OECD Conference on Genome Editing
APPLICATIONS IN AGRICULTURE
Implications for Health, Environment and Regulation
28-29 June 2018
Programme

OECD Conference on Genome Editing

Applications in Agriculture – Implications for Health, Environment and Regulation
BACKGROUND INFORMATION

As part of OECD's overall Programme of Work and Budget for the biennium 2017-2018, the OECD Council agreed for a project on 'Health and Environmental Safety in Genome Editing Applications' to be implemented with the support of the Central Priority Fund (CPF). CPF funding is given to activities addressing topics which have a multi-disciplinary component and would not otherwise be covered in one particular OECD committee's work programme. In this context, an ‘OECD Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation’ will be held at the OECD Headquarters on 28-29 June 2018. The event is also being sponsored by OECD’s Co-operative Research Programme (CRP).

The Conference will contribute to OECD work on several issues: science and technology policies including the innovation strategy; food and agricultural policies; environment, health and safety; involving the Directorates of Environment (ENV), Science, Technology and Innovation (STI), Trade and Agriculture (TAD) and Public Governance and Territorial Development (GOV). The Environment Directorate leads the project and coordinates internal preparation through the Internal Co-ordination Group for Biotechnology (ICGB).

ABOUT GENOME EDITING

Genome editing refers to techniques in which specialised enzymes which have been modified, can insert, replace, or remove DNA from a genome with a high degree of specificity. Genome editing, and one of its most discussed techniques the CRISPR/Cas9 system, has received increasing attention in the academic press and the 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.

Genome editing has been already successfully used with agricultural organisms of commercial importance such as agricultural crops and farm animal husbandry, improving the efficiency of plant and animal breeding, and offering possibility of new methods for the control of pests and diseases. The rapidly growing use of genome editing has policy implications and human health and environmental safety considerations.

The OECD’s two-day Conference will focus on applications of genome editing in the agricultural sector, including any associated health and environmental safety considerations. Within the context of this Conference, the term ‘health’ refers to food and feed safety. The Conference will bring together policy makers, academia, innovators and other stakeholders involved in the topic.

THE CONFERENCE STEERING GROUP

A steering group consisting of delegates nominated by OECD member countries has developed a balanced Conference agenda that is organised in three main sessions: i) applications of genome editing in agriculture – plant and animal breeding; ii) risk and safety considerations; and iii) regulatory considerations. The event will aim to provide a clearer understanding of the regulatory considerations raised by products of genome editing, aiming to favour a coherent policy approach to facilitate innovation involving genome editing.

The steering group comprises approximately twenty-five participants nominated by OECD delegations to the: Working Party on Biotechnology, Nanotechnology and Converging Technologies; the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology; the Working Group for the Safety of Novel Foods and feeds; and the Co-operative Research Programme.
THE CONFERENCE OUTPUTS

The Conference will provide participants with an update on the current status and future possibilities for genome editing applications in agriculture. The event will facilitate exchanges on their implications in health, environment, and regulation.

The main deliverable of the Conference will be a proceedings document comprised of a written version of each of the presentations. The publication of these proceedings is expected by the end of 2018.

At the same time, each of the Committees or subsidiary bodies contributing may wish to consider key elements and issues raised for any follow-up work if necessary. These outputs would remain for OECD internal use only.
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<tr>
<th>Time</th>
<th>Event</th>
<th>Speaker</th>
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<tr>
<td>09:00</td>
<td>Registration</td>
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<tr>
<td>09:30</td>
<td>Welcome by the OECD</td>
<td>Masamichi Kono, Deputy Secretary General, OECD</td>
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<td>09:45</td>
<td>Innovation in agriculture</td>
<td>Ken Ash, Director, Trade and Agriculture Directorate, OECD</td>
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<td>09:45</td>
<td>An overview of OECD activities related to the Co-operative Research Programme</td>
<td>Gary Fitt, Health and Biosecurity Deputy Director – Science, Commonwealth Scientific and Industrial Research Organisation; Chair of the OECD CRP Scientific Advisory Body</td>
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<td>10:00</td>
<td>Key-Note 1: Global perspectives in genome editing</td>
<td>Fyodor Urnov, Deputy Director, Altius Institute for Biomedical Sciences, United States</td>
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10:45

An overview of OECD activities related to modern techniques of biotechnology and genome editing

This overview will consider OECD activities related to modern techniques of biotechnology including genome editing in light of previous OECD conferences and workshops and technical products, such as consensus documents.

Speaker: Peter Kearns, Environment, Health and Safety Division, OECD

11:00

Key-Note 2: Global developments of genome editing in agriculture

The second Key-Note presentation will cover the scope of agricultural applications of genome editing by describing the relevance of these techniques to agriculture especially crop plants, farm animals as well as the foods and feeds derived from them.

The presentation will also address the potential impacts of genome editing applications in agriculture; for example: Will they lead to the faster development of new crop varieties and animal breeds at a lower cost? Could they present any new health and environmental safety considerations? Can they impact sustainable development? What are the potential consequences for farmers? Are there impacts for consumers, society, and the environment?

Speaker: Agnès Ricroch, Evolutionary Genetics and Plant Breeding, AgroParisTech; Pennsylvania State University

Session 1: Applications of genome editing in agriculture

Session 1 will consider specific case studies or examples of agricultural applications of genome editing, particularly plant varieties or animal breeds that may be on or close to the market or under research and development.

The session will also indicate how genome editing approaches may be used to produce desired characteristics in plants and animals that are not readily achievable with other methods, and thus the benefits that genome editing approaches may offer to agriculture. This could include any horizon-scanning analyses conducted in different countries. The session should also consider to what extent these applications match sustainable development goals.

Session Moderator: Elselien Breman, European Agricultural and Fisheries Policy and Food Security Department, Ministry of Agriculture, Nature and Food Quality, Netherlands

11:45

An overview of agricultural applications of genome editing: Crop plants

The presentation will give an overview of genome editing applications in relation to crop plants. The aim will be to have a better understanding of the specific features of genome editing in comparison with classical breeding and genetic engineering techniques. It will give an overview of some examples of agricultural applications that may be on or close to the market or under research and development. It will also consider the possibility of foreseeing future applications (e.g. variations in CRISPR/Cas applications, DNA-free application, agricultural pest control), if possible.

Speaker: Caixia Gao, State Key Laboratory of Plant Cell and Chromosome Engineering, Institute of Genetics and Developmental Biology, People’s Republic of China
13:35
**An overview of agricultural applications of genome editing: Farm animals**
The presentation will cover similar ground to the previous one, but with respect to farm animals.

Speaker: Simon Lillico, The Roslin Institute and Royal (Dick) School of Veterinary Studies, The University of Edinburgh

The following series of presentations will describe specific products under development, demonstrating the types of modifications introduced into plants and animals through genome editing techniques, and how such modifications were achieved. The process from discovery to final product, including proof of concept, early and advanced development processes, will be described. Some presentations will cover the breeding steps taken between the initial editing event and the final product, as well as the characteristics and performance of the product.

14:00
**Application of genome editing 1: Crop plants: DNA-free genome editing with CRISPR enzymes**

Speaker: Sunghwa Choe, School of Biological Sciences, College of Natural Sciences, Seoul National University

14:20
**Application of genome editing 2: Crop plants: Next-generation waxy corn**

Speaker: Robert Meeley, Corteva Agriscience, DowDuPont

14:40
**Application of genome editing 3: Crop plants with improved culture and quality traits**

Speaker: Peter Rogowsky, ENS Lyon, French National Institute for Agricultural Research

15:00
**Application of genome editing 4: Crop plants with enhanced disease resistance**

Speaker: Vladimir Nekrasov, Plant Sciences Department, Rothamsted Research, United Kingdom

15:20
**Application of genome editing 5: The global need for plant breeding innovation**

Speaker: Petra Jorasch, European Seed Association; International Seed Federation

15:40 Tea / Coffee Break

16:10
**Application of genome editing 6: Farm animals: Chicken**

Speaker: Mark Tizard, Australian Animal Health Laboratory, Commonwealth Scientific and Industrial Research Organisation
16:30
**Application of genome editing 7: Farm animals: Cattle**
Speaker: Alison Van Eenennaam, Department of Animal Science, University of California, Davis

16:50
**Application of genome editing 8: Farm animals in aquatic systems**
Speaker: Anna Troedsson-Wargelius, Molecular Biology Section, Institute for Marine Research, Norway

17:10
**Panel discussion Session 1: Applications of genome editing in agriculture**
The panel discussion will include the moderator and speakers from Session 1. Amongst other things, the panel will aim to summarise the types of current and proposed applications of genome editing for the development of agricultural products and the techniques being used. The similarities and/or differences between applications and products in plants and animals, and any opportunities and challenges associated with various techniques and types of application will be discussed. The panel will also consider the realistic prospects for the various applications of genome editing in agriculture. Which applications are available in the near-, medium- and long-term future?

18:10 Reception
Session 2: Risk and safety considerations

Session 2 will explore any risk and safety considerations that may be associated with the application of genome editing techniques in agriculture. It will recap the evolution and state of risk/safety assessment for the products of modern biotechnology, both for food/feed and environmental assessments. The session will consider how genome editing techniques are applied and the nature and specificity of the genetic changes they create, including specificity of targeted changes and evidence about the nature of any off-target changes. This will comprise comparison with the body of knowledge of genetic changes (intended and unintended) from other approaches such as conventional breeding, radiation or chemical mutagenesis, and ‘classical’ genetic modification/engineering.

Each presentation should highlight the practical approaches to identifying any hazards and addressing any potential risks, including the methods applied and the information needed.

Session Moderator: Huw Jones, Institute of Biological, Environmental and Rural Sciences, Aberystwyth University, United Kingdom

9:00
Risk and safety considerations 1: Current risk assessment approaches for environmental and food & feed safety

This presentation will provide an overview of the history of development and the current application of risk and safety assessment approaches to agricultural products including genetically engineered/modified organisms (GEOs/GMOs) with a variety of introduced traits. It will comprise information on common standards and developments at the international level (Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Cartagena Protocol on Biosafety, and OECD technical documents and guidance for risk/safety assessment of GM/GE plants).

The presentation will also address the following topics:

- What methods/systems are used to ensure the environmental safety? Why and how did they develop?
- What are (potential) safety assessment approaches for products developed through the use of different technologies (e. g. novel foods, GEOs/GMOs): Why and how did they develop?

Speaker: Jeffrey Wolt, Biosafety Institute for Genetically Modified Agricultural Products, Iowa State University; Crop Bioengineering Center
**Risk and safety considerations 2: Genetic variations and potential risks – Traditional breeding and genome editing**

This presentation will reflect on intentionally introduced genetic variations found in the products obtained by traditional breeding, genome editing, and genetic modification/engineering to compare the types and specificity of genetic changes arising from these breeding methods, including a qualitative analysis of differences and similarities between the breeding methods, in the light of scientific research and practical experience in the field.

It will also address the following topics:

- How do genetic changes relate to changes at the phenotype level?
- What is the scientific evidence about numbers and types of mutations that arise in various breeding approaches and postulated or observed adverse effects for environment and food/feed?

**Speaker:** Yutaka Tabei, Institute of Agrobiological Sciences, National Agriculture and Food Research Organization, Japan

**10:00**

**Risk and safety considerations 3: Considerations of unintended effects in genome editing applications**

Recognising that all breeding techniques have the potential to cause unintended phenotypes, this presentation will explore safety considerations arising from unintended/off-target effects in genome editing applications including frequency, and detection of off-target effects, and how these compare to other breeding techniques during the process of product development. Consideration such as accelerated development of applications as well as techniques will be also addressed.

**Speaker:** Marie-Bérengère Troadec, Institute of Genetics and Development of Rennes, The National Centre for Scientific Research; Scientific Committee of the High Council for Biotechnology, France

**10:30 Tea / Coffee Break**

**11:00**

**Panel discussion Session 2: Considerations of risk and safety**

The panel discussion will include the moderator, the speakers from Session 2, and two additional experts. Amongst other things, the panel will aim to discuss any potential considerations for environmental and food/feed risk/safety assessments of products developed using genome editing. Questions to be addressed:

- Are there novel risk/safety considerations related to genome editing techniques in comparison to those associated with ‘conventional’ breeding methods as well as products derived from genetic modification/engineering?
- Are there knowledge gaps and uncertainty relevant to risk/safety assessment for the products of new genome editing techniques that can be identified? How can the knowledge gaps be addressed?
- Are there risk/safety considerations related to the fast development of genome editing methods and potential products?
- Do the risk/safety considerations raised for agricultural products of genome editing relate to the specific technique(s) applied or to the characteristics of the products?

**Additional panellists:** Odd-Gunnar Wikmark, Biosafety of Genome Editing, GenØk – Centre for Biosafety, Norway and Alan Raybould, Syngenta Crop Protection AG
Session 3 will address the regulatory questions associated with genome editing applications in agriculture, with a view to discussing approaches to address them. A short introduction will suggest key issues to be considered regarding the regulatory oversight of genome edited products. The following series of presentations will consider policy frameworks in specific countries.

They will address the regulatory approaches to genome editing, including legal definitions of genetic modification/engineering in relation to genome editing and risk assessment considerations, taking into account the safety of plant breeding practices and existing regulations of agricultural products. For example, how regulatory frameworks may address different types of risks and enforceability of regulations (identification, monitoring, traceability, labelling). Other topics might arise if relevant to national frameworks such as sustainability considerations, socioeconomics and innovation.

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<tr>
<th>Session Moderator: François Pythoud, Ambassador, Representative of Switzerland to FAO, IFAD and WFP</th>
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<td><strong>11:50</strong></td>
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<td><strong>11:55</strong></td>
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<td>Speaker: Martin Lema, Biotechnology Directorate, Ministry of Agro-Industry; The National University of Quilmes</td>
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<td><strong>12:15</strong></td>
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<td>Speakers: Peter Thygesen, Office of the Gene Technology Regulator and Lisa Kelly, Food Standards Australia New Zealand</td>
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<td><strong>12:35 Lunch Break</strong></td>
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<td><strong>14:05</strong></td>
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<td>Speaker: Christine Tibelius, Plant Health Science Division, Canadian Food Inspection Agency</td>
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<td><strong>14:25</strong></td>
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<td>Speaker: Chantal Bruetschy, Biotechnology Unit, Food and feed safety, innovation, DG SANTE, European Commission</td>
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<td><strong>14:45</strong></td>
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<td>Speaker: Murali Krishna Chimata, Ministry of Environment, Forest and Climate Change</td>
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15:05

Country 6: United States

Speakers: Sally McCammon, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Kathleen Jones, Center for Veterinary Medicine, U.S. Food and Drug Administration and Mike Mendelsohn, Biopesticides and Pollution Prevention Division, U.S. Environmental Protection Agency

15:25 Tea / Coffee Break

15:50

Panel discussion Session 3: Regulatory aspects

The panel discussion will include the moderator and speakers from Session 3. The panel will discuss the regulatory considerations for genome editing applications identified during the Session to explore the prospects of genome editing applications for sustainable development in agriculture. It will identify the similarities and differences in the regulatory approaches to agricultural products developed by genome editing tools, including the legal framework existing in different countries/regions. It will also consider the issues arising from lack of global harmonisation in the regulations for genome edited applications.

16:40

Conference outcomes & wrap-up

16:40

Wrap-up and leaving address

Speaker: TBC

17:05

Summary of next steps

Speaker: OECD Secretariat

17:20 Closure of the Conference
This event is supported by the OECD Central Priority Fund, the OECD Co-operative Research Programme, USDA-FAS and held under the auspices of the OECD Global Forum on Biotechnology.

For more information:

- ehs.contact@oecd.org
- www.oecd.org/environment/genome-editing-agriculture
- @OECD_ENV @OECDagriculture @OECDinnovation