCLG is currently in the process of implementing European Directive 2014/52/EU; a recent consultation sought views on draft regulations which will replace the existing regulations implementing the requirements of the Environmental Impact Assessment Directive insofar as they apply to the town and country planning and nationally significant infrastructure regimes.

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.

The UK recognises the importance and value of participation by stakeholders and the public in consideration of applications for approval of genetically modified crops.

Prior to EU Exit, new applications to market traits for GM feed or food since 2004 were made under Regulation 1829/2003, which set out a requirement for a mandatory written 30-day public consultation period that must

happen before the GM traits for food or feed use could be approved at EU level for marketing. Article 6 (7) [food] & Article 18 (7) [feed] requirements in our retained EU regulation 1829/2003 have been kept and amended in the EU Exit Statutory Instrument (SI) to reflect the same intention. (https://www.legislation.gov.uk/uksi/2019/705/regulation/10/made; https://www.legislation.gov.uk/uksi/2019/705/regulation/22/made).

Transparency and public participation is a fundamental principle contained within the UK's regulation. The FSA intends to remain as transparent as the EFSA through its own wider Risk Analysis process, which is currently being developed and scheduled for 2021.

UK Competent Authorities publish applications for the deliberate release of GMOs allowing public access to non-confidential information; invite representations on potential risks of damage being caused to the environment by the proposed release; publish advice from the UK's independent, statutory Advisory Committee on Releases to the Environment; publish the decision on the application; publish a list of locations where GM trials have, or are, taking place; and hold information, including representations made, on a public register accessible by contacting the relevant Competent Authority.

In the case of GM research trials, Competent Authorities in the UK take their own decisions in accordance with the relevant regulations. 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 is made on the gov.uk website (https://www.gov.uk/genetically-modified-organisms-applications-and-consents) where a full copy of the application (excluding commercially sensitive information) is placed; information is repeated on the public register. 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 GM trail 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 any risks of damage being caused to the environment 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 independent 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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