European Advisory Committees on Biosafety

In the field of contained use and deliberate release of GMOs

Description of tasks and responsibilities

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Contents

Introduction

At the 10th Meeting of the European Advisory Committees on Biosafety in the field of contained use and deliberate release of GMOs (March 2023, Amsterdam) representatives of nineteen different countries and twenty-nine organisations were present. The attendees of the MEACB expressed the wish to have an up-to-date overview of European GMO Advisory Committees, their tasks and contact details. The Netherlands Commission on Genetic Modification (COGEM) therefore asked them to provide information on their advisory committee and used this information to compile this booklet.

European GMO Advisory Committees that are not yet included in the booklet are invited to send information on their committee to COGEM. Please also contact COGEM if information on your advisory committee needs to be updated. COGEM will update the booklet when it receives new information. Updated versions of the booklet will be available upon request, and an up to date public version of the booklet (without personal contact details) will be published on our website: www.cogem.net

COGEM can be contacted via info@cogem.net

Austria

Austrian Advisory Board on Gene Technology and scientific boards

The Austrian Advisory board on Gene technology (Gentechnikkommission) and the three respective scientific boards (wissenschaftliche Ausschüsse) are implemented by Austrian law. The competent authority is the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz).

The Advisory board give advice to the federal ministry regarding on issues of gene technology and propose chapters of the book on gene technology (Gentechnikbuch). They are also involved in preparing the annual reports on the use of gene technology, based on Austrian law.

The members of the Advisory board are proposed by the Austrian Academy of Science, various federal ministries and institutions (e.g. the Austrian Chamber of Labour, the Austrian Chamber of Agriculture and the Austrian Chamber of Commerce). The members then will be nominated by the federal minister of Social Affairs, Health, Care and Consumer Protection for a period of five years

There are three scientific boards established at the federal ministry: the scientific board for contained use (2009/41), the scientific board for deliberate release and placing on the market (2001/18), and the scientific board for genetic analyses.

The scientific board of contained use give mandatory advice for applications in BSL 3 and 4, with regrade on the safety precaution measures, provides statements regarding the safety levels of GMOs, prepares chapters of the book on gene technology and provides statements regarding ordinances according to the Gene technology Law (Gentechnikgesetz).

The scientific board of deliberate release and placing on the market assess applications for deliberate release of GMOS into the environment and applications for placing on the market, prepares chapters of the book on gene technology and provides statements regarding ordinances elated to the Gene Technology Law.

The scientific board for genetic analyses assess applications for genetic analyses for human medical uses, prepares sections of the book on gene technology and provides statements regarding ordinances according to the Gene Technology Law.

The members of the scientific boards are proposed by the Austrian Academy of Science, several federal ministries and institutions (e.g. the Austrian medical universities and the Austrian theological faculties). The members are nominated by the federal minister of Social Affairs, Health, Care and Consumer Protection for a working period of five years

Belgium

The Service Biosafety and Biotechnology (SBB) of Sciensano

The SBB was created in 1995 and is composed of a multidisciplinary group of about ten scientists performing scientific expertise and research focusing on biosafety-related matters. The SBB is a unit of Sciensano, the Belgian Scientific Institute of Public Health. As part of a public scientific institution, the SBB holds an independent position with regard to expertise in biosafety, accessible to any public or private organisation.

Scientific support to the authorities
The official tasks of the SBB are defined by Law. The main task is to assess the risks for human health and the environment potentially associated with any activities involving GMOs and/or pathogens. In particular, the SBB advises the regional authorities in relation to the contained use of pathogens and GMOs. The SBB is also in charge of the secretariat of the Belgian Biosafety Advisory Council. It provides ongoing administrative and scientific support to the Council in the frame of its activities related to the risk assessment of applications concerning the environmental release and the commercial use of GMOs. Broadly speaking, the SBB offers a permanent, responsive and reliable source of scientific support to the Federal and Regional Competent Authorities for all biosafety-related matters.

On specific issues, the SBB can rely on the support of external scientists within the framework of the scientific evaluation of regulatory dossiers and other biosafety-related matters. To this end, a common list of experts shared by the SBB and the Biosafety Advisory Council has been established.

International player
The SBB provides scientific support to the Belgian Competent Authorities in official fora dealing with biosafety matters at EU and international level, ensuring the continuity of technical and scientific expertise and the scientific consistency of Belgium's position within the different bodies. It also contributes to activities of various professional organisations working to support actors in the field of biosafety.

Scientific Research
The SBB is actively involved in scientific research dealing with biosafety matters. Through extensive literature reviews on emerging topics and participation in research projects at Belgian and European levels, the SBB contributes to improve the scientific knowledge in support of the assessment of the health and environmental impacts of GMOs and pathogens.

Communication and Information
The SBB strives to meet the needs of the general public and stakeholders via different forms of communication and information. Various initiatives also aim at reinforcing the link and partnership with scientists that are interested or involved in biosafety-related issues and whose domain of research and expertise might help to develop a better understanding or evaluation of the potential risks associated with the use of GMOs.

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The Belgian Biosafety Advisory Council (BAC)

The BAC is one of the two pillars (with the Service Biosafety and Biotechnology - SBB) of the scientific evaluation system that has been set up in Belgium to advise the Federal and Regional competent authorities about the biosafety of activities involving GMOs and/or pathogens.

The BAC is composed of 12 effective and 12 substitute members designated by the different Regional and Federal authorities with competence in biosafety. Members are appointed for a term of four years which can be renewed. It is assisted in its scientific work by the SBB, which also provides the secretariat, and by external experts from academic institutions.

The BAC advises the authorities for all regulatory dossiers related to to the placing on the market of products consisting of or containing GMOs, for applications for field trials of transgenic plants, and for applications relating to clinical trials in which a release of GMO into the environment is possible. The BAC can be consulted by the Regions for contained activities involving GMOs and/or pathogens. The BAC can also give an advice on its own initiative or at the request of a Minister.

The BAC provides all relevant information concerning its activities in an open, transparent and readily accessible manner. Advices issued by the BAC are available on its website.

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Denmark

Danish National Center for Ethics (Nationalt Center for Etik)

Our purpose:
In recent years, technological advancements have accelerated rapidly, increasingly demanding ethical considerations that span across research, data, health, and biotechnology. Simultaneously, the technological, physical, and biological worlds are becoming more and more intertwined, and the path from innovation in the laboratory to application in the healthcare system and dissemination throughout society is getting shorter.

This presents new opportunities, but it is also crucial that ethics form a foundational element before these advancements impact our lives and daily routines.

The ethical issues we face now and in the future require scientific evidence, practical experience with relevant technologies, legal expertise, and philosophical reflection. To address this development, Denmark has established the Danish National Center for Ethics as the first country in the world to provide a common foundation for ethics.

By bringing together the necessary skills and expertise under one roof, a stronger platform has been created to place ethical considerations on the agenda not only in Denmark but also internationally.

The Danish National Center for Ethics was established on January 1, 2022, and supports the work of four independent bodies: The Danish Council on Ethics, the Danish Data Ethics Council, the Danish National Committee on Health Research Ethics, and the Danish Medical Research Ethics Committees.

Our task is to focus on and safeguard the ethical principles and values that shape our society. Among other things, we advise authorities when drafting new legislative proposals. We create debate and contribute to public education on ethical and science ethics issues within the center's area of responsibility. We help ensure the rights of test subjects and the scientific integrity of research projects. We stay ahead and address tomorrow's ethical dilemmas, make recommendations to promote essential ethical values and principles, and develop reports, statements, and articles to ensure that democratically agreed decisions are based on relevant ethical standards and considerations.

The goal is to promote ethics and give ethics a powerful voice so that we, and future generations, can look back with confidence on the framework we collectively established for innovation in the years to come.

Contact details
Website: About Us | NCE (nationaltcenterforetik.dk)

The Danish Environmental Protection Agency and GMO

The Danish Environmental Protection Agency (EPA) administrate the regulations concerning applications, research and production of and with genetically modified organisms (GMOs) in an environmental perspective.

The EPA administrate the regulations concerning the application, research and production of, and with, genetically modified organisms (GMOs) in an environmental perspective.
The definition 'contained use' is understood as any operation in which genetically modified organisms, plants and animals are genetically modified or in which such genetically modified microorganisms are cultured, stored, used, transported, destroyed or disposed of and for which physical barriers, or a combination of physical barriers together with chemical and/or biological barriers, are used to limit their contact with the general population and the environment

Read more about the definition of "contained use" in the Directive 2009/41/EC

Approval
The EPA process applications regarding permission to work with GMO. Such applications are processed in accordance to the European Directive 2009/49/EC which have been national implemented into the law of environment and gene technology. An example of GMO for contained use in research and production could be genetically modified bacteria used to produce enzymes, which will be a functional ingredient in e.g. detergents or foodstuffs.

Read more about Production with GMO or Research with GMO.

Inspection
The EPA oversee that the responsible takers of the approval maintain the conditions in respect to the:

- General conditions in the law of environment and gene technology.
- Prerequisite conditions for the approval according to the law.
- Compliances of the prohibitory and mandatory demands of the law.
- External environment when working with genetically modified plants, animals and microorganisms in the laboratory, the area of the laboratory, pilot plants and production facilities.

The law of environment and gene technology harmonize work with GMO to the environment. Different authorities in Denmark work with regulation of GMOs. These authorities are The Danish Veterinary and Food Administration, The Danish Agricultural Agency, The Danish Health Authority, The Danish Working Environment Authority and The Danish Environmental Protection Agency. There is also a collaboration with the municipalities.

Read more about the different GMO Authorities

Read more about the Regulation

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E-mail: mst@mst.dk
Website: https://eng.mst.dk/trade/gene-technology/the-danish-environmental-protection-agency-and-gmo/

Estonia

Gene Technology Committee (Geenitehnoloogiakomisjon – GTK)

Role of GTK
The Gene Technology Committee is an advisory body established within the area of government of the Ministry of the Climate of Estonia.
The function of the Gene Technology Committee is to: 1) advise governmental authorities in issues of gene technology and environmental risks arising from genetically modified organisms or products; 2) advise notifiers applying for authorisation for release of genetically modified organisms into the environment, and notifiers applying for authorisation for placing genetically modified organisms or products on the market; 3) review notifications for authorisation for release of genetically modified organisms into the environment, notifications for authorisation for placing genetically modified organisms or products on the market and notifications for contained use of genetically modified organisms; 4) give an opinion on the deliberate release of genetically modified organisms into the environment, placing genetically modified organisms or products on the market and contained use of genetically modified organisms indicated in the notifications; 5) provide consultations to the Labour Inspectorate on issues related to the contained use of genetically modified micro-organisms; 6) provide consultations to the Agriculture and Food Board on issues related to the conduct of animal experiment involving genetically modified animals.
The working language is Estonian.

Organisation of GTK
The membership of the Gene Technology Committee is established by an order of the Government of the Republic, taking into account that the Gene Technology Committee should comprise of members who hold a relevant academic degree and represent various relevant research areas. The statutes of the Gene Technology Committee are approved by a regulation of the Government of the Republic. The statutes of the Gene Technology Committee establish the rights, obligations, rules of procedure, procedure for making decisions, operations procedure and procedure for remuneration of the Committee.

The Gene Technology Committee includes 8 members to be appointed on the proposal of the ministers in charge of the relevant policy sectors. One of these members must represent crop growers and one must represent crop processors and will be appointed by the Minister of Regional Affairs and Agriculture. Four members to be appointed on the proposal of the Rectors of the University of Tartu, the Estonian University of Life Sciences and Tallinn University of Technology . Three members to be appointed on the proposal of the President of the Estonian Academy of Sciences. Two members to be appointed on the proposal of environmental organisations.

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France

French agency for food, environmental and occupational health & safety (ANSES)

ANSES is the French Agency for Food, Environmental and Occupational Health & Safety. It is a public administrative body reporting to the Ministries of Health, the Environment, Agriculture, Labour and Consumer Affairs.

As an agency working for the benefit of all society, ANSES is fully committed to advancing knowledge and preparing for tomorrow's challenges in health and the preservation of ecosystems.

Since 2010, it has been providing the scientific benchmarks needed to protect us from health risks related to food, the environment and the workplace, or from risks affecting the health of animals and plants. An agency of scientific expertise, it monitors and assesses these health risks, and devotes research activities to them. It helps advance scientific knowledge to support public decision-makers, including during health crises.

- Created in 2010
- Five supervisory ministries: Health, the Environment, Agriculture, Labour and Consumer Affairs
- Over 1400 employees
- Nine research and reference laboratories located throughout France
- Calls on more than 800 independent experts
- An annual budget of 140 million euros

The principles guiding our work

A comprehensive approach to risks
ANSES's work has always been at the interface between human, animal and plant health. The vast scope of its activities has led the Agency to adopt a comprehensive view of health threats to living organisms and ecosystems. It has developed an interdisciplinary approach to assessing the risks of today and anticipating those of tomorrow.

Scientific excellence
ANSES calls on experts who are recognised in their respective fields, implements reference scientific methods and takes all the available scientific knowledge into account. This ongoing commitment to excellence enables it to provide benchmark scientific expertise. The Agency has established multiple partnerships with scientific assessment and research players in France, Europe

and the rest of the world. It relies on its Scientific Board to guarantee the quality of its expert appraisals.

Transparency & independence
ANS ES takes great care to ensure that all of its activities comply with principles of ethics and scientific integrity. Ever since it was created, the Agency has operated within an exacting ethical framework that it is constantly strengthening, and it is advised by a Committee for Ethical Standards and Prevention of Conflicts of Interest. To assess health risks, it relies on multidisciplinary expert groups and transparent, collegial working methods that guarantee the

independence and impartiality of the expert appraisals on which the Agency's opinions are based. All of its expert appraisal work is made publicly available.

Openness and dialogue with society
Health issues are a source of both interest and concern for society. Voluntary associations, trade unions, businesses, elected officials and government ministries are all represented on ANSES's Board of Administrators and discuss its strategic orientations. To foster informed debate that benefits public action, the Agency systematically publishes its opinions and reports, and accounts for scientific uncertainties. ANSES has also set up dialogue committees on nanomaterials, radiofrequencies and plant protection products. These provide it with forums to address the questions of stakeholders and explain its expert appraisals and the methods used.

The role of the agency in the area of genetically modified organisms

Since 2022, the "Biotechnologies" Unit is in charge of the evaluation of environmental risk assessments in the field of deliberate release of genetically modified organisms. The Unit is also in charge of the evaluation of health risk assessments of genetically modified food and feed requesting a market authorization under Regulation (CE) n°1829/2003.

Scientific opinions can also be requested from the "Biotechnologies" Unit for any question related to the safety of genetically modified organisms.

Website: www.anses.fr

Germany

The German Central Commission on Biological Safety (ZKBS)

Role of ZKBS
The German Central Commission on Biological Safety (ZKBS) is an independent body of honorary experts institutionalized by the German Genetic Engineering Act which evaluates genetically modified organisms (GMOs) with regard to the potential risks for humans, animals and the environment and issues opinions on this subject. It advises the government and the German Competent Authorities on contained use and deliberate release of GMOs to the environment as well as placing on the market. The ZKBS is also commissioned by the Ministry to monitor developments in the field of Synthetic Biology in order to expertly and critically examine current scientific developments in various fields of research. Monitoring also contributes to biosafety in case adaptation to existing regulations is required.

ZKBS does not advice on potential risks of GMOs used in clinical trials or in medicinal products for humans. The Committee does not advise on ethical or social issues related to genetic modification.

Organisation of ZKBS
The ZKBS consists of twelve honorary experts from the specialist fields of microbiology, cell biology, virology, genetics, plant breeding, hygiene, ecology, toxicology and technical safety, as well as eight honorary competent persons from the following areas: labour unions, occupational safety, economy, agriculture, environmental protection, nature conservation, consumer protection and research-funding organisations. The members of the ZKBS and their deputies are appointed for the duration of three years by the Federal Ministry of Food, Agriculture and Consumer Protection in agreement with the Federal Ministries of Education and Research, for Economic Affairs and Energy, of Labour and Social Affairs, of Health as well as the Federal Ministry of the Environment, Nature Conservation and Nuclear Safety.

The ZKBS elects themselves a chair as well as two deputies for a period of 3 years.
ZKBS`s work is supported by a secretariat (Geschäftsstelle) situated at the Federal Office of Consumer Protection and Food Safety (BVL) made up of a multi-disciplinary staff.

Research Programme
ZKBS has no budget to support research programs.

Communication
ZKBS provides all relevant and general information in an open, transparent and readily accessible manner. General position statements of the ZKBS and a regularly updated list of micro-organisms which have been assigned to risk groups are published in the Federal Gazette and on the ZKBS website. In addition, the administrative office provides databases on vectors, oncogenes, and cell lines which have been subjected to risk assessment on the ZKBS website. Yearly activity reports are published in order to provide information to the general public.

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Phone: +49 30184456200
Website: https://www.zkbs-online.de/ZKBS/DE/Home/home_node.html

Hungary

The Hungarian Gene Technology Advisory Committee (GEVB)

Role of GEVB

The Hungarian Gene Technology Advisory Committee (HU: Géntechnológiai Eljárásokat Véleményező Bizottság, GEVB for short) was set up by Act No. XXVII of 1998 on gene technology activities. GEVB is an independent body and it advises the gene technology authority on applications submitted for GMO authorisations. Depending on the scope of the application either the Ministry of Agriculture (in the case of gene technology activities in the field of agriculture and the food industry including technological adjuvants used in food production; contained use; and other industrial applications) or the National Institute of Pharmacy and Nutrition (in the case of human medicinal products; human pharmaceuticals; and chemicals in direct contact with the human body) acts as the gene technology authority and tasks GEVB to deliver its opinion.

Organisation and operation of GEVB

GEVB has 19 members, divided into three standing subcommittees (Human Health, Environment, and Agriculture/Industry). Members of the board are delegated by the Hungarian Academy of Sciences; the Ministers responsible for Agriculture, Environment Protection, Human Health and Education, respectively; the National Research, Development and Innovation Office; NGOs for environment protection; and NGOs for health and consumer protection. Expertise of the members encompasses a broad area ranging from molecular biology to law. GEVB has a strict conflict of interest policy in place and each member can serve for a 4 year term (renewable once). The Chair and the Secretary of the Board are elected by the members.

Depending on the workload, GEVB convenes usually on a monthly basis. Meetings can take place either in-person or online. Applicants are routinely invited for hearings.

Communication

The opinion of GEVB and questions asked to the applicant for additional information are included in the final authorisation decision. These can be consulted in the Register of Gene Technology Authorisations (http://gmo.fm.gov.hu/).

Contact details

E-mail: gmo@am.gov.hu (functional Government mailbox for GMO matters)
Website: https://gmo.kormany.hu/gentechnologiai-eljarasokat-velemenyezo-bizottsag

Ireland

The GMO Advisory Committee (GMO AC) – Ireland

Role of the EPA
The Environmental Protection Agency (EPA) in Ireland is the Competent Authority responsible for the regulation of:

- The contained use of Genetically Modified Organisms (GMOs);
- The Deliberate Release of GMOs into the environment (inclusive of field/clinical trials and placing on the market);
- The Transboundary Movement of GMOs.

Legislative basis for GMO AC
In accordance with national legislation (The GMO (Deliberate Release) Regulations S.I. No 500 of 2003), the EPA is required to appoint a Committee (The GMO Advisory Committee) "*for the purposes of consultation on any aspect of its* [EPA's] *functions in relation to GMOs which the Agency considers appropriate*"

GMO AC appointment
In accordance with the legislation, the EPA seeks nominations to the AC from the following:

- Government Departments and Agencies; (including the EPA), as well as,
- Organisations representative of persons whose professions relate to biotechnology research or the biotech industry;
- Organisations concerned with environmental protection;
- Organisations concerned with consumer affairs.

The EPA requests that persons nominated should ideally have knowledge of the use, control, research, development or commercial exploitation of GMO, or the wider biotechnology field.

Following receipt of all nominations, the EPA will decide on the structure of the Committee and will appoint not more than 14 members, including a chairperson. The Committee will have a duration not exceeding three years.

The GMO AC meets at least annually, with the majority of the work being carried out electronically.

Contact details
E-mail: gmo@epa.ie (functional mailbox for GMO related matters)
Website: https://www.epa.ie

Italy

The Italian National Committee on Biosafety, Biotechnology and Life Sciences (CNBBSV)

(Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita)

Role of CNBBSV

The National Committee on Biosafety, Biotechnology and Life Sciences (CNBBSV) main role is to advise the Government on matters related to biosafety, the applications of modern biotechnology, including the potential risk of genetically modified organisms (GMOs) to human health and the environment, and matters in general related to life sciences. The scope of CNBBSV covers all fields, ranging from agriculture to medicine and from contained use to deliberate environmental release. The CNBBSV provides advice, when prompted by the Government (Prime minister or any other ministry or bureaucrats thereof) but can also advise (e.g. propose statements and evaluation on matters related to the expertise of its members) also independently of specific requests by the Government or Ministries.

Organisation of CNBBSV

The chairman and the members of CNBBSV are appointed by the Prime Minister. At present the committee is composed of 16 members, nine of which are from the following disciplines: Microbiology, Molecular biology, Genetics, Chemical engineering, Agronomy, Pharmacological ecology and Hygiene), six are experts in Medical genetics, three are experts in other fields of relevance for the committee (Industrial & Environmental Biotechnology, Agricultural Microbiology, and Technological innovation). All members are selected on the basis of their scientific expertise. In addition, the committee seeks the opinion of external experts in specific matters.
CNBBSV's work is supported by a secretariat composed of several staff.

The Committee has an executive board whose members are the chairman and vice chairman of CNBBSV and three other members. The work is pursued through several 'scientific working groups': Infectious disease biosafety/ antibiotic-resistance; Innovative biotechnologies; Food safety and food security; Biosafety (control tools and surveillance); Health cities/ communicable and non-communicable diseases; Quality of health education and scientific information on bio-medical and health matters.
The Committee or the Working groups produced documents on the following issues: gene therapy, tissue engineering, national biotech development, infrastructures and European excellence networks, cloning, xenotransplants, intellectual property protection of biotech inventions, biological risk assessment, higher education, wide genetic screening, national and international institutional relationship, bioinformatics, auditing of biobanks, biological risks in working places, bio-nano-technologies, white biotechnology, endocrine disruptors exposure surveillance, industrial biotechnologies, New Breeding techniques, microbiome

Specific duties

The committee has the following specific duties:

- Propose criteria for defining safety rules on biotechnology, biosafety and life sciences, in particular those related to contained use and deliberate release into the environment of Genetically Modified Microorganisms
- Evaluate the risks connected with biological agents
- Contribute to the drafting of law proposals for the transposition of European Directives into the national laws

The committee is also in charge of supervising the compliance of the National DNA Data Bank & Central Laboratory and of the various laboratories providing data to the DNA data bank in respect to the rules and technical standards.

Financial support

The committee has a budget to support the work of the secretariat and to cover travel expenses of its members to participate in meetings of the committee and other meetings of relevance.
The committee does not fund research to support its advisory role. The committee organizes national workshops and symposia to present its views to stakeholders and to discuss issues with the parties involved.

Communication

The committee provides all relevant information concerning its activities in a transparent and accessible manner, apart from specific cases where confidentiality is requested by any of the parties involved. Advices issued by the committee are made available on the CNBBSV website. Reports or advice of interest to the international scientific and regulatory communities are made available also in the English version.

Contact details

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Latvia

In Latvia we have the Scientific Expert Commission established by Law on the Circulation of Genetically Modified Organisms in 2007. The commission is established by the State scientific Institute of Food Safety, Animal Health and Environment "BIOR" and consists of 13 scientific experts which on the basis of invitation made by the Institute BIOR are nominated by scientific institutions employing experts who correspond to the requirements. Experts must have a scientific degree in biology, medicine, veterinary medicine, science of agriculture, engineering science, forestry science, environmental science or in a similar area; the expert must have knowledge in the area of bio-safety as well as publications that have been included internationally available scientific data basis SCOPUS, Web of Science during last five years.

The Scientific Expert Commission is a group of experts, which examines risk assessment documents submitted by the persons, as well as prepares and submits to the State scientific institute Institute of Food Safety, Animal Health and Environment "BIOR" a scientifically substantiated opinion on the risk assessment of genetically modified organisms and a monitoring program. On the basis of its opinion, a decision to issue the permit for the contained use of genetically modified micro-organisms and the release into the environment of genetically modified organisms for field trials is taken.

The Scientific Expert Commission prepares and submits proposals to the State scientific institute Institute of Food Safety, Animal Health and Environment "BIOR" on the improvement of the development strategy of the national biological safety system and promotes the public involvement in the decision-making process on circulation of genetically modified organisms.

The Scientific Expert Commission examines the opinions of the European Food Safety Authority, the European Medicines Agency and other competent authorities of other Member States of the European Union regarding the risk assessment related to deliberate release of genetically modified organisms, and prepares an opinion in accordance with Regulation No 1829/2003 in respect of placing on the market of genetically modified organisms of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The Scientific Expert Commission provides a scientific opinion on the level of threat caused by the genetically modified organisms to the human and animal health or the environment based on the request of the supervisory and control authorities.

Contact details
Website: https://bior.lv/en/valsts-delegetas-funkcijas/restricted-use-gmo
Phone: 0037128642520
Executive secretary of the commission is Dr. biol. Lelde Grantiņa-Ieviņa (Leading researcher, Department of Risk Assessment and Epidemiology, Food safety, animal health and environmental scientific institute "BIOR")

Luxemburg

The legislation for GMOs is currently under revision. The proposed future situation, which is in part already in place in practical terms, is described below. The current formal legal situation can be consulted under the following link:

https://securite-alimentaire.public.lu/content/dam/securite_alimentaire/fr/publications/link-liste/plan-control-rapports/tc-mancp-doc-612-ogm.pdf

The responsibilities in Luxembourg concerning GMO's are under the responsibility of three administrations.

Luxembourg Veterinary and Food Administration (ALVA)

The Administration

The Luxembourg Veterinary and Food Administration was created in 2022 by bringing together most of the food chain control bodies in a single administration. The Luxembourg Veterinary and Food Administration is under the sole supervision of the Minister of Agriculture, Viticulture and Rural Development.

Following the logic of Regulation 2017/625, which defines common and uniform criteria for all controls in the agri-food chain, the ALVA is made up of the following pre-existing units:

- Administration of Veterinary Services
- Food Safety Division of the National Health Directorate
- Feed Control Department of the Administration of Agricultural Technical Services
- Government Commissariat for Quality, Fraud and Food Safety

Missions

The Luxembourg Veterinary and Food Administration role in the field of GMOs:

1. Official controls on GM food and feed (part C of Directive 2001/18);
2. Analysis of samples taken during official controls and other official activities;
3. Implementation of procedures for the placing on the market of GM food and feed;
4. Management of crisis situations in cooperation with other relevant institutions;
5. Risk communication;
6. Development of integrated multi-annual management and control plans;
7. Organization of the administrative cooperation with the European Commission, EU agencies and international organisations as a contact point and national correspondent;
8. Ensure the necessary administrative and penal actions in case of non-compliance with the regulations;
9. Formulate written opinions on the basis of scientific data, analysis results, publications of risk assessment agencies;
10. Respond to technical questions, requests for advice, complaints related to GMOs.

Contact details

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Phone: +352 2477 5620
Website: https://securite-alimentaire.public.lu/fr.html

Administration of Agricultural Technical Services (ASTA)

Missions

Directive 2001/18 on the deliberate release into the environment of genetically modified organisms Part B.
Measures to prevent unintended contamination of conventional and biological crops by GMO crops.

Contact details

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L-1019 Luxembourg
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Phone: +352 457172-200
Website: https://agriculture.public.lu/de/dienststellen/asta.html

Directorate of Health

Missions

Directorate of Health: Directive 2009/41 on the contained use of genetically modified micro-organisms.

Contact details

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The Netherlands

The Netherlands Commission on Genetic Modification (COGEM)

Role of COGEM
The Netherlands Commission on Genetic Modification (COGEM) advises the government on the potential risk of genetically modified organisms (GMOs) to human health and the environment. The scope of COGEM covers all fields, ranging from agriculture to medicine and from contained use to deliberate release. However, COGEM solely advises on environmental risk and does not advise on animal welfare, or patient safety (e.g. in relation to gene therapy). In addition to scientific advice on potential risks of GMOs, COGEM brings ethical and social issues related to genetic modification to the attention of the relevant ministers.

COGEM advises both independently and at the request of the Minister for the Environment. Advice requested by the minister is often linked to specific dossiers or notifications. There are three different notification categories: contained use, deliberate release into the environment, and placing on the market of GMOs.

Organisation of COGEM
The chairman and the twenty members of COGEM are appointed by the Minister for the Environment. The Board of COGEM appoints a further twenty associated members. All members are selected on the basis of their scientific expertise. The independent scientific members have expertise in various fields such as ecology, bacteriology, virology, genetically modified plants and animals, public perception, and ethics. In addition, COGEM seeks the opinion of external experts in specific cases.

COGEM has a board and three scientific subcommittees, i.e. a Subcommittee on Agricultural Aspects, a Subcommittee on Medical and Veterinary Aspects, and a Subcommittee on Ethics and Societal Aspects. The board members are the chairman of COGEM, and the chairmen of the different subcommittees. COGEM's work is supported by a secretariat made up of a multi-disciplinary staff.

Research Programme
COGEM has a research budget, and commissions research that supports and improves its advisory role. Both desk studies and small research projects are carried out. Furthermore, COGEM organizes national and international workshops and symposia. These symposia allow COGEM to present its views to stakeholders and to discuss issues with all of the parties directly involved.

Communication
COGEM provides all relevant information concerning its activities in an open, transparent and readily accessible manner. Advices issued by COGEM, and the research reports it commissions are available on COGEM's website. Reports or advice of interest to the international scientific and regulatory communities are available in English.

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Norway

The Norwegian Biotechnology Advisory Board

Role
The main tasks of the Norwegian Biotechnology Advisory Board are to:

- on request from the government (or on its own initiative) issue statements in cases pursuant to legislations on human medical use of biotechnology and on the production and use of genetically modified organisms.
- generally, assess discuss and issue statements sustainable use and social and ethical consequences of modern biotechnology and genetic technology in humans, animals, plants and microorganisms.
- place great emphasis on information for the public and contributing to debate between the public, authorities, professionals and interest organisations.

Organisation and way of working
The Norwegian Biotechnology Advisory Board is an independent body consisting of 15 cross disciplinary members (and 5 deputy/substitutes) appointed by the Norwegian government for 4 years.

Each board member has different backgrounds and education which makes him/her competent to discuss questions regarding modern biotechnology covering the cross disciplinary topics relevant in society. All members represent only them self. The board has approximately seven regular board meetings annually and also participate in several public meetings. All statements are non-consensus driven with arguments for different positions mandatory to be evident. All statements are submitted to the relevant governmental stakeholders but are also made public on the webpage.

The secretariat of the Norwegian Biotechnology Advisory Board has eight employees assisting and coordinating the board, five with medical or natural science, one with social science background, one with journalist background and one with administrative background. The secretariat prepares the cases for the board and is also responsible for all communication work with the public including organising debate meetings and bringing subjects to the interest of the daily press.

On general information the secretariat publishes the free, quarterly journal GENialt in Norwegian (on paper and electronically), produce monthly podcast episodes and organise multiple public meetings and presentations. The webpage (in Norwegian) provides high-school level background information on various topics regarding modern biotechnology and gene technology, training topics for schools, archives of podcasts and recordings from public meetings etc.

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Slovenia

Slovenian scientific Committee on the Deliberate Release of GMOs into the Environment and Placing on the Market (SCDR)

Role of SCDR
The SCDR was established by the Act on the Management of Genetically Modified Organisms (MGMOA) (Official Gazette RS, Nos. 23/05 - consolidated text, 21/10 and 90/12 - ZdZPVHVVR) to provide scientific support to ministries responsible for decisions on the management of GMOs.

The SCDR provides scientific advice on environmental risk assessment in administrative procedures for the handling of GMOs for the deliberate release of GMOs into the environment or the placing of products on the market. However, at the request of the relevant ministries, the SCDR also provides scientific advice and proposals for the development of regulations and in other matters related to GMO management.

Organisation of SCDR
The thirteen independed members of the SCDR and their alternates are appointed by the Government of the Republic of Slovenia for four years on the proposal of the Ministry responsible for science prepared on the grounds of the expert system for the evaluation of scientific achievements. The members of the committee have expertise in various fields, including genetics, biology, agriculture, veterinary science, biochemistry and molecular biology, microbiology, medicine, toxicology, allergology, food science, plant protection, animal nutrition and ecology. In addition, the SCDR may invite other experts from the fields relevant to the notification and preparation of a scientific opinion to participate in the discussions.

Decree on the operation of scientific committees in the management of genetically modified organisms (Official Gazette RS, Nos. 66/03 and 59/11) regulates the functioning of the SCDR and the forms of scientific advice, reporting and procedures to ensure that conflicts of interest do not exert undue influence within the Committee, as well as the protection of confidential data related to the work of the SCDR. The SCDR also has its own rules of procedure.

In addition, the SCDR also cooperates with other institutions in this field. The member of the SCDR is also elected as the representative of the Scientific Committee in the Slovenian GMO Commission in each mandate.

Transparency
The SCDR advocates for a transparent GMO notification process that is accessible to the public. To achieve this, all SCDR scientific advice related to the notification procedures is publicly available. In addition, under the MGMOA, the SCDR produces an annual report on its work, which is submitted to the government and published in a manner that is accessible to the public.

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Slovenian scientific Committee for the Contained Use of GMOs (SCCU)

Role of SCCU

The SCCU was established by the Act on the Management of Genetically Modified Organisms (MGMOA) (Official Gazette RS, No. 23/05 - consolidated text, 21/10 and 90/12 - ZdZPVHVVR) to provide scientific support to ministries responsible for decisions on the management of GMOs in the contained use.

The SCCU provides scientific advice on environmental risk assessment in administrative procedures for dealing with GMOs in contained systems and for working with GMOs in contained systems. However, at the request of relevant ministries, the SCCU also provides scientific advice and proposals for the development of regulations and in other matters related to the management of GMOs in contained use.

Organisation of SCCU

The seven independent members of the SCCU and their alternates are appointed by the Government of the Republic of Slovenia for four years on the proposal of the Ministry responsible for science prepared using the expert system for the evaluation of scientific achievements. The members of the committee have expertise in various fields, including microbiology, genetics, medicine, biochemistry and molecular biology, pharmacy, biotechnology, occupational health and safety, toxicology and ecology. In addition, the SCDR may invite other experts in fields relevant to the notification and preparation of a scientific opinion to participate in the discussions.

Decree on the operation of scientific committees in the management of genetically modified organisms (Official Gazette RS, Nos. 66/03 and 59/11) regulates the functioning of the SCDR and the forms of scientific advice, reporting and procedures to ensure that conflicts of interest do not exert undue influence within the Committee, as well as the protection of confidential data related to the work of the SCDR. The SCDR also has its own rules of procedure.

In addition, the SCDR also cooperates with other bodies in this area. The member of the SCDR is also elected in each mandate to represent the Scientific Committee in the Slovenian GMO Commission.

Transparency

The SCCU advocates for a transparent GMO notification process that is accessible to the public. To achieve this, all SCCU scientific advice related to the notification procedures is publicly available. In addition, under the MGMOA, the SCCU produces an annual report on its work in the previous year, which is submitted to the government and published in a manner that is accessible to the public.

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Spain

National Commission of Biosafety (CNB)

Organization
The National Commission of Biosafety is attached to the Ministry for the Ecological Transition and the Demographic Challenge, and it is a scientific and technical consultative body regulated by the Law 9/2003 and the Royal Decree 178/2004 on GMOs. It is the advisory body of the Government (Interministerial Council of Genetically Modified Organisms, (CIOMG) and the Autonomous Communities (Spanish regions).
The CNB is a collegiate body and it is made up of representatives of the different Ministries involved (Agriculture, Health, Industry, Science…), representatives of the Autonomous Communities, and experts of scientific institutions with experience in different fields such us microbiology, virology, agriculture, animals, biosafety for confined used facilities, etc.

Role
The CNB, in response to the mandatory request from the Competent Authorities, (as appropriate CIOMG or Autonomous Communities), elaborates environmental/health assessment reports for confined use facilities and activities with GMOs, for deliberate release notifications (clinical trials, plants field trials…) and placing on the market GMOs or products consisting or containing GMOs. These reports are considering by the Competent Authorities to take a final decision for the authorization (consent or no).

Transparency
The CNB share its activity with transparency by publishing on the web page of the Ministry of Ecological Transition and Demographic Challenge its members composition, operating rules, minutes of its meetings and scientific and technical reports from different issues related to GMOs.

Website CNB

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Sweden

The Swedish Gene Technology Advisory Board

The Swedish Gene Technology Advisory Board should promote an ethically sound and safe use of gene technology while protecting the environment as well as human and animal health. The Board should also ensure a healthy research political climate.
The Board provides opinions on deliberate release of genetically modified organisms, according to the Swedish Environmental code and Directive 2001/18, implemented in Swedish law 2002:1068. The scope is broad and spans from clinical trials of gene therapies to field experiments with genetically modified plants. The Board also provides opinions and informs on specific questions relating to gene technology to relevant competent authorities and private actors in matters relevant to their activities.
Each year the Board compiles a report with an over view of scientific developments in gene technology, including information on how research and development have been affected by laws and regulations on genetically modified organisms.
Another important task is to spread knowledge on genetically modified organisms and research on gene technology to the public. The Board should also stimulate to debate on ethical and safety matters relating to the use of gene technology.

Organization
The Swedish Gene Technology Advisory Board is a Swedish authority. The board consists of a chair, a vice chair and 15 members. All members of the Board are appointed for a period of four years. The chair and vice chair are lawyers and work or have been working as judges. Eight members of the Board are members of Parliament, representing the different political parties of the Parliament. Seven members are scientists with expertise on ethics, animal welfare, ecology, plant science and medicine. Each of the 15 members has a personal substitute.
The Board is supported by a secretariat consisting of two experts, one with expertise in plant science and one in medical genetics. The secretariat is employed by the Swedish Research Council which acts as host for the Swedish Gene Technology Advisory Board.

Communication
The Swedish Gene Technology Advisory Board provides all relevant information concerning its activities in an open, transparent and readily accessible manner. Protocols from meetings, opinions issued, yearly reports and information of yearly activities are available on its website. On the website one can also find news on research or regulations relating to gene technology summarized in a popular manner with the intention to inform the public. The website also contains continuously updated background information on genetics and molecular biology relating to gene technology. The website is frequently used by schools, and an important task of the Swedish Gene Technology Advisory Board office is to lecture and inform on topics relating to gene technology and genetically modified organisms in schools and university courses as well as engage in other kinds of outreach activities.

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Switzerland

Swiss Expert Committee for Biosafety (SECB)

Role of SECB

The Swiss Expert Committee for Biosafety (SECB) is a permanent federal advisory committee. It gives scientific advises to the government (Swiss Federal Council and the federal agencies) on the drafting of laws, ordinances, guidelines and recommendations on the potential risk of genetically modified organisms (GMOs), pathogenic or alien organisms for human and animal health as well as the environment.

It advises the federal and cantonal authorities also on the enforcement of these regulations.

It takes position to the attention of the competent authorities e.g. on license applications / notifications / dossier related to the use of genetically modified (GMOs), pathogenic or alien organisms in contained systems, deliberate release into the environment, clinical studies as well as market authorizations Therefore, the remit of the SECB is very broad, ranging from agriculture to human and veterinary medicine and from contained use of organisms to deliberate release. The SECB advises on environmental risks and animal and human health, including patient safety, close contacts as well as the safety of health workers (e.g. in relation to gene therapy) and lab workers. In addition, the SECB elaborates and publishes recommendations on safety measures for the use of genetically modified, pathogenic or alien organisms (e.g. for contained use to the attention of lab workers) or recommendations on early detection and containment (e.g. for alien plants in the environment).

Organisation of SECB

The chairman and the other 14 members of SECB are appointed by the Federal Council. The SECB appoints a further 10 to 15 associated members for the advice on gene therapy applications on clinical studies as well as market authorizations. All members are elected on the basis of their scientific expertise and the language region of the country. They provide special knowledge in gene technology, biotechnology (e.g., molecular biology, microbiology, genetics, biochemistry) and in environmental (e.g. ecology, botany, zoology, agronomy) and health affairs (e.g. clinic, phytopathology, epidemiology, hygiene, veterinary sciences, toxicology), representing different interest groups such as universities, economy, agriculture and forestry as well as environmental and consumer organisations. In addition, the SECB can seek the opinion of external experts in specific cases. The SECB work is supported by an executive office made up of a scientific staff.

Studies

The SECB disposes of a small budget, and commissions financed studies have the aim of filling important knowledge gaps in biosafety relevant topics and to support and improve the advisory role, including the elaboration of recommendations. Both literature studies and small research projects are carried out.

Communication

The SECB provides all relevant information concerning its activities in an open, transparent and readily accessible manner. Advices issued by the SECB, recommendations, publications and the activity report are available on SECB website. Reports or advice of interest to the international scientific and regulatory communities are usually available also in English.

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