



Report on the Webinar on the International Databases on Biosafety

Organized by FAO, UNEP-CBD and OECD

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Acronyms

BCH – Biosafety Clearing House

CBD – Convention on Biological Diversity

CPB – Cartagena Protocol on Biosafety

FAO – Food and Agriculture Organisation of the United Nations

GM – Genetically Modified

LLP – Low Level Presence

OECD – Organisation for Economic Cooperation and Development

UNEP – United Nations Environment Programme

UI – Unique Identifier

WHO – World Health Organization

1. Introduction

1.1 Background

In order to facilitate the exchange of information on biosafety, there are several initiatives at the global level to provide access to a variety of scientific and other relevant information. Food and Agriculture Organization of the United Nations (FAO) maintains a platform entitled the FAO GM Foods Platform (<http://fao.org/gm-platform>) to share information on safety assessment of foods derived from recombinant-DNA plants authorized in accordance with the Codex “Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003, annex III adopted in 2008, http://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf)”. The Platform also facilitates the effective utilization of food safety assessment in situations of Low Level Presence (LLP) of r-DNA plant materials in food.

The Biosafety Clearing-House (BCH, <http://bch.cbd.int>) is a mechanism set up by the Cartagena Protocol on Biosafety to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. The BCH is maintained by the Convention of Biological Diversity (CBD) of the United Nations Environment Programme (UNEP).

The Organisation for Economic Co-operation and Development (OECD) hosts the BioTrack Product Database (<http://www2.oecd.org/biotech/>) that allows regulatory officials and others to easily share basic information on products derived from the use of modern biotechnology, as well as some products with novel traits acquired by the use of conventional breeding or mutagenesis, that have been approved for commercial application in at least one country, in terms of food, feed or environmental safety.

While the abovementioned three initiatives closely collaborate together at the international level to enhance the effort in creating the synergetic information systems, differences do exist in the number of Member States and the scope of the data/information hosted (food and feed safety, environmental risk assessment, decisions on commercialization and other relevant data/information). There have been several requests from Members and Parties of the concerned organizations to clarify the respective mandates, scopes, and coverage of information hosted on the relevant databases.

Based on the requests, on the 12th of November 2014, a Webinar entitled “FAO/UNEP-CBD/OECD Joint Webinar on the International Databases on Biosafety” was held.

1.2. Scope

The scope of the Webinar is strictly technical, inviting primarily technical officers from various governmental agencies who are tasked to work with international databases on biosafety. As the format of the Webinar is best suitable to have interactive discussions, the Webinar has been expected to play a role to facilitate inter-sectoral forum for national participants for their continuous communication. Regulatory decisions and political discussions have been excluded from the scope of the Webinar as these issues need to be addressed with the respective governing bodies.

1.3. Objectives

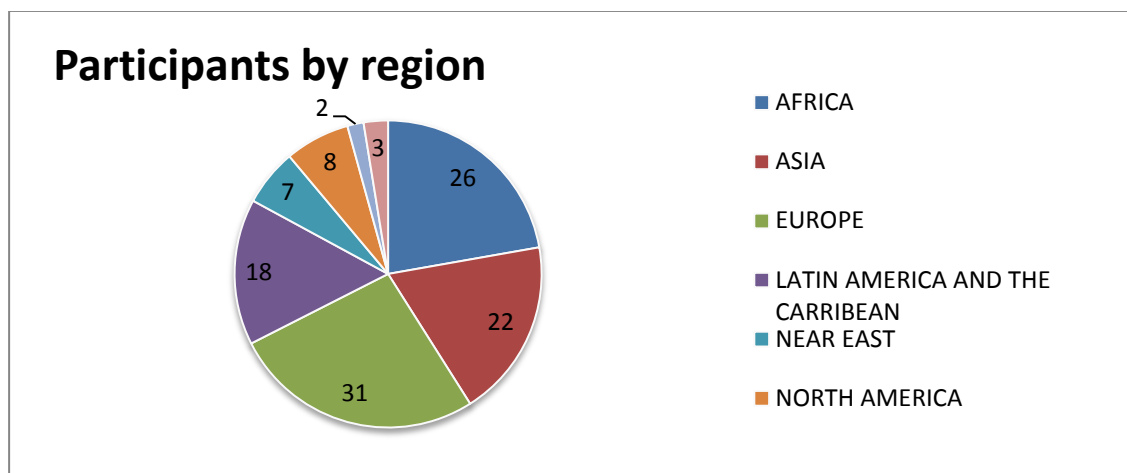
The Webinar was organized as an online forum for interactive discussions. The specific objectives of the Webinar were:

- To share key information regarding three relevant databases maintained by FAO, UNEP-CBD and OECD;
- To link national participants from different sectors (agriculture, food, health, environment, trade, commerce, and others) to facilitate effective communication; and
- To provide a forum for members/parties to discuss possible ways to maximize collaboration and achieve synergies at the national and international levels.

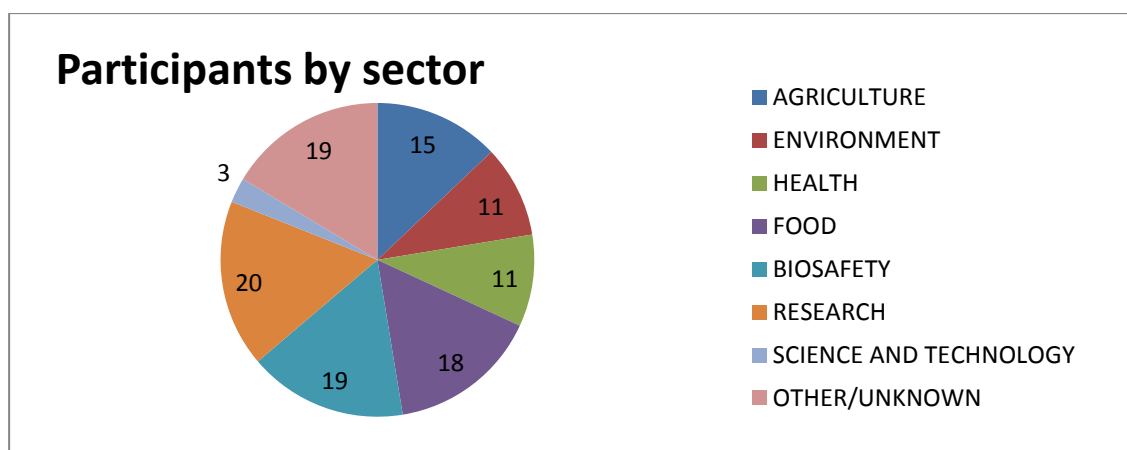
2. Participation and proceedings

2.1. Participation

Among 170 people from 76 countries pre-registered to the Webinar, a total of 120 people from 55 different countries actually participated in the Webinar. 34 participants (28.3%) were from Asia, 30 (25.0%) from Europe, 24 (20.0%) from Africa, 17 (14.2%) from North America, 10 (8.3%) from Latin America and 2 (1.7%) from the Pacific. Furthermore, 3 participants (2.5%) from inter-governmental organizations joined.



Most participants were working in public sector entities as the Ministry of Agriculture, the Ministry of Health, the Ministry of Environment or their National Food Safety Competent Authority.



The complete list of participants and their affiliation is attached in Annex 1. Other registered people are also listed in Annex 2.

2.2. Methods

The webinar was held in two sessions to accommodate different global time zones. Session 1 took place from 09:00-11:00 AM (Rome Time, GMT+1) and Session 2 took place from 16:00-18:00 PM (Rome Time, GMT+1). The online conference tool Adobe Connect was used for this webinar as this platform could facilitate both presentations and interactive discussions. During the webinar a chat box was available for all participants to submit questions or comments to the organizers. In addition, some participants complemented the comments from the chat box by delivering verbal interventions on the different discussion topics. A list of frequently asked questions is attached in Annex 3.

2.3. Proceedings

The webinar followed the agenda below.

Session 1	Session 2		
09:00	16:00	Welcome	FAO
09:05	16:05	Presentations different Databases <ul style="list-style-type: none"> • FAO GM Foods Platform • Biosafety Clearing House • BioTrack Product Database 	FAO UNEP-CBD OECD
09:50	16:50	Questions and Answers on Presentations	FAO
10:00	17:00	Interactive Discussion <ul style="list-style-type: none"> • Areas within biosafety where further synergy can be achieved among the organizations • Communication among different national users of databases • Practical challenges in the use of the databases 	OECD FAO UNEP-CBD
10:50	17:55	Closing Remarks	OECD

First, after a quick welcome from Ms Masami Takeuchi (FAO), three presentations were delivered by FAO (Ms Takeuchi), UNEP-CBD (Mr Giovanni Ferraiolo), and OECD (Mr Bertrand Dagallier). The presentations files are available for download at the below URLs.

- FAO:
http://www.fao.org/fileadmin/user_upload/agns/topics/GMO/FAO_Masami_Presentation_20141112.pdf
- UNEP-CBD:
http://www.fao.org/fileadmin/user_upload/agns/topics/GMO/CBD_BCH_Giovanni_Presentation_20141112.pdf
- OECD:
http://www.fao.org/fileadmin/user_upload/agns/topics/GMO/OECD_Bertrand_Presentation_20141112.pdf

A brief questions and answers session was held after the set of three presentations, followed by 3 sessions of the structured and interactive discussions. The first discussion session

focused on the areas within biosafety where further synergy can be achieved among the organizations (facilitated by Mr Peter Kearns, OECD). The second discussion session focused on the topic of communication among different national users of databases (facilitated by Ms Takeuchi, FAO). The third discussion session focused on the topic of the practical challenges in the use of the databases (facilitated by Mr Ferraiolo, UNEP-CBD). The webinar was closed with the closing remarks provided by Mr Kearns (OECD).

3. Notes on terminologies

3.1. Various terminologies and definitions

The terminologies and definitions used during the Webinar can be either very similar or totally different among the users of the different databases, as they are determined or commonly used by the governing bodies of the different organizations. Some terminologies are specially defined by a certain organization while the very same terminologies are not at all defined by others. For this reason, this Webinar focused on common understanding during the Webinar, rather than discussing terminology and definition issues. If required and requested, the harmonization effort should be made at a more official forum.

3.2. An important terminology: OECD Unique Identifier

The OECD Unique Identifier (UI) was developed by the OECD as a tool to identify each GM plant according to its transformation event in such a manner that each UI should be unique to that transformation event. The OECD UI has been adopted by all three databases to identify individual GM events and represents an important tool to enable interoperability among the databases and to foster synergies. The OECD UI is assigned by the developer following the defined algorithm detailed in the document entitled “Revised 2006: OECD Guidance for the designation of a Unique Identifier for transgenic plants” available at: <http://www.oecd.org/science/biotrack/46815728.pdf>.

4. Summary of the presentations

4.1. Mandate and objective of the databases

All databases maintained by FAO, UNEP-CBD and OECD deal with biosafety and clear differences can be observed in terms of mandate/purposes, scope and users. During the webinar, three short presentations were provided on the different databases in a comparative approach. The following sections highlight the mandate, scope and users of the databases.

The mandate of FAO is to achieve global food security and food safety is one of the core pillars in achieving this goal. The FAO GM Foods Platform was developed based on the official request by Codex Alimentarius, which is a joint FAO/WHO intergovernmental standard setting body. Codex established an ad hoc task force on food derived from biotechnology and this task force developed various guidelines on the conduct of food safety assessment of GM foods, including plants, microorganisms and animals. By adopting the annexes of the guideline on foods derived from GM plants, all 186 member countries of Codex Alimentarius agreed to make available the information on food safety assessment of GM crops through a publicly accessible, central database to be maintained by FAO (FAO GM Foods Platform).

The Biosafety Clearing House (BCH) is mandated under the Cartagena Protocol on Biosafety (CPB). Article 1 of this Protocol describes the objective according to the precautionary

approach as following: ‘to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms’. In particular, the mandate of the BCH is to facilitate the exchange of information on LMOs and to assist the Parties to better comply with the obligations under the Protocol. These obligations describe a set of information requirements that all Parties to the Protocol need to make available.

The objective of the OECD BioTrack Database is to allow regulatory officials to easily share information on approved GM products. The database, together with other OECD biosafety activities, is based on the cooperation of national authorities responsible for environmental safety and the safety of novel foods and was founded upon request of the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds. The submission of information to the BioTrack Database is done on a voluntary basis.

4.2. Scope of the databases

The scope of the different databases can be compared along five different criteria:

1. Type of information

Each of the databases has a strictly defined scope that determines what documents are collected. The scope of the FAO GM Foods Platform is on data and information of safety assessments performed in accordance with the relevant Codex guideline. In addition, if countries would like to share information on biosafety regulations and laws this is possible through the platform as well. On the BCH, all national records are included including biosafety laws and regulations, risk assessments and decisions. The OECD BioTrack Database includes national decisions approving GE products and the official risk assessments that precede these decisions.

2. Target and focus

The main focus of the FAO GM Foods Platform is on food. However, some countries also share feed related information, since that can be in line with our platform’s purpose as feed crops might occasionally enter the food supply chain. The focus of BCH is on information about all uses of LMOs. The submission of information regarding LMOs for introduction into the environment and direct use as food or feed, or for processing is mandatory, whereas information on LMOs in transit and for contained use is accepted, although not mandatory. The OECD BioTrack database contains risks assessment information on food, feed and environmental release.

3. Type of organisms

In accordance with its mandate, the FAO GM Foods Platform only contains information about GM plants. This may change in the future depending on the Codex Members’ requests to include GM animals and GM microorganisms. The BCH covers information on all types of LMOs as defined under the Cartagena Protocol. The OECD BioTrack Database currently only contains information on plants. Information on animals and microorganism is accepted but not yet present.

4. Scale of data/information

The different mandates of the different databases also define the scale of the assessment covered by the database. The FAO GM Foods Platform only collects information on food crops commercialised after a risk assessment has been conducted in accordance with the Codex Guidelines. No information on field trials is collected. The BCH includes all risk

assessments generated through regulatory processes, including risk assessments of LMOs for domestic use and those for intended transboundary movements. The OECD BioTrack Database only includes information on commercialized organisms and approved products and thus not on varieties tested in field trials.

5. Database users

FAO covers 186 Codex Members. Non-member countries are also invited to share information. The data/information shared on the GM Foods Platform is available for anyone, but uploading data/information is restricted to the Focal Points who are official nominated by their countries Contact Point to the Codex Alimentarius.

BCH serves 169 Parties to the Cartagena Protocol that are mandated to provide data/information to the BCH. Non-Parties are also invited to share information.

OECD covers 34 OECD Members, however, any country is invited to share relevant information on the OECD Biotrack Product Database. To date 9 countries and EU have shared data/information on the database.

5. Discussions

5.1. Content and scope of the databases

Participants discussed the content and scope of the three databases and indicated that all databases are useful in sharing information of GMOs at the global level. Prior to the Webinar, many participants thought that the three databases were rather similar and possibly overlapping, but the presentations helped improve the understanding that due to their different scopes and mandates, the three databases need to co-exist, and that this can be done with minimal duplication of efforts. One person commented that the choice and use of the database depends on the regulatory instruments and requirements set by the country, therefore it has been often the case that the country needs to use multiple databases to share information. One participant noted that improving coordination and communication at the national level would be the most effective starting point rather than asking three databases with three different groups of members/parties to be merged. Some participants followed this and agreed that in this way many people could benefit from all three databases.

5.2. Mechanisms for uploading data to all three databases

Several participants indicated that their main challenge was to keep all the databases up-to-date with the latest information. As some countries already maintain national databases on biosafety, uploading records on one or more international platforms is an additional work costing both human and financial resources. Another participant proposed that linking to information available on other databases might help avoiding the duplication of work for the contributors of the databases. Another participant responded that this would be a challenge since the focal points are different for the different databases. In conclusion it was proposed that a better mechanism to be established for national colleagues to work together towards synchronized entry formats that streamline the information requirements for submitting new entries at the national level.

5.3. The OECD Unique Identifier (UI) and other terminologies

The OECD UI is adopted and actively used by all three databases and provides a common approach to identify GM plants according to the transformation event. To date the OECD guidelines for assigning UIs are mainly used to identify GM plants, but in the future it may

also be applied to GM animals, microorganisms and viruses. It was acknowledged that the common use of the OECD UI is important for achieving further synergies among the databases as it provides a tool that facilitates common classification and exchange of information.

A practical challenge in the current use of the OECD UI lies in the fact that it is typically assigned by the developer after a product is approved for commercialisation, implying that in earlier stages of development a product is not classified. As a result the OECD UI is sometimes not available for LMOs undergoing field trials and other experimental releases and for which records are included in the BCH. This issue might be overcome by developers assigning OECD UIs to their GM products at an earlier stage of the development process.

During the webinar also multiple suggestions were made to further extend the harmonisation efforts to work on relevant terminology at the international level. It was proposed to develop harmonized terminology for genetic elements, for example by working on a joint glossary. Furthermore, it was proposed that the titles of national risk assessments and authorisation documents could include the OECD UIs of the GMOs/LMOs they refer to .

5.4. Collaborations and synergies

Substantial efforts have been made towards more efficient information sharing by database owners. To date a Memorandum of Agreement exists between OECD and UNEP-CBD in which is agreed to immediately notify each other when new information is uploaded. Furthermore, UNEP-CBD has been working to make data available on the BCH that is derived from other available online databases maintained by non-governmental organizations (NGOs, private sectors, etc). Some participants indicated that the possibility to link to information present on such databases should be carefully reviewed and explored, as some databases (e.g., FAO and OECD) are expected to host official information only.

Another effort that can be made is to facilitate further harmonization among the databases by developing a common pool of LMOs (GMOs), listed by their OECD UIs, to which relevant information can be attached by the uploaders. By gathering data on a centralized point it will be easier and more efficient for contributors to upload information as the submission of identical data to different platforms is circumvented. This was proposed by UNEP-CBD Secretariat, however as this has a substantial cost-implication to all three organizations, this may not be readily implemented without extra-budgetary funds.

Another possible way for the three organizations to further increase collaboration is to continue organizing joint activities such as this webinar. Many participants commented that this event should not be a single one-time-only event. FAO, UNEP-CBD and OECD assured that the present webinar will be followed by a next session in 2015. It can be envisaged that after this event more thematic webinar sessions to be organized that address specific biosafety related topics and stimulate discussion among the merged community of focal points to the relevant databases. It was echoed by many participants that organizing more webinars would be extremely useful.

5.5. The role of governing bodies in achieving harmonisation

Participants became aware that the development of the three databases was done upon the explicit requests of the member countries or parties of each organization. Each database operates independently under a specific mandate that is provided by its governing body. In these governing bodies the member countries decide in what direction its activities and work

should move forward. Discussions on the future direction of the databases and the degree of further integration and/or harmonization should take place in the governing bodies, not at the level of the operators (international organizations). Moreover the allocation of sufficient financial and human resources required to realize possible future harmonization and/or integration activities should be considered in the respective governing bodies.

5.6. Collaboration among Focal Points at the national level

Regulating and assessing risks of GMOs is a multidisciplinary issue with divided responsibilities among different governmental bodies that, among others, can include ministries/departments of Health, Agriculture, Environment and possibly others (Trade, Science and Technology, Economics, Bureau of Standards, etc). This cross-cutting nature of the issue requires a multi-agency collaboration that can pose a challenge. It was noted that in the experience of OECD members, the communication within a country with a longer history on commercializing GM products has been more effective than others, indicating that the need to establish a national communication/coordination mechanism was realized much earlier and improved along with the growth of the national regulatory experience on this topic. Other participants expressed the need to learn from the experience and suggested to work for more collaboration among all the focal points of three databases at the national level, as they are not necessarily always working together. It was mentioned that organizing regular national meetings that can facilitate interagency collaboration can be useful to streamline the national contribution to all the databases.

During the discussion, the participants of several countries shared their experience on the national coordination mechanisms. In Germany, for instance, it was noted that all focal points to the databases are working for the same agency which greatly facilitates the communication among them. Participants of other countries explained that they needed to work hard to maintain a regular dialogue among the relevant agencies. In some countries a formal mechanism such as a national biosafety committee has been established to formalize such a mechanism. In this type of mechanism all involved regulatory agencies convene meetings regularly to exchange information. The participant from Kenya explained that the Government has established a National Biosafety Authority that unites regulatory agencies in environment, wildlife, plant health, public health and veterinary services. This has proven to be an effective approach in Kenya for inter-sectoral collaboration and communication, although it still was considered to be a challenge to sensitize all involved national stakeholders with the potential benefits of using the databases. The representative of the UNEP-CBD stated that engaging the public in the regulatory process is an obligation under the Cartagena Protocol. He further informed the participants that capacity building efforts are undertaken to stimulate the development of this type of structures in the national biosafety frameworks.

5.7. Improving the practical usability of the databases

One participant noted that search and filter options should be tailored to the ultimate goals of each database. Differences exist in the complexity and amount of different filters available on each database. On the OECD BioTrack Product Database and the FAO GM Foods Platform search criteria are purposefully limited, making them easy to access for less experienced users. In contrast, the BCH has a broader range of search criteria allowing more refined data retrieval. It was noted that this can be extremely useful for experienced users but can be considered too complex for others. Another point raised was the lack of information in languages other than English. However, it was also noted that translating the websites and hosted data/information into 6 UN official languages will have enormous costs thus this

option will be considered if/when funds are available. Another suggestion was made to improve the databases to include the trade name in the search criteria and to develop interfaces that can be accessed from mobile devices. The representative of the UNEP-CBD informed that efforts are being made to launch a mobile application for the BCH in the near future.

For the process in uploading information, a series of small suggestions was made to improve usability. For the FAO GM Foods Platform, a participant suggested to create a complete list of OECD UIs for stacked events. For the BCH, a participant suggested to make available a user-friendly guidance (e.g., e-learning) for uploading information on LMOs that are still in the field trials and have not yet been assigned with an OECD UI. For the OECD UI, a participant suggested to develop a tool to have an algorithm to check the accuracy of calculating and assigning the OECD UIs.

6. Conclusions and a way forward

The webinar provided an informal but effective forum for users and contributors of all three databases to have a common understanding of the respective scopes, purposes and contents of the databases. The webinar also provided useful information from the side of the users in order to further improve the practical and operational aspects of the database management.

The OECD UI was recognized as an important common tool for all three databases. A common function around OECD UI can be a starting point to achieve further harmonization of three databases. Achieving synergies among the databases can be successful only if the agencies/authorities at the national level coordinate their work and activities on this topic.

A formal mechanism such as a national biosafety authority can be useful to facilitate inter-sectoral dialogue among the various agencies/departments and stakeholders.

Participants suggested that more webinars to be jointly organized by FAO, UNEP-CBD and OECD on the topic. The next webinar can be on a specific topic that provides a training opportunity to the database users and collaborators.

Annex 1 List of Attended Participants

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Annex 3 Frequently Asked Questions (FAQ)

Content, scope and terminology of the databases

1. What is the scope of the risk assessment of the FAO GM Food Platform in terms of safety?

The scope of the food safety risk assessment dealt on the FAO GM Foods Platform is strictly following the scope of the related Codex Guidelines available at http://www.codexalimentarius.org/download/standards/10021/CXG_045e.pdf.

2. Why does the FAO GM Food Platform not include information on environmental risk assessment?

The FAO GM Foods Platform was developed to address the specific request officially raised by the Codex Alimentarius Commission (Codex Members). As the environmental assessment falls outside of the remit of the Codex Alimentarius Commission, the Platform does not deal with the issue.

3. How do FAO and OECD define ‘novel’ food and feed?

FAO Members have not requested FAO to define the terminologies such as “novel food” and “novel feed” therefore there is no official definition of the term. On the FAO GM Foods Platform, data and information related to GM feed are accepted and some countries have specific legislations and regulations about GM feed while many other countries do not. For OECD, “Novel foods and feeds” means foods and feeds derived through modern biotechnology, equivalent to Genetically Modified (GM) foods and feeds (Please note that other than GM, Living modified (LM) or Genetically engineered (GE) are also used in the same meaning). Taking into consideration that currently cultivated GM crops such as maize or soybean are largely used as feed and the live stock is in turn consumed as food, feed safety is usually considered among many countries closely linked to food safety. One of the examples is the legal framework in the EU on novel foods and feeds, which is Regulation (EC) 1829/2003.

4. When will animals and microorganisms be added to OECD’s scope and activities?

They have been already in the activities of OECD. Atlantic salmon and mosquito in terms of animal, and eukaryotic micro-algae in terms of microorganism are under discussion.

5. How are stacked events managed in the three databases?

FAO recognizes that stacked events are managed differently among various countries. Therefore, the Platform offers a single text field (voluntary) on the “Country Profile” page labeled as “Information on stacked events”, and focal points are encouraged to share information on how they manage such events. For CBD, each living organism possessing a *novel combination* of genetic material obtained through the use of modern biotechnology is considered under the Cartagena Protocol on Biosafety (CPB) a new LMO and, as such, is added to the BCH list (see LMO list in the BCH at <http://bch.cbd.int/database/lmo-registry/>). For example, different transformation events, crosses where one parent is an LMO, and re-transformation are all considered as new LMOs. In the OECD database, stack is identified by the combination of UIs such as ACS-BN005-8 x ACS-BN003-6xMON-00073-7.

6. Where can the information on stacked events be uploaded on the FAO GM Foods Platform?

A specially designated field is available for the Focal Point to fill information on staked events on the Country Profile page of the FAO GM Foods Platform.

7. Do FAO or CBD include information on the cultivation period of a GM crop in their database?

The FAO GM Platform collects only “food/feed safety assessment” related data and information and does not require record on approvals (decisions) or information on the actual cultivation period. However, if a country set an expiration date to an assessment result, considering the possibility to obtain new data for revisiting the safety assessment, then the Platform offers a voluntary field to specify the date that the assessment results would/might expire. Decisions registered in the BCH according to the AIA (Advance Informed Agreement prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import) focus on approval or prohibition of the import (*rather than cultivation*), with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism (offline common formats, containing the metadata required to register information in the BCH are available at <http://bch.cbd.int/resources/common-formats/>).

8. Does CBD consider new techniques of genetic improvement (at the border between r-DNA technology and conventional breeding) to result in a LMO?

As long as the resulting organism fit into the CPB definition of "Living modified organism", i.e. “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology”, they will fall under the scope of the Protocol. “Living organism” and “modern biotechnology” are also defined in the Protocol (see Article 3: Use of Terms at <https://bch.cbd.int/protocol/text/>).

9. Does CBD advises its member countries to directly use/adopt the information on risk assessment that is shared through the BCH?

The BCH is established to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs; and to assist Parties to implement the Protocol (CPB, art. 20 at <https://bch.cbd.int/protocol/text/>). The Protocol requires that risk assessments be carried out on a case-by-case basis where each release of a LMO is considered relative to the LMO in question, its intended use and the environment in which the release is to occur. Therefore, even in cases where an LMO has already been approved for similar uses by other countries, a Party wishing to import that LMO for introduction into the environment must carry out a risk assessment focusing on the receiving environment, which will likely differ from previous approvals by other countries.

10. What is the role of the organizations and their databases in establishing a regulatory framework for GM products?

Making regulatory decisions on the release or use of GM products is the responsibilities of the countries. The goal of the databases/platforms is to provide members/parties a platform to share data and information that enables countries to make informed regulatory decisions.

11. Did COP-MOP7 decide to make field trials information mandatory?

The Advance Informed Agreement (AIA, CPB art. 7 at <https://bch.cbd.int/protocol/text/>) applies to *all* first intentional transboundary movements of LMOs for intentional introduction into the environment of the Party of import, independently of the purpose of the introduction (e.g. field trial or commercial cultivation). The fifth meeting of the Parties to the CPB (COP-MOP 5) reminded Parties of their obligations, to provide to the BCH complete and accurate information on final decisions pertaining to LMOs and the risk assessment summaries regarding such decisions, “*including, inter alia, intentional introductions of living modified organisms into the environment for field trials regardless on whether or not the living modified organism will be subjected to future transboundary movements or commercialization*” (BS-V/2 at <https://bch.cbd.int/protocol/decisions/?decisionID=12315>). The most recent COP-MOP 7, in recalling the previous decision on this subject, urged Parties and invited other Governments to register in the BCH all their final decisions on the first intentional transboundary movements of LMOs for intentional introduction into the environment of the Party of import and related risk assessments as requested under the Protocol, “*with special emphasis on the first intentional transboundary movement of living modified organisms intended for field trials, since this category is currently underrepresented in the Biosafety Clearing-House*” (BS-VII/2).

12. Does the CPB require information on LMOs used for pharmaceutical purposes to be submitted to the BCH?

The CPB requires the submission to the BCH of all final decisions regarding the import or release of any LMO as well as any risk assessments or environmental reviews of LMOs generated by regulatory process (CPB, art. 20 at <https://bch.cbd.int/protocol/text/>); the Protocol does not apply to the transboundary movements of LMOs that are “*pharmaceuticals for humans that are addressed by other relevant international agreements or organisations*” (CPB art. 5). It is worth noting that for this exemption to be applicable, (i) the living modified organism itself must be pharmaceutical for humans (as opposed to a product of the LMO) and (ii) it must be addressed by other relevant international agreements or organizations. To my knowledge, there are currently no LMOs that fulfil these two criteria.

13. Do the databases consider commercialized products?

All three databases (FAO, UNEP-CBD and OECD) deal with the commercialized products.

Mechanisms for data collection

14. Is there a determined frequency for updating the information registered in all presented databases?

For the FAO GM Foods Platform members are asked to submit relevant information within three months after the risk assessment has been conducted or regulatory approval has been granted. The objective is to complete uploading all backlogs by the end of 2015. For uploading on the BCH, CBD members are obliged to submit a notification of transboundary movement of a LMO 270 days after consent. When considering domestic regulatory decisions made on LMOs this period is 15 days. For the frequency of uploading information on the OECD BioTrack Product Database no strict requirements exist as uploading information is done on a voluntary basis. A reminder to OECD members with a call for data is sent out annually.

15. How does the CBD collected data for the BCH database?

The BCH contains two main categories of records: National Records and Reference Records. National records (such as *National Biosafety Website or Database / Competent National Authorities / Biosafety Laws, Regulations, Guidelines & Regional and International Agreements / Country's Decisions or any other Communications / Submissions from Parties & other Governments / Risk Assessments Generated by a Regulatory Process / Biosafety Experts and report on their assignments*) are directly registered online by countries and validated by the BCH national focal point (one per each country), directly appointed by the Government. Reference Records (such as *Capacity Building Activities & Needs Assessments / Biosafety Organizations & Laboratories for LMO detection / Submissions from relevant organizations / Virtual Library - BIRC) / BCH News / Risk assessments generated by an independent or non-regulatory process / Living Modified Organisms / Genetic elements / Organisms*) may be submitted to the BCH by any registered user and are validated and published by the CBD Secretariat “guided by the principles of inclusiveness, transparency and equity” (see BCH Modalities of operation at <https://bch.cbd.int/about/operation-modalities/>).

16. Are countries obliged to upload data on field trials on the BCH?

The CPB does not require a mandatory risk assessment of a LMOs developed in the same country where field trials will take place (i.e. in the case the LMO is not yet subjected to transboundary movements); however, if the country regulatory process requires a risk assessment prior to a field trial, there is an obligation under the CPB to submit that risk assessment to the BCH. On the other hand, if the LMO has been developed in a different country and is imported in the country where the field trials will take place (i.e. it is subject to a first intentional transboundary movements for intentional introduction into the environment of the Party of import), then the Advance Informed Agreement applies (AIA, CPB art. 7 at <https://bch.cbd.int/protocol/text/>), and it requires Parties to communicate, in writing, to the notifier and to the BCH, within 270 days of the date of receipt of notification, the decision about whether the intentional transboundary movement may proceed (CPB art. 10). The notification submitted to the competent national authority shall contain “at a minimum, the information specified in Annex I” (CPB art. 8) where, among other information, “a previous and existing risk assessment report consistent with Annex III” (CPB Annex I) is required.

Members/parties of the databases

17. Is the submission of information to OECD limited to her 34 member countries?

It is encouraged for non-member countries to submit their information to OECD database since we strongly consider it important to increase the value of database. Please note that only official is eligible for data submission.

18. Does CBD engage in direct discussions on issues that can arise in her member countries?

This depends on the topic of the discussion. The BCH hosts many online discussions, established during the Meeting of the Parties (COP-MOP), and focusing on specific topics (e.g. risk assessment, detection and identification, socio-economic considerations, etc). During these online fora, representatives from Parties, non-Parties and relevant organizations have the opportunity to discuss. The outcomes of these discussions are brought for consideration of the Parties during the COP-MOPs when the Parties agree on a way forward. In legal terms, the relationship between Parties and non-Parties is regulated by CPB art. 24.

19. How is information of the United States, that is no member of the Cartagena Protocol, included in the databases?

The USA is one of the leading data contributors to the FAO GM Foods Platform. The US Focal Point has been very active to share data and information related to food/feed safety assessment to the Platform and FAO is confident that by the end of 2015, the Platform will have all up-to-date data from the US. For OECD, data registration in the database is based on the request by officials. OECD takes every opportunity to encourage officials to submit the data, one of which is the meeting at OECD where the United States also participates in.

Since BCH inception, the US Government agreed, as a non-Party, to voluntarily set up an automatic feed of US decisions to the BCH and, as of today, the BCH hosts 119 US decisions on LMOs taken by the three relevant US agencies (USDA, EPA and FDA). The automatic feed stopped in March 2013 when the US Government decided to decommission the US Biotechnology Regulatory Database which was centrally collecting all information on LMOs. Contextually, the CBD Secretariat was informed by the US Administration of its intention to remain supportive of transmitting their data to the BCH and it is actively working with the three agencies for setting-up new mechanisms to exchange data. Notwithstanding the absence of recent US data, the BCH hosts, as of today, decisions from 43 countries (39 Parties and 4 non-Parties) on more than 400 LMOs and, as such, remains the world largest online repository on LMO information.

Current collaboration among FAO, UNEP-CBD and OECD

20. What are the main items three database owners have in common?

The major commonality among three databases is the use of the OECD Unique Identifier. UI is widely recognized among officials and developers and has become de facto standard of identifying the products derived from modern biotechnology.

21. What are key areas for collaboration among the FAO GM Foods Platform, BCH and OECD BioTrack Product Database?

The manager of the FAO GM Foods Platform actively attends the relevant meetings organized by UNEP, CBD and OECD. For example, FAO is a regular participant in the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds. In 2014, FAO attended two relevant meetings that were organized by CBD and UNEP respectively. Also for the international technical consultation on LLP organized by FAO in March 2014, both OECD and UNEP were the core resource persons and they both chaired several sessions during the consultation. At a technical level, FAO keeps frequent communication (more than once per month) with the officers who work on BCH website and OECD BioTrack Product Database. All three organizations continuously discuss possible ways to improve the synergies among three databases. The idea of having this joint Webinar came from such discussions.

22. The Memorandum of Cooperation between OECD and BCH prescribes that "Unique Identifiers and 'relevant information' on LMOs are transferred from OECD to the BCH database". What is considered relevant information in this perspective?

“Relevant information” includes any kind of information registered in the OECD database such as name of event, applicant, genes or traits.

23. Is it possible to expand the Memorandum to the FAO Platform?

Technically it is possible for FAO to have a memorandum with any organizations for possible positive results. However the official request should come from the Members (FAO Members or Codex Members).

24. Is it possible to broaden the scope of the Memorandum so that it allows the transfer of information between all three databases?

“Relevant information,” referred to in the Memorandum, includes any kind of information registered in the OECD database. The purpose of the database is to allow regulatory officials to easily share basic information on products derived from modern biotechnology. In this sense, sharing the information with not only CBD but also FAO definitely serves the purpose and it is welcome.

Usefulness in using the common OECD Unique Identifiers among all three databases

25. What is the purpose of the UI?

The purpose of UI is as a key to accessing information not only in the OECD product database but also in other interoperable system. It is widely recognized among officials and developers and has become de facto standard of identifying the products derived from modern biotechnology

26. Is there an algorithm that can check the correctness of a UI?

Once request for registration is received, the validity is checked by the OECD secretariat. The process includes checking the correctness of the UI by using algorithm.

27. Is there a way to uniquely identify other relevant information as laws or risk assessments?

When it comes to UI on other records like laws or risk assessment report, one of the biggest challenges is the scope as to what kinds of records should be covered since regulatory framework itself is different among countries. For the convenience of users, related records to UI such as risk assessment report or regulation are showed in the same location of UI and linked to the original.

Quality control of the data on the databases

28. How can it be ensured that the data and information uploaded on the databases are accurate, up-to-date and not contradicting among three databases?

Each database works with national Focal Points who have a responsibility in sharing relevant, accurate and up-to-date national data/information to the databases. FAO, UNEP-CBD and OECD make maximum efforts to encourage and stimulate respective Focal Points to establish a mechanism for regular national-level communication to streamline the data sharing process. Several countries have developed an effective communication system among different Focal Points as well as other stakeholders in a form of “national biosafety committee”. This approach may work well in many countries to support achieving synergies and increased harmonization between the organizations on the national level.

Increasing the efficiency in working with different databases

29. Is there a possibility to develop a mechanism that synchronizes the uploading of information on all three databases?

FAO GM Foods Platform specifically asks Members to submit data/information on food/feed safety assessment that has been conducted in accordance with the Codex Guidelines. If this condition can be satisfied with other databases (BCH and OECD), then automatic synchronization can be considered. However if this condition is not fulfilled, this will pose a difficulty in maintaining the quality of the data on the FAO GM Foods Platform. OECD fully understands our mission to pursue better databases where users can easily share information according to their preference. Similarly, OECD has to pay attention to the efficient way of data registration. In this sense, it considers a synchronized or “one-stop” database to be an interesting idea that is worth exploring.

30. Is it possible, taking into account the different scopes of the databases, to make linkages among the three databases?

Notwithstanding the absence of financial resources dedicated to this task, CBD, FAO and OECD are actively working toward the best use of the common OECD Unique Identifier which serves as index for all the decisions and safety assessments registered in the three databases; once this first goal is achieved, each database will be able to retrieve and link information to each specific LMO contained in the other databases. It is worth noting that such cross-referencing with an external database (such as ones maintained by NGOs and private entities) is already in place in the BCH.

31. What efforts do FAO and CBD make to share data between their databases?

FAO considers this a political decision and requires a Members’ request for implementing an automatic retrieving system. Currently FAO Members are not in favour of the automatic synchronization because the FAO GM Foods Platform has a condition that the data/information regarding food/feed safety assessment should be strictly following the Codex Guidelines. There is no such condition in other databases.

From CBD’s perspective there are limited actions that the three organizations (CBD, FAO and OECD) could do without a specific mandate from their Parties or members; so far CPB Parties have repeatedly requested to the CBD Secretariat to “*continue its collaboration with other biosafety databases and platforms, including those of the Food and Agriculture Organization of the United Nations, other clearing-houses of the Convention and the Organisation for Economic Co-operation and Development*” (BS-VII/2) and the Secretariat is working together with FAO and OECD in this direction. However, in order to address more efficiently the problems of data overlapping, it would be very helpful to have a common harmonized mandate from the Parties or members of the three organizations. Having an official common mandate would help in accessing financial resources.

32. Can the databases be merged to avoid overlap?

Each organisation has its own database and any changes (e.g. merging) should be directed by the governing bodies. The countries thus have the governing power. The database is considered the core area where synergies can be achieved and integrated data listing through OECD UI is supported by all three organisations. On the national level differences are seen

between inter-organisational coordination between the databases and collaboration between the different focal points can be further strengthened.

33. Does the OECD database include information on detection methods?

Since it is usually difficult to differentiate the phenotype of GM crops and the crops derived by conventional breeding, detection method is quite important to identify its existence. OECD considers the importance and covers the information in the database.

34. Would it be possible to develop a common format for uploading data on the databases?

This is something FAO, CBD and OECD can work together on and suggest members/parties to consider. However, the final support and the official request should come from all three organizations' members/parties.

Other information resources on biosafety

35. Is it considered to collaborate with other databases that contain information on non-authorized GMOs?

OECD considers it useful for importing countries to be able to access the information of GM crops in the pipeline of development since such information makes it possible to predict the schedule of application. It is considered interesting to explore the feasibility. One of key challenges is the availability and accuracy of data since such type of information is not in officials but in developers.

Collaboration and communication at the national level

36. How can synergies and harmonization among the three organizations at the national level be achieved?

In FAO's perspective, establishing and maintaining a mechanism for regular communication and coordination seems to be a good practice on this topic. FAO, UNEP-CBD and OECD can assist in bringing together the respective Focal Points so that such effort can be supported at the national level.

37. Can the organizations suggest their focal point in a country to get in touch with the other focal points?

FAO, UNEP-CBD and OECD strongly recommend this exercise and FAO/CBD/OECD can assist in bringing together the respective Focal Points so that a communication mechanism can be established.

Suggestions for improving the databases (practical aspects)

38. Can the databases include information on the status of cultivation of a GM crop?

In terms of including the status of actual cultivation in the database, the biggest challenge will be that many officials don't have such information. Once approval is given, choice of cultivation usually leaves to the market. In many cases, although GM crops varieties have been continuously replaced by newly-developed varieties, approved status still remains and then list of approvals include varieties commercially uncultivated.

39. How can information on LMOs that have not yet been assigned with an OECD UI be registered on the BCH?

LMOs can be registered in the BCH even if they do not have Unique Identifiers (UIs). The CBD Secretariat is also actively involved, together with OECD and the Global Industry Coalition (GIC), to solicit, as much as possible, the early attribution of UIs by their developers, particularly for LMOs that are being commercialized or are near commercialization.

40. Can focal points change or edit information that is already uploaded on the databases?

On the FAO GM Foods Platform, Focal Points can change, add or edit already submitted and uploaded data by contacting FAO at GM-Platform@fao.org. The OECD database is based on the voluntary request by officials, and data registration or modification in the database is made by the secretariat.

41. Can FAO assist in increasing the technical capacity of African countries?

FAO welcomes comments and feedback from African countries on this issue so that we can assess and identify the capacity development needs.

42. Is it possible to enable other users than the nominated focal point to upload records on the FAO GM Foods Platform?

Anything is possible with FAO Members' official request/consensus. Currently the Platform is tasked to collect only official data and information that are submitted by the nominated Focal Points.

43. Where are the final report, recordings and presentations made available?

The presentation files, final report and the recording are available at <http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/biosafety-events/>