European Food Safety Authority

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TECHNICAL REPORT

Annual report of the EFSA Scientific Network for Risk Assessment of GMOs for 2013[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with EFSA's strategy for cooperation and networking with Member States, the EFSA Scientific Network for Risk Assessment of GMOs (GMO Network) was launched in 2010. The overall goals of the GMO Network are to: improve dialogue among participants; build mutual understanding of risk assessment principles; enhance knowledge on and confidence in the scientific assessments carried out in the EU; and increase the transparency of the process among Member States and EFSA. The Annual reports of the GMO Network inform the public and the EFSA Advisory Forum about its specific activities and achievements. During its meeting in 2013, the GMO Network discussed the principles of statistical relevance and biological significance, the use of animal feeding trials in the risk assessment of GMOs, the development of environmental protection goals and the EFSA Guidance on the environmental risk assessment of GM animals. Following requests from EFSA, the GMO Network provided input to EFSA's scientific report "Considerations on the applicability of OECD TG 453 to whole food/feed testing" and to the project "Review of statistical methods and data requirements to support post market environmental monitoring of agroecosystems".

KEY WORDS

GMO Network, food and feed risk assessment, environmental risk assessment, Member States, Directive 2001/18/EC, Regulation (EC) No 1829/2003

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SUMMARY

Developing networking and stronger cooperation with the Member States and strengthening EFSA's relationship with its institutional partners (European Union and international) and stakeholders are among the key recommendations formulated by EFSA's Management Board. In accordance with EFSA's strategy for cooperation and networking with Member States, the EFSA Scientific Network for Risk Assessment of GMOs (genetically modified organisms—hereafter referred to as "the GMO Network") was launched in 2010. The GMO Network had its inaugural meeting in November 2010 and since then it has met once per year.

The overall goals of the GMO Network are to: improve dialogue among participants; build mutual understanding of risk assessment principles; enhance knowledge on and confidence in the scientific assessments carried out in the EU; and increase the transparency of the process among Member States and EFSA. It aims to raise the level of harmonisation of the risk assessments developed in the EU.

Currently 24 Member States and Norway are members of the GMO Network. Each country was allowed to nominate two Member Organisations: one for competence in molecular characterisation and food/feed safety (MC/FF) and one for competence in environmental risk assessment (ERA). These Member Organisations have appointed in total 60 selected scientific experts (and substitutes) to attend the yearly meetings in the light of the topics on the agenda. A maximum of two experts per country are invited to the yearly meetings.

The fourth meeting, held in May 2013, was attended by 36 scientific experts from Member States, Norway and EU Candidate Countries (Bosnia and Herzegovina, Croatia (became a Member State on 1 July 2013), the Former Yugoslav Republic of Macedonia, Montenegro, Serbia and Kosovo) as observers, one representative of the European Commission (Directorate General for Health and Consumers) as an observer, five EFSA GMO Panel members, one EFSA Food Additives and Nutrient Sources Added to Food (ANS) Panel member, one EFSA Scientific Committee (SC) member, one external expert as invited speaker, and 12 EFSA scientific staff from the GMO, Scientific Committee and Emerging Risks, and Pesticides Units.

and Quality Sector (Slovenia); Ministerio de Ciencia e Innovacion-Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA)—Departamento de Tecnologia de los Alimentos (Spain); National Food Administration (Sweden); Food Standards Agency—Novel Foods, Additives and Supplements Division (United Kingdom); (2) the Member Organisations nominated for the environmental risk assessment (ERA) area: Federal Environment Agency—Umweltbundesamt (Austria); Scientific Institute of Public Health (IPH)—Biosafety and Biotechnology Division (Belgium); National Centre of Public Health Protection—National Multisectoral Expert Committee on Risk Assessment Related to Foods (Bulgaria); Ministry of the Environment (Czech Republic); Ministry of Environment—Environmental Protection Agency (Denmark); Ministry of Environment—Nature Conservation Department (Estonia); Ministry of Social Affairs and Health—National Institute for Health and Welfare (Finland); Ministère de l'écologie, de l'énergie, du Développement durable et de l'aménagement du territoire—Haut conseil des biotechnologies (HCB) (France); Environment Ministry—Federal Agency for Nature Conservation (BfN) (Germany); Ministry of Rural Development and Food (Greece); Ministry of Agriculture and Rural Development—Hungarian Food Safety Office (Hungary); Minister for Health and Children—Food Safety Authority (Ireland); Ministro della Salute-Istituto Superiore di Sanità (Italy); Ministry of Agriculture—Food and Veterinary Service (FVS)—Scientific Expert Committee on GMO RA (Latvia); Ministry of Environment—Department for Protection of Nature (Lithuania); Malta Environment & Planning Authority (MEPA)—Genetically Modified Organisms (GMOs) & Biosafety (Malta); Minister of Housing, Spatial Planning and the Environment (VROM) and Institute for Public Health and Environment (RIVM)—the Netherlands Commission on Genetic Modification COGEM (the Netherlands); Ministry of Health and Care Services—Scientific Committee for Food Safety (Norway); Warsaw University of Life Sciences—Faculty of Horticulture and Landscape Architecture (Poland); Comenius University in Bratislava—Faculty of Natural Sciences—Natural-Scientific College (Slovak Republic); Ministry of the Environment and Spatial Planning (Slovenia); Ministerio de Ciencia e Innovación-Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC)—Centro de Investigaciones Biológicas (CIB) (Spain); National Board of Agriculture (Sweden); Department for Environment, Food and Rural Affairs (DEFRA)—GMO team (United Kingdom); (3) the invited organisations from EU Candidate Countries: National Food Authority (Albania); Food Safety Agency (Bosnia and Herzegovina); Food Agency (Croatia); Food and Veterinary Agency (the Former Yugoslav Republic of Macedonia); Food and Veterinary Agency (Kosovo); Veterinary Directorate (Montenegro); Ministry of Agriculture, Trade, Forestry and Water Management (Serbia); Ministry of Food, Agriculture and Livestock (Turkey); and (4) the invited speakers Joe Perry, Dominique Parent-Massin and Fern Wickson, and EFSA staff, Jaime Aguilera and Irina Olaru, for the support provided to this output.

At the fourth meeting, the appointed experts were informed about active mandates of the EFSA GMO Panel, including GMO applications, risk assessment guideline development, requests for scientific advice, procurements, etc. This was followed by a discussion on statistical significance and biological relevance, debating the advantages and limitations of the tests of difference and equivalence used in the risk assessment of GMOs. As in 2012, two breakout sessions were organised according to the expertise of the two groups of experts to allow in-depth discussion of specific topics. The experts in the field of MC/FF discussed animal feeding trials and their role in the risk assessment of GMOs. The experts in the ERA field discussed the development of protection goals and their importance in the context of a harmonised environmental risk assessment. At the following joint plenary session, one of the topics discussed by the GMO Network members and EFSA was the design of protocols for long-term animal feeding trials and the added value of data obtained from such trials was debated. Related to this item, EFSA informed GMO Network members of its draft Scientific Report on the applicability of the OECD (Organisation for Economic Co-operation and Development) guideline for two-year animal feeding studies and invited them to provide input to this draft. The third topic discussed during the joint plenary sessions was the recently adopted EFSA Guidance on the environmental risk assessment of GM animals, its structure and applicability. Finally, EFSA reminded the Network members about activities requiring involvement from Member States and about ongoing calls for participation in procurement and grants.

All details of the meeting are recorded in the minutes.[4]

[4] http://www.efsa.europa.eu/en/events/event/130522d-m.pdf

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BACKGROUND AS PROVIDED BY EFSA

The European Food Safety Authority (EFSA) is the keystone of European Union risk assessment regarding food and feed safety, animal health and welfare, nutrition, plant protection and plant health. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent and transparent scientific advice and clear communication on existing and emerging risks associated with the food chain. On request from the European Commission, European Parliament or Member States or on its own initiative EFSA provides scientific opinions on issues falling within its remit.

The Scientific Panel on Genetically Modified Organisms provides independent scientific advice on the safety of:

- Genetically modified organisms (GMOs) such as plants, animals and micro-organisms, on the basis of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms
- Genetically modified food and feed, on the basis of Regulation (EC) No 1829/2003 on genetically modified food and feed.

The Panel carries out risk assessments in order to produce scientific opinions and advice for risk managers. Its risk assessment work is based on reviewing scientific information and data in order to evaluate the safety of a given GMO. This helps to provide a sound foundation for European policies and legislation and supports risk managers in taking effective and timely decisions. The Panel carries out much of its work in the context of authorisation applications, since all GM food and feed products must be evaluated by EFSA before they can be authorised in the EU.

According to Regulation (EC) No 1829/2003 EFSA shall, within the context of assessing each GMO application, consult with Member State Competent Authorities (CAs) during a three-month consultation period. In order to fulfil this requirement, EFSA has formed the GMO ExtraNet for applications. Members of the GMO ExtraNet for applications are affiliated with federal and national agencies, authorities and ministries of all EU Member States. GMO ExtraNet members submit to EFSA comments and questions regarding content of specific applications. Due to different organisational structures, some Member States have multiple members in the GMO ExtraNet for applications while some do not cover the full remit of the GMO Panel. The members of this network do not convene in person. Instead, electronic submissions of comments and questions by members and weekly newsletters from EFSA to members constitute the mode of operation. Questions and comments raised by network members have assisted the EFSA GMO Panel to pinpoint weaknesses and strengths in applications and have been useful in the context of the risk assessment. Each comment or question is addressed by the GMO Panel in an annex to the EFSA overall opinion, once adopted.

During the last years the EFSA GMO Panel has met several times with Member State scientists. The context of meetings has ranged from colloquia or workshops on the risk assessment of GMOs organised by EFSA and open to CAs from all Member States, to small meetings between specific Member State CAs and the GMO Panel to discuss a specific issue. Based on the benefits of these discussions EFSA finds that regular direct face-to-face discussion with Member State CA risk assessors on issues linked to principles of risk assessment does effectively complement the already established consultation in the frame of the GMO ExtraNet for applications.

Developing networking and stronger co-operation with the Member States and strengthening EFSA's relationship with its institutional partners (EU and international) and stakeholders are among the key recommendations formulated by EFSA's Management Board. In accordance with EFSA's strategy for cooperation and networking with Member States, the GMO Network was launched in 2010. The GMO Network had its first meeting in 2010, followed by yearly meetings in 2011–2013.

Members of the GMO Network are organisations nominated through the EFSA Advisory Forum contact point from the Member States: one Member Organisation for MC/FF area of competence and one Member Organisation for ERA area of competence. The Member Organisations appoint selected experts (and substitutes) to attend the meeting in light of the topics on the agenda. A maximum of two experts per country are invited to the yearly meetings.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The overall objective of the Scientific Network for Risk Assessment of GMOs is to build mutual understanding of the principles underlying the risk assessment of GMOs and to provide increased transparency in the current process between Member States and EFSA.

The purpose of the GMO Network is to enhance cooperation between scientists involved in GMO risk assessment at EFSA and in the EU Member States in order to continue to strengthen and to better harmonise risk assessment practices within the EU. The GMO Network will share information and experience as well as discuss both the principles and the approach for risk assessment.

Appointment is personal as this network will find value in holding meetings with the same scientists on a regular basis thus building understanding of different points of view.

The specific objectives of the Scientific Network for Risk Assessment of GMOs are:

- To facilitate harmonisation of risk assessment practices and methodologies by:
  - Sharing best practices in GMO risk assessment
  - Discussing ongoing issues of GMO risk assessment such as new guidance developed or new opinions adopted
  - Discussing new scientific developments in GMO risk assessment and discussing their implications on risk assessment practice
- To enhance exchange of information between EFSA and Member States by:
  - Discussing issues of availability and quality of data required for GMO risk assessment
  - Sharing information on new scientific developments in the field of GMO risk assessment.

EFSA may entrust to the GMO Network certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, and collection of data.

The activities of the GMO Network should be recorded in the meeting minutes. In addition, an Annual Report summarising the activities will be produced.

MEMBERS

The Member organisations of the GMO Network, nominated by the Advisory Forum of EFSA, are listed in Table 1. The profile of the Member State scientists appointed to attend the yearly meetings of the network should include the following:

- experience in GM food and feed or environmental risk assessment and research at the national level;
- knowledge of the national status and of the European and/or international context of GM food and feed and environmental risk assessment.

The chair of the GMO Network is the Head of the EFSA GMO Unit, Elisabeth Waigmann.

Table 1: Member Organisations and appointed experts of the GMO Network

Country	Nominated Member Organisation MC/FF	Appointed experts (and substitutes) MC/FF	Nominated Member Organisation ERA	Appointed experts (and substitutes) ERA
Austria	Austrian Agency for Health and Food safety	Markus Woegerbauer	Federal Environment Agency—Umweltbundesamt	Andreas Heissenberger
Belgium	Scientific Institute of Public Health (IPH)—Biosafety and Biotechnology Division	Philippe Herman	Scientific Institute of Public Health (IPH)—Biosafety and Biotechnology Division	Adinda de Schrijver
Bulgaria	National Center of Public Health Protection—National Multisectoral Expert Committee on Risk Assessment Related to Foods	Tzveta Georgieva	National Center of Public Health Protection—National Multisectoral Expert Committee on Risk Assessment Related to Foods	Dimitar Djilianov
Cyprus	Ministry of Health—State General Laboratory, Genetically Modified Organisms and Allergens	Andri Varnava-Tello	–	–
Czech Republic	Ministry of Agriculture	Jaroslava Ovesná (Vladimír Ostrý; Petr Hanák)	Ministry of the Environment of the Czech Republic	Zuzana Doubkova (Josef Kubíček)
Denmark	Ministry of Food, Agriculture and Fisheries—Danish Veterinary and Food Administration (DVFA)	Jan W. Pedersen	Ministry of Environment—Environmental Protection Agency	Gösta Kjellsson
Estonia	Veterinary and Food Board (VTA) Office for Food of Non-animal Origin, Retail Sale and Organic Farming	Katrin Argus (Jaak Truu; Maili Vodi)	Ministry of Environment—Nature Conservation Department	Liina Eek (Andres Mäe)
Finland	Finnish Food Safety Authority Evira	Kimmo Peltonen	Ministry of Social Affairs and Health—National Institute for Health and Welfare	Matti Sarvas
France	Agence française de sécurité sanitaire des aliments (Afssa)	Chantal Arar	Ministère de l'écologie, de l'énergie, du développement durable et de l'aménagement du territoire—Haut conseil des biotechnologies (HCB)	Patrick Saindrenan (Catherine Regnault-Roger)
Germany	Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)—Federal Institute for Risk Assessment (BfR)	Anke Meisner (Andrea Scheepers)	Environment Ministry—Federal Agency for Nature Conservation (BfN)	Beatrix Tappeser
Greece	Ministry of Rural development and Food—Hellenic Food Authority (EFET)	Margarita Karavangeli (Boulis Argirios; Dionyssia Stefanitsi)	Ministry of Rural Development and Food	–
Hungary	Ministry of Agriculture and Rural Development—Hungarian Food Safety Office	Barnabas Jenes	Ministry of Agriculture and Rural Development—Hungarian Food Safety Office	Zsuzsana Bardocz
Ireland	Minister for Health and Children—Food Safety Authority of Ireland	Patrick O'Mahony	Minister for Health and Children—Food Safety Authority of Ireland	Tom Mcloughlin
Italy	Ministro della Salute—Istituto Superiore di Sanità	Carlo Brera (Roberta Onori)	Ministro della Salute—Istituto Superiore di Sanità	Massimo Delledonne

Country	Nominated Member Organisation MC/FF	Appointed experts (and substitutes) MC/FF	Nominated Member Organisation ERA	Appointed experts (and substitutes) ERA
Latvia	Ministry of Agriculture—Food and Veterinary Service (FVS)—Scientific Expert Committee on GMO RA	Indrikis Muiznieks	Ministry of Agriculture—Food and Veterinary Service (FVS)—Scientific Expert Committee on GMO RA	Indrikis Muiznieks
Lithuania	The State Food and Veterinary Service (SFVS)—National Food and Veterinary Risk Assessment Institute	Vaclovas Jurgelevicius	Ministry of Environment of the Republic of Lithuania—Department for Protection of Nature	Odeta Pivoriene
Malta	Malta Standards Authority	Flavia Zammit (Ingrid Busuttil)	Malta Environment & Planning Authority (MEPA)—Genetically Modified Organisms (GMOs) & Biosafety	–
Netherlands	Wageningen University and Research Centre—RIKILT Institute of Food Safety	Robert van Gorcom (Esther Kok)	Minister of Housing, Spatial Planning and the Environment (VROM) and Institute for Public Health and Environment (RIVM)—the Netherlands Commission on Genetic Modification COGEM	Frank van der Wilk (Boet Glandorf)
Norway	Ministry of Health and Care Services—Norwegian Scientific Committee for Food Safety	Arne Mikalsen	Ministry of Health and Care Services—Norwegian Scientific Committee for Food Safety	Merethe Aasmo Finne (Bjarte Rambjør Heide)
Poland	Plant Breeding and Acclimatisation Institute—Department of Plant Biotechnology and Cytogenetics—GMO controlling laboratory	Slawomir Sowa (Twadorwski)	Warsaw University of Life Sciences—Faculty of Horticulture and Landscape Architecture	Zbigniew Dąbrowski
Slovak Republic	Slovak Academy of Science (SAS)—Institute for Molecular Biology	Jozef Timko	Comenius University in Bratislava—Faculty of Natural Sciences—Natural–Scientific College	Ján Turňa (Hana Drahovská)
Slovenia	Ministry of Agriculture, Forestry and Food—Food and Feed Safety and Quality Sector	Alenka Zupancic	Ministry of the Environment and Spatial Planning	Martin Batic
Spain	Ministerio de Ciencia e Innovación—Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA)—Departamento de Tecnología de los Alimentos	Carmen Cuadrado	Ministerio de Ciencia e Innovación—Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC)—Centro de Investigaciones Biológicas (CIB)	Félix Ortego
Sweden	National Food Administration	–	National Board of Agriculture	Staffan Ekloff (Elisabeth Lundkvist)
United Kingdom	Food Standards Agency—Novel Foods, Additives and Supplements Division	Sandy Lawrie	Department for Environment, Food and Rural Affairs (DEFRA)—GMO team	Louise Ball

OBSERVERS

Country	Organisation MC/FF	Appointed experts (and substitutes) MC/FF	Organisation ERA	Appointed experts (and substitutes) ERA
Albania	National Food Authority	Edi Misja	–	–
Bosnia and Herzegovina	Food Safety Agency	Miroslav Vidović	–	–

Country	Organisation MC/FF	Appointed experts (and substitutes) MC/FF	Organisation ERA	Appointed experts (and substitutes) ERA
Croatia	Croatian Food Agency		Croatian Food Agency	Sanja Miloš (Domagoj Šimić)
FYR of Macedonia	Food and Veterinary Agency	Suzana Popovska	–	–
Kosovo	Food and Veterinary Agency	Naser Krasniqi	–	–
Montenegro	Veterinary Directorate	Ervin Bučan	–	–
Serbia	Ministry of Agriculture, Trade, Forestry and Water Management, Plant Protection Directorate, Group for Plant Variety Protection and Biosafety	Vanja Kojić	–	–
Turkey	Ministry of Food, Agriculture and Livestock, General Directorate of Agricultural Research and Policy, Field Crops Research Department	Ali Osman Sari	–	–

ACTIVITIES

1. Follow-up from the establishment of the GMO Network

The term of the current mandate of the GMO Network is from 2010 to 2013. Advisory Forum Members from Luxembourg, Portugal and Romania have not appointed Members to this Network. All appointed experts and substitutes have been encouraged to submit Confidentiality Statements and Annual Declarations of Interest. Most of the appointed experts have completed this procedure. Croatia, which joined the EU as a Member State on 1 July 2013, will appoint organisations as members of the GMO Network in its forthcoming mandate commencing in 2014.

2. Electronic tools of the GMO Network

Participants at the 2013 meeting had successfully used the secure online tools for document sharing: the information exchange platform (IEP) for all EFSA national contacts and the more specific Sciencenet for EFSA GMO Network members. The GMO Unit offered further support to the GMO Network experts in accessing documents online.

E-mail addresses of all GMO Network contacts (from Member Organisations and from appointed experts and their substitutes) remain available to the network through an Excel file in Sciencenet.

The background documentation relating to the GMO Network, as well as agendas and minutes of its annual meetings, are published on the EFSA web page: http://www.efsa.europa.eu/en/gmo/gmonetworks.htm

3. Participation of the GMO Network in consultations on EFSA outputs

Upon request by EFSA, the GMO Network experts provided written comments to EFSA's draft Scientific Report on the applicability of OECD test guideline 453 to whole food/feed testing[5] (EFSA, 2013), which was developed by EFSA following a request from the European Commission (see also Section 4.4). The final report was published in July 2013.

EFSA also requested the GMO Network to provide information to the EFSA Scientific Assessment Support (SAS) Unit on Environmental Surveillance Networks in the frame of the project "Review of statistical methods and data requirements to support post market environmental monitoring of agro

[5] Available online at: http://www.efsa.europa.eu/en/efsajournal/doc/3347.pdf

ecosystems" (see also Section 4.6). The final report on this project is expected to be published in January 2014.

4. Annual meeting 2013

The annual meeting was held on 22 and 23 May in Parma, and was attended by 36 representatives of 22 Member States, one European Free Trade Association country (Norway), six EU Candidate and pre-Candidate Countries (Bosnia and Herzegovina, Croatia (became a Member State on 1 July 2013), the Former Yugoslav Republic of Macedonia, Kosovo, Montenegro and Serbia) and one representative of the European Commission. Five GMO Panel members, one ANS Panel member, one SC member, one external speaker and 12 EFSA scientific staff from the GMO, Scientific Committee and Emerging Risks, and Pesticides Units also attended the meeting.

The following issues were discussed in the 2013 meeting.[6]

4.1. Update on recent and current EFSA activities on GMOs

EFSA presented to the GMO Network an overview of its current activities in the field of GMOs. In addition to the assessment of applications for GM food and feed and cultivation of GMOs, which is a standing activity, several guidance documents (GDs) had been published. The overview also included: ongoing mandates, such as safeguard clauses on GM maize and potato cultivation; calls for procurement and grants to outsource various scientific activities in the field of GM plants; and foreseen self-tasks, among them being the development of a GD for the comparative assessment of agronomic and phenotypic characteristics of GM plants.

4.2. Statistical significance and biological relevance in the risk assessment of GMOs

Joe Perry (invited speaker), Chair of the EFSA GMO Panel, presented how the GMO Panel performs the comparative assessment of GM plants, and the underlying principles, which are reflected in the EFSA Guidance for the risk assessment of GM plants (EFSA GMO Panel, 2011). The statistical approach is based on two tests: a test of difference, in which the null hypothesis (H_0) is that the GM plant is not different from the conventional counterpart; and a test of equivalence, in which the H_0 is that the GM plant is not equivalent to a set of reference varieties that establish a range of natural variation for each endpoint to be compared. The test of equivalence avoids the risks of subjective interpretations of differences between the GM plant and the conventional counterpart by providing a range of variation based on experimental evidence. The principle for the comparison is that the reference varieties have a history of safe use. Unlike the food/feed (FF) safety assessment, the use of reference varieties is not recommended for the ERA. Instead, the equivalence limits must be set by the applicant based on the protection goals (PGs) set by Member States. The translation of PGs into equivalence limits and assessment endpoints is challenging, and little progress has been made in recent years by risk managers, although efforts continue.

The interpretation of differences found in the comparisons should take into account the fact that a statistically significant difference may not reflect biological importance. To enable a better interpretation of the results of the tests, the size of the difference to be considered biologically relevant should be defined in advance, and the tests should be designed to be able to detect such differences, in case they exist.

After the presentation, there was a general discussion on issues such as: the amount of evidence necessary to demonstrate safety; consumers' opinion versus scientific reasoning in establishing safety standards for GM crops; defining the limits of concern for the ERA of GM crops; the comparative approach in the context of regional effects; the advantages and limitations of pre-defining the percentage of difference to be considered of concern; historical data for equivalence limits; the interdependence of endpoints; the use of data from laboratory experiments in combination with field trials; and the challenges of using surrogate species to establish the safety limits.

[6] See detailed meeting minutes at: http://www.efsa.europa.eu/en/events/event/130522d-m.pdf

4.3. Breakout sessions

4.3.1. Breakout session FF: animal feeding trials. Current state of the art and practice for the risk assessment of GMOs

Overview of 90-day animal feeding studies provided in applications

EFSA presented an overview of the various designs used in 90-day animal feeding studies conducted in the frame of GMO applications submitted under Regulation (EC) No 1829/2003, for which the EFSA GMO Panel had adopted a scientific opinion. All studies except one were conducted without a specific request from the Panel. In accordance with the EFSA Guidance for the risk assessment of GM plants (EFSA GMO Panel, 2011), a 90-day feeding study is necessary if the composition of the food or feed derived from the GM plant is substantially modified, or if there are indications of the potential occurrence of unintended effects based on the molecular, compositional or phenotypic analysis. This happened in a single case, for which the EFSA GMO Panel requested that the study be conducted.

After the presentation, issues related to diet formulation were discussed, in particular the percentage of soybean or maize included in the diets used in these studies.

EFSA protocol for 90-day animal feeding studies

EFSA presented the SC's Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole FF (EFSA SC, 2011). It was explained that this guidance complements the existing OECD test guideline 408 and provides advice for the protocol design, analysis and reporting of 90-day animal feeding studies carried out with whole FF. The aim of this GD is to set the frame for a proper experimental feeding study design in order to detect possible toxicological effects of the test diet compared with a control diet. It was emphasised that, although the fundamental principles are similar, the OECD test guideline 408 is intended for chemical substances, whereas the EFSA GD is intended for whole FF. It was pointed out that the performance of 90-day feeding studies will become mandatory for GMOs containing single events, according to the new Implementing Regulation (EU) No 503/2013.

At the end of the session, EFSA asked for further feedback from all delegates. While acknowledging the difficulties, there was a general agreement on the importance of harmonising the 90-day animal feeding studies in terms of study design and analytical endpoints, in order to make such studies comparable and therefore useful for risk assessment. At the same time, some delegates cautioned that the motivation of conducting such studies should remain case by case, and overstandardisation of the experimental findings may lead to weak results.

4.3.2. Breakout session ENV: protection goals

Development of protection goal options for ERA of pesticides

EFSA presented how PGs are developed for the ERA of pesticides. In order to conduct a robust ERA, EFSA has developed a conceptual framework to define specific PGs. The framework consists of the following steps: (1) listing the ecosystem services (ESs); (2) identifying ESs that are potentially affected by the use of pesticides, both in the in-crop and off-crop areas; (3) identifying key drivers for each of the ESs (major taxonomic or functional groups that support the ES); (4) developing specific PGs by the identification of six dimensions for each ES/key driver combination—ecological entity, attribute, magnitude, temporal scale, spatial scale and degree of certainty; (5) identifying vulnerable species; and (6) developing protective risk assessment schemes. This framework provides a transparent and systematic way to define PGs and helps risk managers in their decisions.

Following the presentation, several issues were discussed, such as: managing discrepancies among risk managers from different Member States and reaching an agreement among stakeholders; agreeing on PGs for other species, such as those for biological control; setting PGs for endangered species; and considering the temporal scale not only in the in-crop area.

Environmental protection goals, philosophy, policy and publics

Fern Wickson (invited speaker), from the Genøk-Center for Biosafety of Tromsø (Norway), delivered a presentation on the ethical aspects of the definition of PGs and the need to develop a standardised and consistent reasoning to define what must be valued in nature and justify why it should be protected. The presenter stated that there is a diversity in criteria on what is perceived as a harm to the environment. This perception depends on factors such as abundance of the species, extent of the damage in the population, familiarity, and a sense of "friendship" with the species. Moral positions on environmental aspects vary from anthropocentrism to ecocentrism but, in general, there is a feeling that ecosystems have an intrinsic value. In her view, EFSA addresses PGs differently for GMOs and pesticides, however, in both cases the concept of ESs is used. There are a number of criticisms of this concept: it assumes a full understanding of the ecology, gives a pure instrumental value to nature, does not recognise ESs to non-humans, and has a view too polarised towards engineering and economics, leaving aside values such as humility or reverence. The environment has not only ecological but also cultural values. However, the GMO approach does not consider cultural services, unlike the approach in pesticides. "Sustainability" could be chosen as a PG, as referred to in the Norwegian Gene Technology Act. However, EFSA understands sustainability in the sense of an ES without considering its cultural and human dimensions. This might be because of the absence of legislation on social and economic issues of sustainability in the EU.

After the presentation, there was an interchange of views between the presenter and several members of the audience. The audience was reminded that the EFSA Guidance for the environmental risk assessment of GM plants (EFSA GMO Panel, 2010) includes consideration of species of conservation concern. Furthermore, agro-ecosystems are not natural, and it is misleading not to have this present in ethical considerations. The EFSA Guidance for the ERA of GM plants provides a clear rationale on the value of the species for the ecosystem.

Other issues discussed: inclusion of socioeconomic issues in the risk assessment in addition to scientific aspects; the need to be more explicit when taking normative decisions and defining what is acceptable; the importance of incorporating ethical aspects into the definition of PGs; the role of risk managers in defining PGs; data on biodiversity linked to agricultural ecosystems; and new technologies which can influence ecosystems towards the maintenance of the human population.

4.4. Long-term animal feeding trials as a tool for the risk assessment of GMOs

General thoughts about extended duration feeding studies in rodents

Dominique Parent-Massin (invited speaker), member of the EFSA ANS Panel, opened the session by reviewing the principles of repeated dose testing in general toxicology. Repeated dose toxicity testing applied to FF presents several challenges: the compound(s) which might exert toxicological damage are usually below the limit of detection of the test, control diets are not always compositionally equal to GM diets, maintenance of the nutritional balance is sometimes difficult, and a sufficient number of control groups must be included. The selection of the animal species is also problematic. In the case of rats (the most common species for repeated dose testing), they spontaneously develop tumours and other disorders when ageing (especially some strains), which can mask the results.

It is difficult to justify in which cases extended duration tests for toxicological evaluation are recommended. In most cases, toxicological tests such as *in vivo* genotoxic assays or 90-day repeated dose tests and compositional analysis for compounds known as toxic or carcinogenic render long-term studies unnecessary. In the event that an extended duration assay is deemed appropriate, a six-month study would be preferable, rather than a two-year one, since this period already allows detection of pre-neoplastic lesions or variations in parameters.

Recent literature reviews have shown that, notwithstanding some limitations, long-term studies did not find significant differences among GM and control groups, nor did they add new information to the outcome of the previously conducted 90-day tests.

In conclusion, extended duration tests for the toxicological risk assessment of GM FF are considered to have no added value in the absence of strong scientific evidence. Conducting such tests should be decided on a case-by-case basis, such as reasonable doubt remaining after a 90-day study.

During the discussion, it was noted that *in vitro* toxicological assays are currently not very useful as a substitute for animal tests, and that the publication by the group of Séralini on a two-year study with GM maize (published in 2012, just after the literature review mentioned in the presentation) would not fit into the literature review, because the protocol used by the authors was not according to the OECD guideline.

EFSA's draft Scientific Report on the applicability of the OECD guideline for two-year animal feeding studies

EFSA introduced a mandate recently received from the EC to comment on OECD test guideline 453 (two-year carcinogenicity and chronic toxicity feeding study in rodents) with specific considerations related to whole FF. The background to this mandate was the EC's intention to launch a call for a research project to perform a two-year carcinogenicity feeding study in rodents with GM feed. EFSA's output would aid the future establishment of protocols to be used for the study.

To accomplish the mandate, EFSA set up an internal task force to produce a Scientific Report on the applicability of OECD test guideline 453 to whole FF testing (EFSA, 2013), taking into consideration general elements of the previous EFSA opinion on 90-day feeding studies with whole FF. Comments will be provided on the selection of animal species, aspects of housing and feeding, dosage, number of animals, endpoints to be measured, statistical analysis and data reporting. Once finalised, EFSA will submit the draft Scientific Report to the GMO Network in order to receive input from the Member States. In anticipation of this, EFSA invited Network experts to express their views about the statistical requirements for the experimental setup, dose groups selection and dosage, or any other consideration on whole FF testing.

The discussion following the presentation addressed: appropriate methods to be used in order to gain public trust and guarantee the credibility of the study; test material to be used, whether herbicide treated or not; scientific rationale for performing long-term studies; and animals to be used in the study (see also Section 3).

4.5. ERA of GM animals

The recently adopted EFSA Guidance on the environmental risk assessment of genetically modified animals (EFSA GMO Panel, 2013) was presented to the audience by EFSA. The draft GD had been submitted for public consultation. Most of the comments received were from public institutions, National Authorities and non-governmental organisations. There were many opportune and useful comments which contributed to improving the document significantly. This GD considers possible applications in three classes of animals: fish, insects, and mammals and birds. Its structure and content were presented in detail.

Questions raised related to this GD were: whether applications are expected within the next five years; the applicability of the document, considering it did not cover systemic aspects such as interactions among populations or migrations; and how to find differences between GM and non-GM animals from desk studies. EFSA answered that, although the document gives value to literature reviews as potentially informative, the comparative approach is still the key element of the assessment. It was also clarified that issues such as transport of animals, accidental leakage and processing are also covered in the document. Nevertheless, given that no dossier has been submitted to the EU yet, the first assessments of GM animals will be challenging exercises, from which much will be learned to streamline the ERA.

4.6. Any other business

EFSA gave notice to the participants about the following issues: the current mandate of the Network would expire in November 2013 and both Member Institutions and appointed experts would need to

be renewed; the expert database, which members are encouraged to join and/or disseminate through contacts; conducting the initial ERA of cultivation applications, for which EFSA welcomes expressions of interest; answering the request from the EFSA SAS Unit to provide information on environmental surveillance networks in the frame of the project "Review of statistical methods and data requirements to support post market environmental monitoring of agro ecosystems" (see also Section 3).

5. Outputs of the GMO Network

The views expressed at the annual meeting are recorded in the minutes of the meeting and have been subject to review by the intervening participants. The minutes of the meeting are published on the dedicated EFSA website: http://www.efsa.europa.eu/en/events/event/130522d-m.pdf

6. Planned GMO Network activities for 2014

The GMO Network experts expressed their interest in continuing having a yearly meeting. The next meeting will be the first meeting under the second mandate of the GMO Network. EFSA encouraged Network members to get involved in the development of the agenda. Network members willing to develop the next agenda together with EFSA are welcome to contact EFSA in advance. The planning of the agenda usually starts in February.

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