Introduction to OECD work on novel food and feed safety

OECD activities on novel food and feed safety

The OECD Task Force for the Safety of Novel Foods and Feeds was established in 1999, with the primary goal to promote international regulatory harmonisation in the risk and safety assessment of biotechnology products among member countries, by addressing aspects of the assessment of human food and animal feed derived from genetically engineered crops. This body was renamed the Working Group for the Safety of Novel Foods and Feeds (WG-SNFF) from 1 January 2017.

The terms "novel foods and feeds" usually relate to foods and feeds derived from transgenic organisms, that is, partly or fully composed of such ingredients. By extension, these terms can also be understood as foods and feeds containing products obtained from other modern biotechnology techniques. Regulatory harmonisation is the attempt to ensure that the information used in risk/safety assessments, as well as the methods used to collect such information, are as similar as possible. It could lead to countries recognising or even accepting information from one another's assessments. The benefits of harmonisation are clear: it increases mutual understanding among member countries, which avoids duplication, saves on scarce resources and increases the efficiency of the risk/safety assessment process. This, in turn, improves food and feed safety while reducing unnecessary barriers to trade (OECD, 2000).

The WG-SNFF comprises delegates from the 36 member countries of the OECD and the European Commission. The OECD member countries span the globe, from North and South America to Europe and Asia-Pacific. They include many of the world's most advanced countries but also emerging countries like Chile, Mexico and Turkey. A number of observer delegations and invited experts also participate in the WG-SNFF work, from Argentina, Colombia, the Russian Federation and South Africa, as well as the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the Business and Industry Advisory Committee to the OECD (BIAC) and other relevant organisms such as the ILSI Research Foundation and the Biosafety Network of Expertise of the African Union (AUDA NEPAD-ABNE). Since 2004, several additional partner countries (Bangladesh, Brazil, the People's Republic of China, Costa Rica, India, Indonesia, Kenya, Moldova, Paraguay, Philippines, Uruguay, Viet Nam, Thailand and others) have participated occasionally or on a regular basis in the WG-SNFF activities, invited under the auspices of OECD Global Relations Secretariat and its Global Forum on Biotechnology.

Typically, delegates of the WG-SNFF come from government ministries and agencies which have responsibility for the food or feed safety assessment of products of modern biotechnology. In some OECD countries, this is the Ministry of Health; in others, it is the Ministry of Agriculture. Other countries have specialised agencies with this responsibility. Often, it is a shared responsibility among more than one ministry or agency. The expertise that these delegates have in common is related to their experience with the safety assessment of novel foods and feeds.

The emergence of the concept of consensus documents on compositional considerations

By 1997, several OECD countries had gained experience with safety assessment of foods derived through modern biotechnology. An OECD workshop in Aussois, France, examined the effectiveness of the application of substantial equivalence in safety assessment. It was concluded that the determination of substantial equivalence provides equal or increased assurance of the safety of foods derived from genetically engineered plants, as compared with foods derived from conventional methods (OECD, 1997).

At this event, it was also recognised that a consistent approach to the establishment of substantial equivalence might be improved through consensus on the appropriate components (e.g. key nutrients, key toxicants and anti-nutritional compounds) on a crop-by-crop basis, which should be considered in the comparison. It is recognised that the components may differ from crop to crop.

Following the Aussois workshop, the question of whether there was a need to undertake work on food/feed safety at the OECD, and if so, what that work would entail, was examined. The in-depth analysis was conducted by an Ad Hoc Group on Food Safety (established by the Joint Meeting).[1] It took into account the results of national activities and those of previous OECD work, as well as the activities of the FAO and the WHO.

As a result of the Ad Hoc Group on Food Safety's activities, the Joint Meeting established the WG-SNFF, with a major part of its programme of work being the development of consensus documents on compositional data. These data are used to identify similarities and differences following the comparative approach as part of a food and feed safety assessment. They should be useful to the development of guidelines, both national and international, and to encourage information sharing among OECD countries and beyond.

Participation from non-OECD countries is strongly encouraged by the WG-SNFF. In line with the biotechnology development in recent years, "an increasing emphasis has been placed on crops of interest to developing countries and countries in transition including those with tropical climates" (Kearns, Dagallier and Nikaido, 2017). As transgenic crops are grown in several of these economies, their commodities are traded internationally and widely used for food and feeds. This exchange has increased over the years, and now more actively involves their expertise in OECD work. For example: the consensus documents on the composition of cassava, grain sorghum, papaya and common bean were developed under the leadership or co-leadership of Brazil, South Africa and Thailand; the Philippines have actively contributed to the revision of the rice composition document; Nigeria provides expertise for the continuing revision of the potato composition document. This concrete enlargement to non-OECD members' input and competency broadens the expertise available to the WG-SNFF, while addressing a wider range of food and feed products that are of global interest.

Background and principles surrounding the use of consensus documents

The OECD "consensus documents on compositional considerations" are a compilation of current information that is important in food and feed safety assessment. Agreed by consensus among the WG-SNFF participants, they provide a technical tool for regulatory officials, industry and other interested parties, as a general guide and reference source. They complement those of the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology which deal with the environmental safety aspects (biosafety)

(OECD, 2017; 2016a; 2016b; 2006a; 2006b; 2010a; 2010b). They are mutually acceptable to, but not legally binding for, member countries and are also used as key references by other economies beyond the OECD for their assessment of novel foods and feeds. They do not intend to offer a comprehensive description of all the issues considered necessary for a safety assessment but provide a base set for an individual product that supports the comparative approach. In assessing an individual product, consideration of additional components may be required depending on the specific case in question.

The work of the WG-SNFF builds on previous OECD experience in biotechnology safety-related activities, dating back to the mid-1980s. Initially, much of the work concentrated on the environmental and agricultural implications of the use of transgenic crops. By the end of 1990, it was decided to develop scientific principles for food safety assessment of products of modern biotechnology. This work was undertaken in collaboration with the FAO and WHO.

In 1990, a joint consultation of the FAO and the WHO established that the comparison of a final product with one having an acceptable standard of safety provides an important element of safety assessment (WHO, 1991).

In 1993, the OECD further elaborated this concept and advocated the safety assessment based on substantial equivalence as being the most practical approach to addressing the safety of foods and food components derived through modern biotechnology (as well as other methods of modifying a host genome, including tissue culture methods and chemical- or radiation-induced mutation).

In 1996, a Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety elaborated on compositional comparison as an important element in the determination of substantial equivalence. A comparison of critical components can be carried out at the level of the food source (i.e. species) or the specific food product. Critical components are determined by identifying key nutrients and key toxicants and anti-nutrients for the food source in question. The comparison of critical components should be between the modified variety and non-modified comparators with an appropriate history of safe use. The data for the non-modified comparator can be the natural ranges published in the literature for commercial varieties or those measured levels in parental or other edible varieties of the species (FAO/WHO, 1996). The comparator used to detect unintended effects for all critical components should ideally be the near-isogenic parental line grown under identical conditions. While the comparative approach is useful as part of the safety assessment of foods derived from plants developed using recombinant-DNA technology, the approach could, in general, be applied to foods derived from new plant varieties that have been bred by other techniques.

In 2000, the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology (FAO/WHO, 2000) concluded that the safety assessment of genetically modified foods requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions. A comparative approach focusing on the determination of similarities and differences between the genetically modified food and its conventional counterpart aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy for the safety and nutritional assessment of genetically modified foods. The concept of substantial equivalence was developed as a practical approach to the safety assessment of genetically modified foods. It should be seen as a key step in the safety assessment process, although it is not a safety assessment in itself; it does not characterise hazard, rather it is used to structure the safety assessment of a genetically modified food relative to a conventional counterpart. The consultation

concluded that the application of the concept of substantial equivalence contributes to a robust safety assessment framework.

Between 2000 and 2003, the ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology to the Codex Alimentarius Commission ("Codex Task Force") undertook work to develop principles and guidelines for foods derived from genetically engineered plants. The full report of the Codex Task Force included:

- principles for the risk analysis of foods derived from modern biotechnology
- a guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants
- a guideline for the conduct of food safety assessment of foods produced using recombinant-DNA microorganisms (Codex Alimentarius Commission, 2003).

One notable feature of the principles is that they refer to a safety assessment involving the comparative approach between the food derived from modern biotechnology and its conventional counterpart. Annex II (safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits) and Annex III (safety assessment in a situation of low-level presence of recombinant-DNA plant material in food) were added to the guidelines in 2008.

The OECD WG-SNFF continues to collaborate with the Secretariat of the Codex Alimentarius Commission in order to strengthen their complementary activities.

The process for preparing consensus documents on compositional considerations

The consensus documents are prepared by the WG-SNFF on official proposals by countries. Typically, the focus is a food crop or vegetable for which modern biotechnology can be used in the plant-breeding process. New improved varieties of these species are being developed by researchers for future release in at least one country, or even exist already at a commercial level for some of them.

The WG-SNFF establishes ad hoc drafting groups, composed of officials and scientific experts of the species in interested countries. These drafting groups work with all this diversity of inputs, under the co-ordination of "lead countries". The successive revised drafts are reviewed by the full WG-SNFF, with careful examination of the proposed information, data, tables and figures. The several revisions and completions can require a few years, leading to a consensus from all delegations obtained on all elements. Following an OECD internal process for final approval, the document is published and becomes available online for worldwide users.

The OECD BioTrack website provides publications and news from the WG-SNFF, the Series on Novel Food and Feed Safety, contact details of national safety systems and other information. It links to the biosafety (environmental safety) publications, the Series on Harmonisation of Regulatory Oversight in Biotechnology. It also gives free access to the OECD BioTrack Product Database, available at www.oecd.org/biotrack.

Current and future trends

With the growing development of products from modern biotechnology, the production of transgenic crops has increased drastically in the last 23 years (ISAAA, 2018). It might even

expand in the future if new varieties adapted to emerging needs are adopted. Potential applications could encompass agriculture, industry, health and energy sectors.

Resistance to pests and diseases were introduced in plants from the early stages of genetic engineering and still constitute an essential feature of the varietal improvement for agriculture, horticulture and forestry. In parallel, breeders are also working on incorporating new traits in crops to gain other types of beneficial effects. Some of these varieties are about to enter the market or at initial stage of cultivation. In recent years, drought-tolerant varieties (maize, sugarcane) have been developed to contribute to climate change adaptation. "Innovation in plant breeding (including biotechnology) that aims to develop crop varieties that are more resilient to climate change impact (e.g. resistance to drought, soil salinity or temperature extremes) is part of a larger basket of possible adaptation options in agriculture" (Agrawala et al., 2012). Other innovative traits can have a direct beneficial impact on foods and feeds, and some are already promising: staple crops (rice, tubers, other species) offering nutritive improvements with increased content (biofortification) of elements such as pro-vitamins or micro-nutrients, feed plants (for example, maize, alfalfa) modified for higher digestibility and meat productivity, and many other products under development. The range of biotechnology applications to plant breeding continues to widen, leading to an expected increase of derived foods and feeds used and exchanged internationally in the coming future. In addition, strains of Atlantic salmon genetically engineered to include fast-growing trait have been recently approved for commercial production, the first animal species of which novel food can be marketed in a few countries.

Among the new breeding techniques developing at quick pace in recent years, genome editing refers to techniques able to modify specialised enzymes by insertion, replacement or removal of DNA fragment from a genome with a high degree of specificity. Genome editing, and its most discussed techniques such as the CRISPR/Cas9 system, has received increasing attention in the research sector and wider media. This advanced form of genetic engineering provides tools at relatively low cost for innovation in biomedicine, agriculture, industrial biotechnology and other sectors relating to the bioeconomy. Already successfully used in agriculture for plant crops and farm animals' husbandry, genome editing improves the efficiency of the breeding and offers new possibilities for the control of pests and diseases, as well as many other beneficial traits. The rapidly-growing use of genome editing has human health and environmental safety considerations, and policy implications that need to be understood. For facilitating the process in a first initiative, the OECD Conference on Genome Editing: Applications in Agriculture – Implication for Health, Environment and Regulation was organised in June 2018. The event aimed to review the situation and open discussion among policymakers, academia, innovators and other stakeholders involved in the topic. The proceedings of the event were published in 2019 (Transgenic Research, 2019). The WG-SNFF, which was actively involved in the preparation of the conference, keeps the item on its work agenda in order to continue the exchange of information, keep track of scientific and regulatory developments in countries, identify points of divergences and synergies, and contribute to better harmonisation.

A reliable risk/safety assessment of novel foods and feeds is, therefore, more than ever a necessity for many world economies in the context of international trade of commodities. Release of such products should be based on solid information and appropriate tools for leading to national decision-making. Harmonised regulations, common practices and easy access to solid science-based compiled information are sought. The tools developed by the OECD Working Group for the Safety of Novel Foods and Feeds are designed to promote international harmonisation in the field of food/feed safety assessment. These outputs are

recognised and appreciated, and might play an increasing role in fulfilling the safety assessment needs in the future.

The WG-SNFF is continuing its work on a range of issues. The development of consensus documents on compositional considerations should still constitute the main area of the 2021-24 programme of work. Emerging topics are also considered in order to remain reactive to demand, for example other new biotechnology techniques including genome editing, innovative feed ingredients, animal composition data, all of them to be considered in light of food and feed safety issues.

In parallel, the consensus documents are reviewed periodically and updated as necessary to ensure that scientific and technical developments are taken into account. Users of these documents have been invited to provide the OECD with new scientific and technical information and to make proposals for additional areas to be considered. For example, the documents on the composition of low erucic acid rapeseed (canola), soybean and rice, originally published between 2001 and 2004, were completed and revised by the WG-SNFF, leading to updated issues in 2011, 2012 and 2016 respectively. The potato and maize composition documents (both issued in 2002) have initiated a revision process and others might follow in the coming years.

In order to enlarge dissemination of the scientific information and risk assessment tools produced by the WG-SNFF, the consensus documents are regularly collated in "compendia" published in the OECD Series on Novel Food and Feed Safety. Volume 1 and Volume 2 were issued in 2015, containing the consensus documents produced from 2002 to 2008 and from 2009 to 2014 respectively (OECD, 2015b; 2015a). This Volume 3 covers the 2015-19 period, dealing with the composition of common bean, rice (which revises the original version of 2004), cowpea and apple.

Note

[1] The Joint Meeting was the supervisory body of the Ad Hoc Group and, as a result of its findings, established the WG-SNFF as a subsidiary body. Today, its full title is the Joint Meeting of the Chemicals Committee and the Working Party ons Chemicals, Pesticides and Biotechnology.

References

Agrawala, S. et al. (2012), "Adaptation and innovation: An analysis of crop biotechnology patent data", *OECD Environment Working Papers*, No. 40, OECD Publishing, Paris, http://dx.doi.org/10.1787/5k9csvvntt8p-en.

Codex Alimentarius Commission (2003), *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants*, CAC/GL 45/2003, Annexes II and III adopted in 2008, www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf (accessed on 28 Jan. 2015).

FAO/WHO (2000), *Safety Aspects of Genetically Modified Foods of Plant Origin,* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology Food and Agriculture Organization, Rome, www.fao.org/fileadmin/templates/agns/pdf/topics/ec_june2000_en.pdf (accessed on 28 January 2015).

FAO/WHO (1996), "Joint consultation report, biotechnology and food safety", *FAO Food and Nutrition Paper No. 61*, Food and Agriculture Organization, Rome, www.fao.org/ag/agn/food/pdf/biotechnology.pdf (accessed on 28 January 2015).

ISAAA (2018), "Global status of commercialized biotech/GM crops in 2018: Biotech crops continue to help meet the challenges of increased population and climate change", *ISAAA Brief No. 54*, International Service for the Acquisition of Agri-Biotech Applications: ISAAA, Ithaca, New York, http://www.isaaa.org/resources/publications/briefs/54/default.asp (accessed on 5 September 2019).

Kearns, P., B. Dagallier and T. Nikaido (2017), "The sharing of information in risk assessment: How national authorities cooperate", in A.A. Adenle, E.J. Morris and D.J. Murphy (eds), *Genetically Modified Organisms in Developing Countries: Risk Analysis and Governance,* Cambridge University Press, Cambridge, https://doi.org/10.1017/9781316585269.012.

OECD (2017), *Safety Assessment of Transgenic Organisms in the Environment, Volume 7: OECD Consensus Documents*, Harmonisation of Regulatory Oversight in Biotechnology, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264279728-en.

OECD (2016a), *Safety Assessment of Transgenic Organisms in the Environment, Volume 6: OECD Consensus Documents*, Harmonisation of Regulatory Oversight in Biotechnology, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264253421-en.

OECD (2016b), *Safety Assessment of Transgenic Organisms in the Environment, Volume 5: OECD Consensus Documents*, Harmonisation of Regulatory Oversight in Biotechnology, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264253018-en.

OECD (2016c), "Report of the OECD Workshop on Environmental Risk Assessment of Products Derived from New Plant Breeding Techniques (February 2014)", *Series on Harmonisation of Regulatory Oversight in Biotechnology No. 61*, OECD, Paris, www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)5&doclanguage=en.

OECD (2015a), *Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 2, Novel Food and Feeds Safety*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264180338-en.

OECD (2015b), *Safety Assessment of Foods and Feeds Derived from Transgenic Crops, Volume 1, Novel Food and Feeds Safety*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264180147-en.

OECD (2010a), *Safety Assessment of Transgenic Organisms: OECD Consensus Documents: Volume 4*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264096158-en.

OECD (2010b), *Safety Assessment of Transgenic Organisms: OECD Consensus Documents: Volume 3*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264095434-en.

OECD (2009), *The Bioeconomy to 2030: Designing a Policy Agenda*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264056886-en.

OECD (2006a), *Safety Assessment of Transgenic Organisms: OECD Consensus Documents: Volume 2*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264095403-en.

OECD (2006b), *Safety Assessment of Transgenic Organisms: OECD Consensus Documents: Volume 1*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264095380-en.

OECD (2000), *Report of the Task Force for the Safety of Novel Foods and Feeds*, Prepared for the G8 Summit held in Okinawa, Japan on 21-23 July 2000, C(2000)86/ADD1, OECD, Paris, www.oecd.org/chemicalsafety/biotrack/REPORT-OF-THE-TASK-FORCE-FOR-THE-SAFETY-OF-NOVEL.pdf (accessed on 31 January 2019).

OECD (1997), *Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods*, Workshop held in Aussois, France, 5-8 March 1997, final text issued in February 2002 as SG/ICGB(98)1/FINAL, OECD, Paris, www.oecd.org/env/ehs/biotrack/SG-ICGB(98)1-FINAL-ENG%20-Novel-Foods-Aussois-report.pdf (accessed on 31 January 2019).

Transgenic Research (2019), "Proceedings of the 'OECD Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation' held on 28-29 June 2018", *Transgenic Res. Volume 28, Issue Supplement*, August 2019, Springer, https://link.springer.com/journal/11248/28/2/suppl/page/2.

WHO (1991), *Strategies for Assessing the Safety of Foods Produced by Biotechnology*, Report of a Joint FAO/WHO Consultation, World Health Organization of the United Nations, Geneva, out of print.