



Food and Agriculture Organization
of the United Nations

Training on effective use of data on the databases

**The third FAO/CBD/OECD webinar on international
databases on biosafety**

9 December 2015

Executive summary

On 9 December 2015 a webinar was jointly organized by the Food and Agriculture Organization of the United Nations (FAO), the Convention of Biological Diversity (CBD) and the Organisation for Economic Cooperation and Development (OECD) to discuss the effective use of data on the databases hosted by three organizations. Through six presentations delivered by speakers from Japan, the Philippines, Malaysia, Spain, Mexico and Canada, participants recognized that the information and data shared on the respective databases are the critical source of information for monitoring the latest approvals in various countries thus contribute to the understanding of the global biosafety situations. In addition to the core data themselves, technical materials shared on the databases, including the Codex guidelines (FAO), BCH National Reports (CBD) and Consensus documents (OECD) were often found useful for risk managers in their decision making process. The usefulness of the up-to-date contact information of the competent authorities was highlighted as it stimulates effective and timely communication regarding the information/data shared by countries.

The webinar helped the participants in understanding the structure of the databases, enabling them to obtain the necessary technical information and data in a timely manner. During the interactive discussion session, six speakers from Serbia, South Africa, Thailand, Moldova, Germany, and the Kingdom of Bahrain discussed their experience on the effective use of data, in addition to the discussions by all through a chat box. The participants recognized the usefulness of collaboration among multiple countries, in particular, to share their lessons-learned experiences on data-requiring situations such as the processes of risk assessment, public engagement and low level presence management. The webinar successfully provided “good practices” of the database use and the participants expressed the need of more training opportunity provided by three organizations. The full information about the webinar is available at <http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/biosafety-events/>.

Keywords

international databases, GMO, LMO, biosafety, food safety, risk assessment, FAO, FAO GM Foods Platform, CBD, Biosafety Clearing-House, OECD, BioTrack Product Database, webinar

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Contents

- Executive summary 2
- Contents 3
- Organizers..... 4
- Acronyms..... 5
- 1 Introduction..... 5
 - 1.1 Background..... 5
 - 1.2 Scope 5
 - 1.3 Objective..... 6
- 2 Summary of the webinar 6
 - 2.1 Participation 6
 - 2.2 Methodology 6
 - 2.3 Agenda and proceedings..... 6
- 3 Presentations by countries on data/database use..... 7
 - 3.1 Japan..... 7
 - 3.2 The Philippines 7
 - 3.3 Malaysia..... 7
 - 3.4 Spain 8
 - 3.5 Mexico 8
 - 3.6 Canada..... 9
- 4 Discussions on the effective use of data on the databases 9
 - 4.1 South Africa 9
 - 4.2 Thailand 10
 - 4.3 Moldova..... 10
 - 4.4 Germany 10
 - 4.5 The Kingdom of Bahrain 10
- 5 Discussion on the collaboration among countries and database network..... 11
 - 5.1 Regional and database collaboration..... 11
- 6 Other questions and answers on the databases 11
- 7 Conclusion 12
- 8 Next steps..... 12
- Annex 1 Participation by Regions and Sectors 14
- Annex 2 Agenda..... 15
- Annex 3 Attended Participants..... 16
- Annex 4 Other Registered Participants 20

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Acronyms

BCH	Biosafety Clearing-House
CBD	Convention on Biological Diversity
CEE	Central and Eastern Europe
CFIA	Canadian Food Inspection Agency
COFEPRIS	The Federal Commission for the Protection against Sanitary Risk
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FFP	Food, Feed and Processing
GCC	Gulf Cooperation Council
GE	Genetically Engineered
GM	Genetically Modified
GMO	Genetically Modified Organism
LLP	Low Level Presence
LMO	Living Modified Organism
OECD	The Organisation for Economic Cooperation and Development
UI	Unique Identifier
UN	United Nations
UNEP	United Nations Environment Programme

1 Introduction

1.1 Background

On 12 November 2014, the first joint FAO/CBD/OECD webinar was organized and a total of 120 people from 55 different countries participated. During the first webinar, the mandates, scopes and activities of three databases: the FAO GM Foods Platform, the Biosafety Clearing-House and the OECD BioTrack product database were discussed. Participants recognized the clear differences in three databases and the importance of the co-existence of them. The complete report of the first webinar can be accessed at: http://tiny.cc/web1_report. Detailed information on the first webinar is available at: <http://tiny.cc/webinar1>

Following the recommendations made during the first webinar, the second joint FAO/CBD/OECD webinar was held on 27 May 2015 at which 60 people from 41 countries joined. Participants discussed the importance of the national cross-sectoral communication among agencies involved in the biosafety regulatory process and the public engagement in the regulatory process of GMOs. The summary report of the online discussion can be found at: http://tiny.cc/web2_eDis_report. The complete report of the first webinar can be accessed at: http://tiny.cc/web2_report. Detailed information on the second webinar is available at: <http://tiny.cc/webinar2>

The third joint FAO/CBD/OECD webinar was organized on 9 December 2015 to address the request from the participants of the first and second webinars that they benefit from a training opportunity. Thus the topic was determined to be the effective use of the data on three databases, providing practical information for the participants to apply in their day-to-day work.

1.2 Scope

The scope of the third webinar was the technical and practical aspects of the effective use of the data on the respective database, primarily targeting the Focal/Contact Points of the relevant databases

together with governmental officers working in the area of biosafety. Other interested professionals were also welcome to join the event. Regulatory or political factors related to the mandate of the databases were excluded from the scope of the webinar as these issues should be addressed by the respective governing bodies.

1.3 Objective

The objective of the third webinar was to provide training opportunities for participants in understanding the location, contents, specific meanings and possible use of the data that is made available on the databases.

2 Summary of the webinar

2.1 Participation

Among 100 people from 69 countries registered to the webinar, a total of 65 people from 48 different countries participated in the webinar. There were 15 participants (32.1%) from Africa, 15 (23.1%) from Asia, 16 (24.6%) from Europe, 8 (12.3%) from Latin America, 7 (10.8%) from Near East and 4 (6.2%) from North America (Figure 1 – Annex 1). Most participants were working in public sector including the Ministry of Agriculture, the Ministry of Food, the Ministry of Environment, the National Food Safety Agency and the National Biosafety Authority (Figure 2- Annex 1). Among all people attended in the webinar 1, 2 and 3, 30 participants (46.2%) joined the third webinar for the first time, 18 (27.7%) for the second time and 17 (26.2%) for the third time (Figure 3- Annex 1). According to the analysis, more than half of the participants in the third webinar attended the previous webinars. This indicates that a theme of a webinar should not be repeated in order for the participants to avoid discussing the same topic multiple times.

2.2 Methodology

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. Prior to the webinar, practical information and technical instructions were made available at <http://tiny.cc/Biosafety-Events>. Electronic certificates of attendance were provided to all who attended the webinar.

2.3 Agenda and proceedings

The webinar followed the agenda that can be found in Annex 2. After a brief welcome and overview of the previous webinars, participants from Japan (Session 1) and Spain (Session 2) delivered presentations to explain how to use the dataset that they made available on the Biosafety Clearing-House (BCH). Subsequently, a short discussion was facilitated by CBD and participants further discussed on the effective use of data/information on the BCH database. Similarly, participants from the Philippines (Session 1) and Mexico (Session 2) presented their experiences on the OECD BioTrack Product Database, followed by discussion facilitated by OECD. Then, presentations were delivered by participants from Malaysia (Session 1) and Canada (Session 2) on the FAO GM Foods Platform and the discussion was facilitated by FAO. During the last part of the webinar, an interactive discussion session was held for participants to discuss the usefulness of having country-to-country collaboration and the potential use of the database networks for such collaboration.

3 Presentations by countries on data/database use

3.1 Japan

Ms Ayako Yoshio explained that the details of environmental risk assessment of LMOs and regulatory frameworks for environmental risk management in other countries found on the databases are valuable for the control of new traits in Japan. Information on LMOs that are authorized in other countries, but not yet approved in Japan, is useful for monitoring the import from trade partners. Japan's country profile on BCH can be accessed at <http://tiny.cc/CBD-JAPAN>. The presentation pdf-file is available at: http://tiny.cc/web3_japan_pdf and the video of the presentation is available at: http://tiny.cc/web3_japan_video

3.2 The Philippines

Ms Amparo Ampil recognized the OECD BioTrack Product Database as a key source of information when her country goes through its decision making processes in approving GMOs. Ms. Ampil highlighted that the documents shared on the OECD database can be extensively used as a basis for the risk assessment for GMOs and for formulation of related national guidelines. These documents can be found at: <http://www.oecd.org/science/biotrack/>. Since the OECD database is the official source for the Unique Identifiers (UIs), regulators in the Philippines often visit the database to seek the guidance when validating new UIs.

Questions from the participants

Q1. Who are the main users of the BioTrack Product Database in the Philippines?

A1. Ms Ampil: Main users of the database are the decision makers and technology developers.

Q2. What is the main purpose of using of the data on the BioTrack Product Database in the Philippines?

A2. Ms Ampil: The main purpose is to search for a set of documents generated by the working group and task force of OECD in order to incorporate the information for the decision making process.

The presentation pdf-file is available at: http://tiny.cc/web3_philippines_pdf. A video of the presentation is available at: http://tiny.cc/web3_philippines_video.

3.3 Malaysia

Ms Anita Anthonysamy explained that it is important for FAO GM Foods platform to be considered a primary source of official records on the GM food safety assessment shared by Codex members. She also highlighted the usefulness of the up-to-date contact information of the competent authorities in food safety, as it stimulates effective and timely communications on the information/data shared by countries. She explained briefly how to access the records on the FAO GM Foods Platform by country, by commodity, and by trait. She selected the record of "MON-88Ø17-3" as an example to explain the national GM food safety assessment results shared by Malaysia. She stressed that it is essential for countries to have all the information on the different databases up to date and consistent to encourage visitors and fellow country members to use the platform. All the information shared by Malaysia is available at <http://tiny.cc/FAO-MALAYSIA>. The presentation pdf-file is available at: http://tiny.cc/web3_malaysia_pdf. A video of the presentation is available at: http://tiny.cc/web3_malaysia_video.

3.4 Spain

Ms Vanesa Rincón stated that Spain needs to comply with the Cartagena Protocol on Biosafety (CPB) thus sharing the national reports on BCH becomes mandatory. So far Spain has shared 2 national reports that clearly explain the status of the country with respect to biosafety and handling of LMOs. Such reports of all the countries available on the BCH are beneficial to understand the position of each country in terms of implementation of the Cartagena Protocol. Spain has currently shared 181 documents on the country's decision and any other communications, and 184 risk assessment results conducted in the country. All the other data/information shared by Spain is available at <http://tiny.cc/CBD-SPAIN>.

Questions from the participants

Q. Does Spain conduct its own GM food safety assessment? Is EFSA's assessment used?

A. Ms Rincón: Yes, Spain conducts its own GM food safety assessment using the assessment results that EFSA produces.

The presentation pdf-file is available at: http://tiny.cc/web3_spain_pdf. A video of the presentation is available at: http://tiny.cc/web3_spain_video.

3.5 Mexico

Ms Sol García stated that the OECD BioTrack Product Databases is important source of information that is in line with the official guidance in generating OECD Unique Identifiers (UIs) for Genetically Engineered (GE) organisms. It is always helpful for regulators to understand the UI system and subsequently be able to ensure the correct assignment of UIs. The OECD BioTrack Product Database is also useful in maintaining the country information up-to-date, since the structure of the database is harmonized through OECD UI with FAO GM Foods Platform, BCH and national database in Mexico. On the top page of the database, there are links provided to the databases hosted by FAO and CBD, and mentioned that such mutual links are very helpful for those looking for information on GM food/feed safety assessment. All the GE authorization information/data shared by Mexico on the OECD BioTrack Product Database is available at <http://tiny.cc/OECD-MEXICO>.

Questions from the participants

Q1. What are the regulatory options for stacked events in Mexico?

A1. Ms Sol Ortiz García: In Mexico, GM food/feed that contains stacked event(s) is considered as a new product even if all single events that are stacked have already approved. Thus, safety assessments are conducted for all GM food/feed that contains stacked event(s). The Federal Commission for the Protection against Sanitary Risk (COFEPRIS), a branch of the Ministry of Health, is dealing with the issues as a competent authority.

Q2. How does the authority deal with stacked events in terms of food safety assessment in Mexico?

A2. Ms Ortiz García: If the parental non-stacked event has been approved previously, safety assessment needs to consider that previous information on each parental event as well as an interaction among the effects of those events. If the parental event has not yet approved, COFEPRIS conducts all the necessary safety assessments.

The presentation pdf-file is available at: http://tiny.cc/web3_mexico_pdf. A video of the presentation is available at: http://tiny.cc/web3_mexico_video.

3.6 Canada

Mr Luc Bourbonnière highlighted that FAO GM Foods Platform is a technical source of the information on GM food safety assessments for more than 170 countries. A practical use of the database would be the one in the situation of a Low Level Presence (LLP) incident. Any given national regulators could quickly look up the information on the Platform to obtain technical GM food safety assessment data of the GM event that is found in a low level. He believes that the Platform is currently the best place for such information as there is an assurance that the safety information on the Platform is official and in line with the Codex guidelines. The data/information shared by other countries may not be the only source of information in decision making process, but it can facilitate the risk management process. The simple interface of the Platform also facilitates easy comparison of the GM food safety assessment contents between countries. Canada is one of the most active members of the Platform community, contributing to the FAO database with over 80 GM food safety assessment results. All data/information shared by Canada are accessible at <http://tiny.cc/FAO-CANADA>.

Questions from the participants

Q1. How does Canada manage LLP issues?

A1. Mr Bourbonnière: In Canada, Health Canada and CFIA have been working together on LLP issues. Health Canada is responsible for developing the policy regarding food safety standards and conducting the premarket assessment of novel foods including GMOs. CFIA, on the other hand, is dedicated to enforcing the food and drug regulation. Currently, the potential for LLP to enter Canada through imports is low since most of the GM foods that can be found in international trade have been authorized for use in Canada. However, other jurisdictions develop more GM foods intended for domestic use and those products could be threats of LLP in Canada. If Canada faces an LLP issue, Health Canada conducts the safety assessment and submit those results to CFIA to determine the future actions. OECD has published the document dealing with LLP issue available at <http://www.oecd.org/env/ehs/biotrack/> on the BioTrack Product Database.

Q2. How do food sector and feed sector collaborate together in Canada?

A2. Mr Bourbonnière: Both sectors collaborate informally via a working group and a memorandum of understanding between Health Canada and CFIA. Evaluators in Health Canada work closely with the CFIA's feeds counterparts as well as the CFIA biosafety evaluators. Health Canada also has no split approval policy with CFIA so GM foods are not approved until CFIA is ready to approve for feed and biosafety.

The presentation pdf-file is available at: http://tiny.cc/web3_canada_pdf . A video of the presentation is available at: http://tiny.cc/web3_canada_video.

4 Discussions on the effective use of data on the databases

4.1 South Africa

Mr Dean Oelofse stated that it is essential for all the relevant stakeholders to understand the information that is already available on three databases. As an initiative of Department of Science and Technology, Biosafety South Africa provides stakeholders with all the necessary guidance, advice and information to help ensure compliance with the regulatory requirements at all the various levels of GM research and development in South Africa. This service includes ensuring access to current reference databases including the BioTrack Product Database. Regarding the BCH, The South African Biosafety Clearing-House has been established as per Article 20 of the Cartagena Protocol on

Biosafety, in order to facilitate the exchange of scientific, technical environmental and legal information on LMOs at the national level.

4.2 Thailand

Ms Namaporn Attaviroj explained that regulators in Thailand review and use the information relevant to food safety assessment of other countries that has been made available on the FAO GM Foods Platform in order to understand the process of the safety assessment and the detection protocol. Currently, there are 7-8 traits of the imported GM foods that are in the process of the food/feed safety assessment. Ms Attaviroj mentioned that the link from the Platform to the respective country page of the BCH is useful since she obtains more related information from other databases. With this regard, she suggested that it would be useful if FAO/CBD could create similar links to the OECD BioTrack Product Database.

4.3 Moldova

Ms Angela Lozan stated that the national competent authorities in Moldova have access to the data on the BCH and use them as tools and guidelines that are used for domestic needs and training national personnel. Also, the BCH is a source of biosafety information available for different stakeholders and the large public and thus contributes to a better understanding and public participation. In addition, availability of the BCH in 6 United Nations (UN) languages is very useful for all main groups of countries.

4.4 Germany

Ms Karen Bohmert-Tatarev mentioned that the BioTrack Product Database is useful to make sure that UIs are correctly assigned. OECD has developed a tool “Verification digit checker” to ensure the correctness of the UIs available from the top page of the database (<http://www2.oecd.org/biotech/>). This is especially important when the necessary information is missing in the original application for the authorization (e.g. European Food Safety Authority/EFSA application). Ms Bohmert-Tatarev also uses the FAO GM Foods Platform to obtain the information on the molecular characterization of the GMOs since the EU genius database is currently focusing on the detection methods, molecular characterization and authorization of the GMOs.

4.5 The Kingdom of Bahrain

Ms Nujood Almuqahawi explained that Bahrain refers to the FAO GM Foods Platform for developing the standard for the Gulf Cooperation Council (GCC) since the Platform is important to gain the latest information around the world on the GM food/feed safety assessment. Bahrain is the member of GCC countries and has a role not only to develop policies and guidelines but also to participate in the standards formulation, implementation, and evaluation, in particular with the GCC food safety committee, and other relevant activities.

A video of the discussion sessions are available at: <https://youtu.be/7A0vUqwL92Y> (Session 1 - 1), <https://youtu.be/kpJlkbNsF8g> (Session 1 - 2), <https://youtu.be/zvneWCauZw4> (Session 1 - 3), <https://youtu.be/Que7DSWRTOA> (Session 2 - 1), <https://youtu.be/2p8H4xmuzrI> (Session 2 - 2) and <https://youtu.be/p4bx14yYwW0> (Session 2 - 3).

5 Discussion on the collaboration among countries and database network

5.1 Regional and database collaboration

It was discussed that countries belonging to particular regions have collaborations to share the information on risk assessment of GMOs. Having a common language facilitates the easiness of discussion to solve problems. This would be most effective if all the countries in a particular region participate actively. However, due to limited resources, regional collaboration might require assistance from international organizations like FAO, CBD and OECD.

It was also discussed that the face-to-face meetings that are held by BCH on a regular basis could be the first point to generate the country-country collaboration. Having such meetings also with focal points for FAO and OECD might be helpful to initiate collaborations between countries. Ms Anthonyamy, Ms Lozan and Mr Tarasjev stressed that coordination of information sharing not only at international level but also at the focal points level is extremely important so that responsible persons are confident to use all three databases. It was suggested that focal points of three databases can cooperate and further use the data that has been already shared on one database for similar use on the other databases. This could be difficult due to limitation of funds and differences in the scope among the three databases. However, once the aims/scopes are clarified, FAO/CBD/OECD can start looking at the face-to-face regional workshop at three databases.

Mr Bourbonnière stated that when it comes to the LLP issues, for example, country collaboration using the FAO GM Foods Platform might be helpful since there are many related documents that can help stakeholders to make decisions. For the collaboration on the safety assessment on GM foods, a strong point is that Codex Guideline could be a common basis for the discussion.

A video of the interactive discussion sessions are available at: https://youtu.be/3u3f1_JUOtc (Session 1) and <https://youtu.be/r9BHH8b6LI> (Session 2).

6 Other questions and answers on the databases

1. Even if a country has not yet validated its biosafety framework, could the country use the FAO GM Foods Platform to upload the information related to GM issues?

FAO: All countries that registered to the Platform can upload the relevant information. For countries with limited resources, the database could be used as a platform for data/information sharing also at the national level. In fact, most of the member countries do not routinely conduct food safety assessment on GMOs but can share the data on the database.

2. For LMOs that are yet to have unique identifier, how does the secretariat facilitate the submission of decisions to the BCH?

CBD: In cases where the Unique Identifier is not available (for example, LMOs for field trials normally do not have UIs), CBD secretariats require a description of the LMO including its name, genes that were modified, etc, and publish a record for the LMO even if it does not have a UI. In cases where the LMO already has a Unique Identifier but it is not yet entered in the BCH, typically the country will request CBD secretariats to make a record for the particular LMO.

3. Is everything available in 6 UN languages on BCH? Or is it about the navigation on the website?

CBD: The navigation of the BCH is available in the 6 official languages of the United Nations. In addition, the metadata associated with the records (i.e. the data that is not in the form of free text but that is offered as options when someone is registering a record) is mostly translated to all languages. The text content of National Records, which are documents submitted by countries directly to the BCH (for example, national laws and regulations), is only available in the official language in which the records were submitted. Most of the text content of reference records, which are records maintained by the Secretariat (for example, list of LMOs, genes, organisms), is only in English.

4. How do you reconcile national data on the BCH and those available in other databases such as in Bio TrackProduct Database?

CBD: The Secretariat has a role to support countries in meetings that requires to submit information to the BCH. We are constantly searching other international databases to see if and what information is missing in the BCH. We also systematically look for incomplete records that are not in full agreement with the requirements of the Cartagena Protocol. About once a year, we contact national focal points to bring to their attention the information that is missing in the BCH and invite them to submit it. This supportive approach has brought positive results.

5. Would it be possible to establish a central portal for all databases with the UIs as common denominator to access the relevant data in all participating databases?

CBD: It might be very useful to have a centralized database where countries can access all the information contained in the BCH, FAO GM Food Platform and BioTrack Product Database. Three organizations are discussing the possibilities, but unfortunately there are cost and technical limitations that have not yet been overcome. For this to be done, a long-term commitment from the 3 organizations as well as long-term funding will be required in order to maintain the centralized/harmonized information in one place. If there is a country who would like to provide financial assistance to make this possible, it is more than welcome.

7 Conclusion

The webinar provided opportunities to discuss the effective use of the data available on the various platforms. Participants recognized the data uploaded by other countries as a source for learning and monitoring the current situation on biosafety in global scale. The usefulness of the contact information of the responsible persons at the competent authorities were also widely acknowledged for further communications on the information/data shared by the counties. In addition, relevant materials including the consensus documents and Codex guidelines were often referred for decision making process at the national level.

During the interactive discussion session, participants discussed the collaboration between countries and database network. It was also stressed that coordination of information sharing not only at international level but also at the national focal point level is extremely important so that the responsible persons could be confident to share information to the relevant databases. Final remarks were made thanking all the participants for their valuable and active contribution to the webinar. Many participants considered that the webinar collaboration was very effective to learn actual activities and their benefits on the use of the data on the three databases, and further requested to organize the next webinar.

8 Next steps

Following the outcomes of the discussion sessions, the following are the next steps to be taken:

- Available information on the respective databases to be shared among three databases.
 - OECD will seek the possibility to create links to the country information page on the FAO GM Foods Platform and BCH
 - OECD will seek an improvement in having their Consensus Documents readily available for each specific GM event information. This way the link can be useful for both FAO GM Foods Platform and BCH.
- FAO/CBD/OECD will seek the possibility to organize a face-to-face regular meeting to exchange country experiences and information on the topic of biosafety.
- FAO/CBD/OECD will conduct consultation with their members/parties to understand specific needs in organizing more joint webinars in the future.

Annex 1 Participation by Regions and Sectors

FIGURE 1: Attendance record of participants from different regions

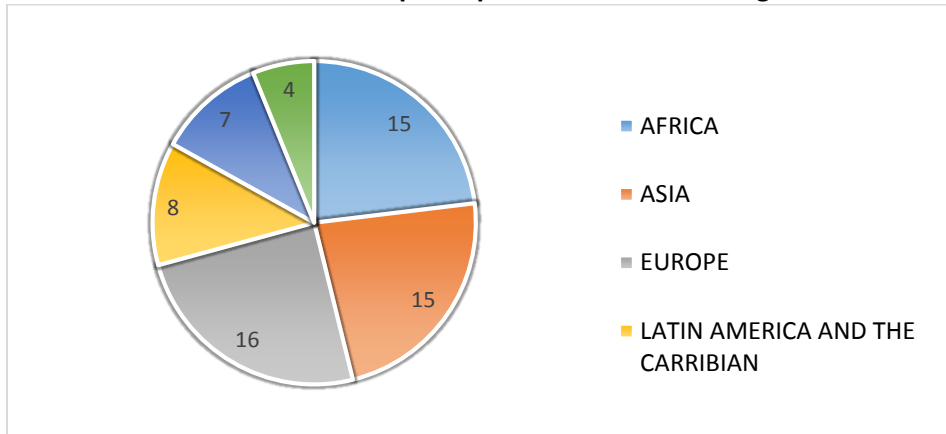


FIGURE 2: Attendance record of participants from different sectors

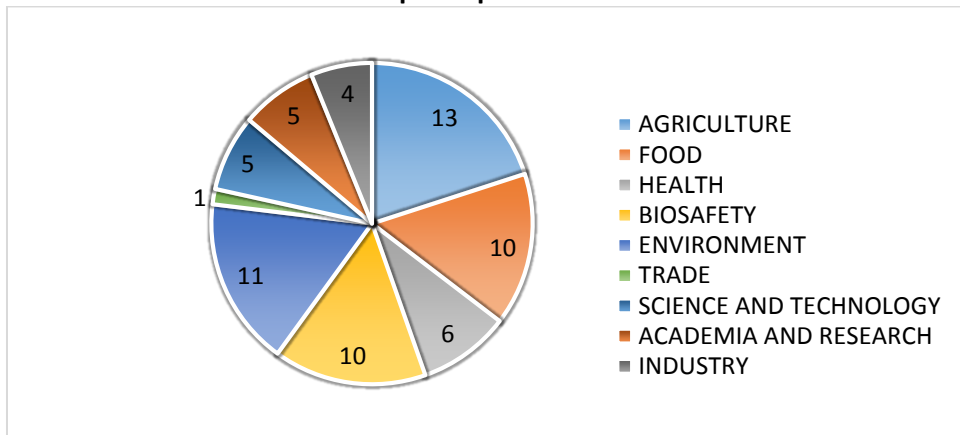
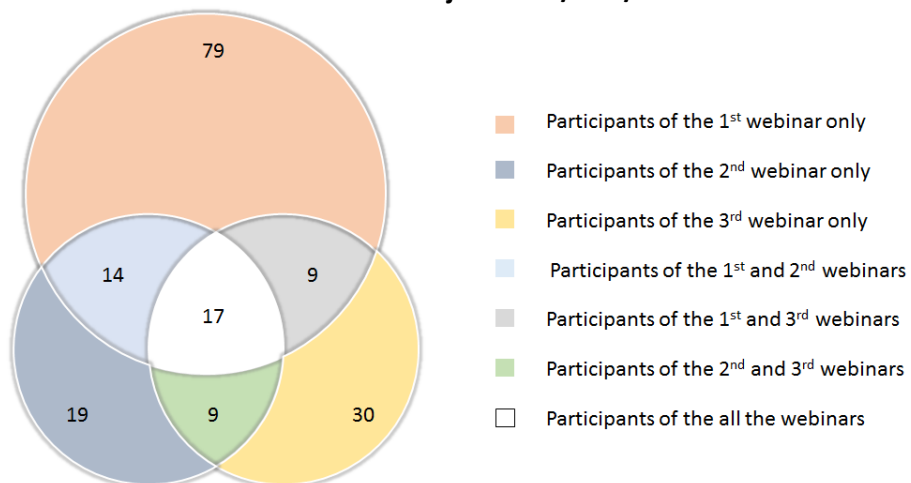


FIGURE 3: Attendance record of the joint FAO/CBD/OECD webinar series



Annex 2 Agenda

Session 1	Session 2	Agenda Item	Presenter/facilitator
09:00	16:00	Opening Summary of the previous webinars	Masami Takeuchi, FAO Kosuke Shiraishi, FAO
09:10	16:10	Country presentation <ul style="list-style-type: none"> • Japan (Session 1) • Spain (Session 2) 	Ayako Yoshio Vanesa Rincón
		Discussion	Facilitated by Manoela Miranda, CBD
09:40:	16:40	Country presentation <ul style="list-style-type: none"> • Philippines (Session 1) • Mexico (Session 2) 	Amparo Ampil Sol Ortiz García
		Discussion	Facilitated by Takahiko Nikaido, OECD
10:10	17:10	Country presentation <ul style="list-style-type: none"> • Malaysia (Session 1) • Canada (Session 2) 	Anita Anthonysamy Luc Bourbonnière
		Discussion	Facilitated by Masami Takeuchi, FAO
10:40	17:40	Interactive Discussion <ul style="list-style-type: none"> • Collaboration between countries • Usefulness of the database networks 	All
10:55	17:55	Closure	Peter Kearns, OECD (Session 1) Manoela Miranda, CBD (Session 2)

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