

Good practices for effective national communication mechanisms

FAO/CBD/OECD Webinar of the International Databases on Biosafety

5/27/2015

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2 Executive summary

On 27 May 2015 a webinar was 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) that addressed the importance of establishing effective national communication and coordination mechanisms on the topic of biosafety. Prior to this webinar, an online discussion was held to gather input and experiences of countries that were used to develop the content. During the webinar, Japan, Mauritius, Iran and Mexico shared their experiences, challenges and best practices in this field. In the interactive discussions session participants acknowledged the importance of national communication and coordination mechanisms. However, they also noted that the lack of resources, awareness or technical capacity is a challenge to the establishment of such mechanisms. Participants also noted the importance of engaging the general public in the decision-making regarding GMOs. Perspectives were shared on public consultation procedures, communication with the media and the use social media systems. It was suggested that international organizations could facilitate cross-sectoral communication by sharing contact information of their Focal/Contact Points.

3 Acronyms

ВСН	Biosafety Clearing House
CBD	Convention on Biological Diversity
СРВ	Cartagena Protocol on Biosafety
FAO	Food and Agriculture Organization of the United Nations
GE	Genetically Engineered
GMO	Genetically Modified Organism
LLP	Low Level Presence
LMO	Living Modified Organism
OECD	The Organisation for Economic Cooperation and Development
UI	Unique Identifier
UNEP	United Nations Environnent Programme

4 Introduction

4.1 Background

Following the recommendations made during the first FAO/CBD/OECD Webinar on the International Databases on Biosafety, which was held on 12 November 2014, the three organizations agreed to hold a second joint webinar that aimed at sharing experiences on national communication and coordination mechanisms in the field of biosafety. The webinar was preceded by an online discussion in which countries shared their experiences, challenges and best practices on the national communication and coordination mechanisms in place in their country.

4.2 Scope

The scope of the webinar was limited to the technical and practical aspects of national communication and coordination mechanisms in biosafety. The target audience was primarily the Focal/Contact Points of the relevant databases together with governmental officers working in the area of biosafety. In addition, other interested professionals were welcomed 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 are addressed by the respective governing bodies.

4.3 **Objective**

The objective of the webinar was to provide a forum where the Focal/Contact Points of the three databases on biosafety (i.e. FAO's GM Foods Platform, CBD's Biosafety-Clearing House and OECD's GM Product Database) could share experiences, challenges and good practices in establishing/improving national communication and coordination mechanisms on the topic of biosafety.

5 Participation and proceedings

5.1 Participation

Eighty-eight pre-registrations were received from 55 countries, and a total of 60 participants from 41 countries actually participated in the webinar. Annex 1 and 2 include all actual participants and registered people.

Figure 1 shows the regional distribution of the participants: 11 (18%) from Africa, 16 (27%) from Asia, 22 (37%) from Europe, 6 (10%) from Latin America and the Caribbean, 1 (2%) from the Near East and 4 (7%) from North America.

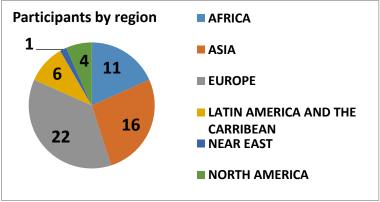


FIGURE 1 Participants by region.

The participants that attended came from different sectors (Figure 2). The majority of participants indicated that they are affiliated to the Ministry of Agriculture or a specialized biosafety organization.

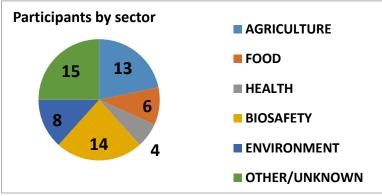


FIGURE 2 Participants by sector

5.2 Methodology

The webinar was held in two sessions to accommodate different global time zones. Session 1 took place at 09.00-11.00 (Central European Time) and session 2 from 16.00-18.00 (Central European Time). The online conference tool Adobe Connect was used to facilitate the webinar. Presentations were made using audio-visual aids. A chat box was available for participants to post comments and questions.

Practical information and technical instructions were made available at http://www.fao.org/food/food-safety-quality/a-z-index/biotechnology/biosafety-events/.

A certificate of participation was awarded to each participant.

5.3 Agenda

The webinar followed the agenda below:

Item	Speaker	Presentations
Welcome (5 min)	Masami Takeuchi,	
	FAO	
Overview on the Databases (15 min)		
FAO GM Foods Platform	Masami Takeuchi, FAO	http://tiny.cc/gm-platform
Biosafety Clearing House	Manoela Miranda, CBD	http://tiny.cc/biosafety_clearing house
BioTrack Product Database	Takahiko Nikaido, OECD	http://tiny.cc/biotrack_product_ database
Unique Identifier (UI) (5 min)	Takahiko Nikaido, OECD	http://tiny.cc/OECD_UI
Summary of the previous Webinar (10 min)	Ward Hermans, FAO	http://tiny.cc/previous_webinar
Outcome of the e-discussion session (10 min)	Masami Takeuchi, FAO	http://tiny.cc/outcome_online_ discussion
Q&A Session (10 min)	Manoela Miranda, CBD	
 Country Presentations (20 min) Mauritius (Session 1) Japan (Session 1) 	Sharmila Buldewo Kazuyuki Suwabe	http://tiny.cc/presentation_mau ritius http://tiny.cc/presentation_japa n

 Iran (Session 2) Mexico (Session 2) 	Behzad Ghareyazie Sol Ortiz García	http://tiny.cc/presentation_Iran http://tiny.cc/presentation_mex ico
Interactive discussion and closing remarks (45 min)	Peter Kearns, OECD (Session 1) Manoela Miranda, CBD (Session 2)	

After a brief welcome, the organizers presented a quick overview on the database maintained by their respective organizations. Subsequently, presentations were made providing overviews of the OECD Unique Identifier, summary of the previous webinar and outcomes of the online discussion. After a session in which technical questions could be addressed, participants from countries, i.e. Mauritius and Japan during the morning session, and Iran and Mexico in the afternoon session, presented their experiences and challenges in establishing effective communication and coordination mechanisms. The webinar was concluded with an interactive discussion session in which participants actively discussed the key issues by typing questions and comments in the chat box.

6 Activities prior to the webinar

6.1 The first joint webinar in November 2014

On 12 November 2014, the first joint webinar organized by the Food and Agriculture Organization of the United Nations (FAO), the Convention of Biological Diversity (CBD) of the United Nations Environment Programme and the Organisation for Economic Cooperation and Development (OECD) was held. That webinar discussed the differences in scope, content and mandate among the databases maintained by these organizations: the FAO GM Foods Platform (<u>http://fao.org/gm-platform</u>), the Biosafety-Clearing House (<u>http://bch.cbd.int</u>) and the OECD BioTrack Product Database (<u>http://www2.oecd.org/biotech/</u>). In this webinar 170 people from 76 countries pre-registered of whom 120 people from 55 countries actually attended. The participants came from various sectors including agriculture, health food, biosafety, environment and science and technology.

The webinar was concluded with an interactive discussion in which participants could deliver comments and question through chat box. In the discussion, the relevance and uniqueness of each database was recognized. Participants emphasised that there was a strong need to achieve further synergies among the databases on the national and international level. In this context, the importance of OECD Unique Identifier as a system to facilitate the exchange of information was widely acknowledged. Since the topic of biosafety is highly cross-sectoral, in which many different regulatory entities are involved, many participants agreed that collaboration among the Focal/Contact Points to the databases at the national level was important. However, it was also noted that achieving an effective mechanism to facilitate such coordination and communication at the national level is a challenge. Finally, many participants praised the content and format of the webinar and suggested that additional follow-up webinars could be organized in the future.

The complete report of the first webinar can be accessed at: <u>http://tiny.cc/webinar_nov14</u> A presentation is available as pdf file at: <u>http://tiny.cc/previous_webinar</u> A video of the presentation is available at: <u>https://youtu.be/C_LZqfqLBtQ</u>

6.2 Pre-webinar online discussion

In preparation of the second webinar, an online discussion was held to provide a forum where participants could share experiences, good practices and challenges in establishing/improving national communication and coordination mechanisms on the topic of biosafety. The discussion was opened between 27 April and 10 May 2015 and was hosted by BCH at: http://bch.cbd.int/onlineconferences/portal_art20/fao-cbd-oecd/discussion/. A total of 327 people registered to this online discussion forum and 50 comments were posted from 33 different countries. Among the comments, 9 came from Africa (18%), 11 (22%) from Asia, 1 (2%) from North America and the South West Pacific, 8 (16%) from the Near East, 8 (16%) from Latin America and the Caribbean, 9

(18%) from Europe and 4 (8%) from international organizations.

In the online discussion many participants acknowledged the importance of cross-sectoral communication among the involved agencies. Biosafety was regarded a multidisciplinary topic and therefore efforts to achieve coordinated actions were considered essential. Many countries have a formal entity in place to facilitate communication and coordination at the national level but the roles of these entities vary among countries. Some countries established bodies acting as regulatory authority, whereas other bodies provide scientific advice by conducting risk assessment or have a coordinating role. This coordination can include the functional delegation of tasks and the responsibilities, the collecting and sharing of information or the harmonizing of regulatory procedures, regulations and standards. Besides formal mechanisms there were also countries that reported effective informal coordination mechanisms among involved agencies and sectors.

Various challenges are encountered by countries in achieving effective interagency collaboration. Some countries have no functional biosafety framework and/or regulations which results in ambiguities about how responsibilities are divided among the various involved agencies. Also difficulties exist in streamlining biosafety policies into national sectoral polices. A lack of awareness among stakeholders, policy-makers and the general public on the importance of biosafety results in insufficient allocation of resources hence challenges effective national interagency collaboration. Finally various countries indicated to have insufficient experience and resources to perform risk assessment on GM plants.

International organizations could play a role by providing webinars, workshops or trainings that can increase the capacity of countries in doing risk assessment. Furthermore, it was recommended that international organizations could stimulate national communication by providing online, facilitating infrastructure for this purpose. Finally the databases maintained by the organizations were looked upon as a useful effort to share information on regulations, risk assessments and regulatory decisions.

The draft summary report of the online discussion can be found at: <u>http://tiny.cc/report_ediscussion</u> The presentation pdf-file is available at: <u>http://tiny.cc/outcome_online_discussion</u> The video of the full presentation is available at: <u>https://youtu.be/TUpQZkRZBr8</u>

7 Databases of FAO, CBD and OECD

7.1 Schematic overview on the three databases

	FAO GM Foods Platform	Biosafety Clearing House	OECD Biotrack Product Database
Host	FAO	CBD	OECD
Governing	Codex Alimentarius	The Cartagena Protocol on	OECD Working Group
body	Commission	biosafety	Harmonisation of
-			Regulatory Oversight in
			Biotechnology
			OECD Task Force for the
			Safety of Novel Foods and
			Feeds
Targeted	186 Codex Alimentarius	170 Parties to the	34 OECD Member
Members ¹	members	Cartagena Protocol on	Countries
		Biosafety	
Type of	Risk Assessment	Risk Assessment	Risk Assessment
information	Regulations	Regulations	Decisions
		Decisions	
Scope of	Food	Food	Food
information	Feed	Feed	Feed
		Environment	Environment
Scale of	Commercial release	Contained use	Commercial release
assessment		Field trials	
		Commercial release	
Type of	Plants ²	Plants	Plants ²
Organism		Microorganisms	
		Animals	
Uploaders of	Focal Points officially	Registered users	OECD Secretariat
information	nominated by the		
	Government		
Source of	Official information	Information and resources	Official information sent by
information	directly submitted by Focal	(official and non-official)	government officials to the
	Points	directly submitted by	OECD Secretariat
		registered users	

TABLE 1 Schematic overview on the databases.

¹Information of other countries also accepted.

²Currently only information on plants is available. However, in the future information on GE animals on microorganisms might be included.

7.2 The FAO GM Foods Platform

The FAO GM Foods Platform was established upon request of the members of Codex Alimentarius and FAO. The mandate of FAO is to achieve global food security and food safety is one of the core pillars towards reaching this goal.

On the Platform information is included on the food safety assessment of GM plants. Information on regulations is not in the primary scope of the platform but is accepted, information on regulatory decisions is excluded from the scope. The primary focus of the database is on information on food safety assessment but since risk assessment on feed is often done simultaneously with food, also

information on feed can be shared on the Platform. Environmental risk assessments are excluded from the scope.

The current mandate of the database only covers GM plants that are commercialized in accordance with the Codex Guideline on Foods derived from r-DNA plants¹. Expanding the scope towards microorganisms and animals can be considered in the future but this has to be decided by the governing body. Information on field trials or the contained use of GM plants is not included in the Platform.

The Platform only publishes official information that is uploaded by a Focal Point who is officially nominated by its national contact point to the Codex Alimentarius Committee. From the 186 Codex members, 163 countries have nominated a Focal Point yet. Countries that are not members of Codex are also welcome to share official information. Most Focal Points are working for the Ministry of Agriculture, the Ministry of Health, the national Food Safety Authority or a specialized Biosafety entity.

The presentation pdf-file is available at: <u>http://tiny.cc/gm-platform</u>

7.3 The Biosafety Clearing House

The BCH has been established as information exchange mechanism under the Cartagena Protocol on Biosafety (CPB)². In includes all information on Living Modified Organisms (LMOs) in relation to environment, human health, feed, transit, processing and contained use. The BCH hosts information on all types of LMOs including microorganisms, plants and animals. Furthermore, information on all types of intended uses is covered in the BCH (e.g. commercial release, field trials, contained use, etc.) even though some of this information is submitted by countries on a voluntary basis.

Currently, the BCH has 7700 registered users from 170 Parties to the Protocol. These users are from 300 different organizations that include government, and organizations in the academic, non-governmental and private sectors.

The BCH contains two main classes of records: National Records and Reference Records. National records can only be registered by National Focal Points and include national documents such as decisions, laws and legislations, as well as risk assessments that are generated in regulatory processes. Reference records can be submitted by all registered users and include, for example, information on a specific LMOs, organisms, genes, capacity building activities and news, as well as risk assessments generated by non-regulatory procedures. Reference Records are validated and approved by the CBD Secretariat prior to their publication, whereas National Records are published directly by the National Focal Points.

The information contained in the BCH is cross-referenced in such a manner that it can be accessed from several entry points. For example, each country contains a page where all of its National Records are listed. Furthermore, each LMO has a unique overview page that compiles available information about the LMO itself, with information contained in the BCH itself as well as links to external databases, which is cross-linked to regulatory decisions and risk assessments on that specific LMO.

The presentation pdf-file is available at: <u>http://tiny.cc/biosafety_clearing_house</u>

¹ Link: <u>http://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf</u>

² Link: <u>https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf</u>

7.4 The OECD BioTrack Product Database

The OECD BioTrack Product Database contains information on regulatory decisions and risk assessment of genetically engineered (GE) organism and covers both food/feed and environment. Laws and regulations are excluded from its scope. At the moment the database only includes information on GE plants, but information on microorganisms and animals is accepted. The OECD BioTrack Product Database only includes information on commercialized plant varieties.

The OECD has 34 member countries, but also non-members are invited to share information. Currently, 9 OECD countries, 2 non-OECD countries and the European Commission have made information available on the database. Only data delivered by government officials are accepted on the database.

The presentation pdf-file is available at: <u>http://tiny.cc/biotrack_product_database</u>

8 The OECD Unique Identifier

The OECD Unique Identifier (UI) is 9-digit alphanumerical code that acts as key to access information in the OECD BioTrack Product Database and other interoperable systems for GM plants. The system has been developed by OECD in 2002 and revised in 2006³. The OECD Unique Identifier is applicable on stacked events by combing the UIs of the single events it is composed of.

Following an explicit request formulated by participants of the previous webinar the OECD UI Checker has been developed by the OECD Secretariat. This tool can check whether an OECD Unique Identifier has been correctly assigned and is online available at: <u>http://www2.oecd.org/biotech/ui%20checker.xlsx</u>.

It was indicated by OECD that no OECD UIs have been assigned to animals and microorganisms yet, but that this is possible by applying the same algorithm. Moreover, OECD confirmed its willingness to assist small developers and academia in assigning the OECD UI. However, it ultimately remains the responsibility of the developer to assign the OECD UI.

The presentation file is available at: <u>http://tiny.cc/OECD_UI</u>

9 Presentations by countries

9.1 Presentation by Mexico

In Mexico small changes in existing laws were covering the use of GMOs in the 1990s. In 1995 official standards were established on the conduct of confined field trials. In 2002 Mexico ratified the Cartagena Protocol on Biosafety and in 2005 the Biosafety Law of Genetically Modified Organisms was accepted. Besides this law several additional bylaws, procedures and regulations exist that address GMOs.

In 1999, the Cibiogem was established as Inter-Secretarial Commission on the Biosafety of GMOs. This body is composed of six ministries and a representative of the National Council on Science and Technology. The presidency rotates among the Ministry of Agriculture and the Ministry of Environment. The Cibiogem is a high-ranking body that is supported by an Executive Secretariat.

³ Link: <u>http://www.oecd.org/science/biotrack/46815728.pdf</u>

Furthermore, three subcommittees exist: the Technical Committee with member from regulatory authorities, the Scientific Advisory Council with scientists from various disciplines and the Multisectoral Advisory Council with representatives from the social sectors, industry and NGOs.

The Mexican biosafety law aims 'to regulate activities with GMOs to prevent, avoid, or reduce potential risks to human health, the environment and biodiversity, and to protect the health of plants, animals and the aquaculture'. Regulations exist on the confined use, environmental release, commercialization and import/export of GMOs. These regulations are implemented by various regulatory authorities and ministries.

For the environmental release the Ministry of Environment or the Ministry of Agriculture is responsible, depending of the specific application of the GMO. The responsible ministry conducts the risk assessment but is required to take into account the technical opinion of the other ministry. The communication between these ministries occurs via formal or informal mechanisms. The final decisions are communicated the Executive Secretariat of the Ciobiogem that further disseminates it to national and international biosafety resources.

Different perspectives from the involved agencies can challenge reaching consensus and hence impede the procedures. Furthermore, Mexico indicated to have a shortage on human and financial resource and that more continuous training is required to increase capacity. An electronic system for automated application management is needed and under development. Another challenge that was mentioned was the need to increase public awareness and to communicate better on trust and transparency.

Sharing relevant information among the different platforms could increase the interconnectivity and facilitate the submission of information. Furthermore, international organizations could play a role in developing innovative communication platforms and by developing tools and strategies to facilitate this. Also, feedback on missing data and a double check on the correctness of information was considered useful.

The presentation pdf-file is available at: <u>http://tiny.cc/presentation_mexico</u>

9.2 Presentation by Iran

In Iran there is high-level support for biotechnology and it is considered a top three priority in science and technology. Iran joined the CBD in 1996, established a biosafety society in 2002 and ratified the Cartagena Protocol on Biosafety in 2003. Prior to the ratification of the National Biosafety Law in 2008 a National Biosafety Committee was established in 2005 according to a cabinet decree. The National Biosafety Law states that 'all issues relating to production, release, import, export, transit and transport, commercialization, use and application of LMOs are permitted according to this law and that the government should take all necessary actions to facilitate these'.

Labelling is required for the transport of LMOs (export and import) and contained research is exempted from regulations. The Ministry of Agriculture Jihad is responsible for approving LMOs for agriculture and hosts the National Focal Point to the Cartagena Protocol on Biosafety, the Ministry of Health approves LMOs used as drug or food and the Environmental Protection Organization reviews the environmental risk assessment conducted by applicants. According to the national biosafety strategy, Iran should grow a minimum of 0.5% of the global area of GM plants in the near future.

The National Biosafety Committee is a very high-level formal cross-sectoral body that is chaired by the first deputy president of Iran. It consists of ministers and high ranking government officials as well as representatives from scientific societies and the parliament. The committee meets 1-2 times

a year and is tasked to develop and implement biosafety policies and standards and to coordinate the legal functions of the competent regulating authorities in accordance with Iran's biosafety act. The Secretariat of the committee is in Environmental Protection Organization. A shortage of scientific capacity under the high-level officials is considered a challenge. In addition to the National Biosafety Committee, a Consultative Committee for the National Focal Point to the CPB has been established that acts as an informal body advising the Focal Point on engagement in international fora and implementing the provisions of the National Biosafety Act. This Consultative Committee meets on average once a month and is composed of wider stake holders.

An immediate challenge is the coordination among agencies involved in GM food safety assessment and environment safety assessment. The Environmental Protection Organization lacks sufficient resources to conduct risk assessment in harmonization with food safety assessment or common agricultural practices. The lack of resources also hampers the implementation of the Protocol and the National Biosafety Act. Another challenge is the general public's fear for GMOs that is perceived to be induced by foreign actors.

International organizations should refrain from contacting multiple stakeholders within the country and streamline their communication through the National Focal/Contact Points. Furthermore, international organizations could help countries in improving national communication mechanisms by capacity building project at the national and regional level or by organizing online forums and webinars.

The presentation pdf-file is available at: <u>http://tiny.cc/presentation_Iran</u>

9.3 Presentation by Mauritius

Mauritius is middle-income country that has currently 1.3 million inhabitants. It is a net importer of food and the European Union is its biggest export market.

Manutius is a member of CBD since 1992 and ratified the Cartagena Protocol on Biosafety in 2002. However, it was indicated that in the implementation of the protocol it is lagging behind due to a lack of supporting legislation, infrastructure and resources. In 2004 the GMO act was published, but few sections have been proclaimed. The act aims to provide measures to regulate the responsible planning, development, use, marketing and application of GMOs in Mauritius. The act is under the responsibility of the Ministry of Agro-Industry and Food Security.

Besides the GMO act, also sectoral legislation exists that addresses certain aspects of using GMOs. The Food regulations (1999) include provisions to regulate the composition and labelling of food containing GMOs and ingredients that are genetically modified.

The Environmental Protection Act (2002) addresses the environmental impact of GMOs and the Plant Protection Act (2002) considers phytosanitary measures for the import of GM plants, products or regulated articles.

The GMO act established a National Biosafety Committee (NBC) that advises the Ministry of Agro-Industry and Food Security on all aspects pertaining GMOs. This committee comprises representatives from the various involved Ministries. The committee was very active in the beginning of its existence but did not function afterwards as some members were involved in the drafting of required regulations. The NBC was reactivated last year. Furthermore, there is a National Codex Committee that meets regularly with national stakeholders on Mauritius' contribution to Codex meetings or electronics working groups. The Focal Points to the biosafety databases are located within the same Ministry and there is need to set up effective formal coordination among these persons although informal communication exists. Also a recently reactivated national SPS committee exists where the various relevant stakeholders in this area convene.

Mauritius experiences capacity problems especially in the field of risk assessment and there is proposal to set up an office in which a team of sufficient competent people can process applications. The role of the different agencies should be better defined and there should be jointly decided on the setting of priorities. Furthermore there is a need to increase the expertise on validation and detection and harmonize laboratory methods and protocols. Also procedures on how to effectively address emergency situations are needed.

In Mauritius perspective international organizations could assist by providing guidance documents on how biosafety policies can be integrated into national policies and how different players in the system can actively participate at the national level. Workshops and trainings on GMO risk assessment and detection were considered a useful effort as well as fora where information and experiences could be shared. Empowering staff was seen as of utmost importance.

The presentation pdf-file is available at: <u>http://tiny.cc/presentation_mauritius</u>

9.4 Presentation by Japan

Japan has three different domestic acts that regulate GMO relating aspects. The Food Sanitation act addresses the food safety of GMOs, the Feed Safety Act deals with feed safety and the Cartagena Domestic act covers the environmental safety. These aspects are interrelated as in Japan both the safety for the environmental and human and animal consumption need to be confirmed.

Six ministries are involved in assessing the environmental safety and they are by law required to take into account consistency with food and feed safety and share information amongst the relevant agencies. The Ministry of Environment coordinates collaboration on the environmental safety regulatory process. There are several meetings a year between the heads of divisions (or assistant directors) to discuss common issues (e.g. aspects to consider in the risk assessment of GMOs) and to share information. Also, there is a list with contact information of the officers in charge to enable the communication amongst them.

Within the entities responsible for food safety there is a similar mechanism in place, but there is no formal mechanism in place to coordinate among the different sectors (e.g. food safety and environmental safety). This is done by informal communication and for this purpose seating arrangements of the responsible agencies are exchanged. Officials contact each other when necessary, for example to share information on approval dates or to coordinate common issues in which smooth collaboration is essential (e.g. Low level presence, LLP). Since officials move every few years it is important to keep the list updated and to regularly meet face-to-face.

International organizations could assist in this process by making available the lists of their contact persons and by collecting and sharing experiences of successful or unsuccessful cross-sectoral collaboration.

The presentation pdf-file is available at: <u>http://tiny.cc/presentation_japan</u>

9.5 Summary of the country presentations

All country presentations mentioned the cross-sectoral nature of biosafety and emphasized the importance of inter-agency collaboration among the involved agencies. Various approaches to establish effective communication have been discussed and these included both formal and informal mechanisms. Challenges mentioned include the communication between safety sectors (environment and food) and insufficient capacity for risk assessment and detection.

Divergent views existed on the role international organization could fulfil. Several suggestions were made that included the organization of capacity building activities, the development of guidance documents and the development of an online interface were contact details among officials can be shared.

10 Questions and Discussion

10.1 National communication mechanisms

Japan indicated there is not decided on a mechanism for informal communication but that there is contact among regulatory officials whenever required. During a call or meeting everything relating to work can be discussed. This approach shows to be very flexible and effective. However, before actual discussions start it should be checked whether the other party has the same dossiers and information at its disposition. If this is not the case, the matter should be discussed in more general terms due to confidentiality issues.

Several questions were raised on the role and foundation of the Consultative Committee to the National Focal Point in Iran. This committee operates informally and all decisions are made in broad agreement without voting. What is decided in the Consultative Committee is always adopted and implemented by the National Biosafety Focal Point. Iran considered it a challenge that international organization communicate directly with various stakeholders at the national level.

Several participants recommended international organizations to develop online infrastructure where the contact details of the Focal/Contact Points of the various databases could be compiled and shared. This could facilitate increased communication among these Focal/Contact Points at the national level.

10.2 Public engagement and the media

One participant stressed the importance of communication on the regulations and risk assessment of GMOs with the general public and asked how public participation could be effectively conducted. Mauritius echoed this comment and indicated that it has organized a workshop with UNEP-GEF support on GMO awareness. In addition, The Food Technology Laboratory of the Ministry of Agro-Industry & Food Security carried out a survey to determine GMO awareness among college students of the age group 18 to 20 years. Also a representative of Consumer Associations is included into Mauritius' National Biosafety Committee. Also in Japan public participation was considered an important issue that is addressed in a formal mechanism. Just before an approval is granted the draft risk assessment is published to give the general public the opportunity to provide comments. After a 30 day comment period the comments are evaluated and a final decision is made. Also for general food safety issues Japan meets regularly with consumer organizations to learn about their opinions and perspectives. In Mexico there is a public consultation process for environmental release in which draft approvals are published through the national GM register. For the use of GMOs as food/feed there is not requirement for public consultation in Mexico.

One participant emphasized the importance of social media systems to communicate with the wider public. Currently much information is disseminated through social media that looks very professional but is not always trustworthy and this could result in misinformation of the public. Several participants expressed the need to explore how social media could be used by biosafety experts more to increase public awareness and provide reliable information.

One participant stressed that also communication to the conventional media is very important as they play a major role in informing the public. It was suggested that practical guidance or training for journalist on GMOs and how to use the databases could be useful. Also scientific articles and expert opinions could be converted into simple, non-technical language to inform journalists and policymakers. CBD organizes biennial fairs on Communication, Education and Public Participation⁴ during the meeting of the Parties to the Protocol. These fairs provide a venue were journalists, the general public and the CBD Parties can interact.

10.3 The scope of and information on the databases

Several participants posed questions on the scope of the databases and the information that they include. One participant specifically asked what GM pharmaceuticals are included in the BCH. It was indicated by CBD that following the provisions of the Protocol only LMOs that are used as human pharmaceuticals and are covered by other international organizations or agreements are exempted. Currently, most GM pharmaceuticals on which information is available on the BCH are viral vaccines. Assigning an OECD UI to these products is done together with the developer but is challenging because not all pharmaceutical companies are aware of the use and importance of the OECD UI. Microorganisms are currently not included in the OECD BioTrack Database and the FAO GM Food Platform. However, when the OECD Secretariat receives a request it will register information on microorganism in the database. The mandate of the FAO GM Foods Platform is currently only on GM plants, but the governing body might upon request consider to expand the scope to animals and microorganisms. In this context it was also mentioned that both organizations published documents on GM microorganisms^{5,6}.

It was also suggested by one of the participants to further increase the connection between the different databases by linking to relevant documents and websites. Another participant suggested exploring the technical possibilities to extract data from the BCH and to import these directly into the FAO GM Foods Platform and the OECD BioTrack Product Database. It was mentioned by CBD that it is currently explored how the synergies with FAO can be improved. However, this requires the governing bodies to provide a mandate and financial resources to realize this. FAO added that, contrary to the BCH, the FAO GM Foods Platform only accepts official information that is in accordance with the guidelines of Codex Alimentarius. The governing bodies are decisive for changing the type and scope of information available on the database.

One participant asked what mechanisms are in place to ensure the information on the database remains updated and correct. CBD regularly follows-up with its Focal Points to ensure everything is correct and nothing is missing. FAO also actively follows-up with her network of Focal Points, but only checks the format in which the information is delivered. The correctness of the information is the responsible of the Focal Point. OECD indicated that data submission is on a voluntary basis and follows a request based approach. OECD only accepts data registration requests from officials.

⁴ Link: <u>https://www.cbd.int/cepa/fair/</u>

⁵ Link: http://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf

⁶ Link: <u>http://www.oecd.org/chemicalsafety/biosafety-and-the-environmental-uses-of-micro-organisms-</u> <u>9789264213562-en.htm</u>

10.4 National regulatory systems

Questions were posted on the operational aspects of the Mexican and Iranian regulatory system on GMOs.

It was indicated by Mexico that once all information is received the authorization procedure takes 6 months in the case of experimental release to the environment. However, if deficits in information are present this timeframe will be delayed, for specific timeframes, until the applicant delivers all information. The Biosafety Commission and other consultative and technical bodies meet 4 times a year but extraordinary meetings can be held if required. Also seminars are organized every 15 days for regulators to keep their knowledge up-to-date.

Iran indicated confined field trials are exempted from regulations once there is proven that they are strictly confined. However, if there is a possibility for environmental release the application has to follow the conventional regulatory procedures. Labelling is required when a product contains more than 2% of GMO.

11 Concluding remarks

During the webinar the importance of cross-sectoral communication among agencies involved in the biosafety regulatory processes was widely acknowledged. Various countries shared their experiences and challenges in the formal and informal mechanisms that they have established for this purpose. It was suggested that the organizations explore the opportunities to collect and share the contact details of the Focal/Contact Points of the databases through an online interface.

Many participants emphasized the importance of public engagement in the regulatory processes of GMOs. Experiences and perspectives were shared on public consultation procedures, communication with the media and the use of social media systems. It was suggested that international organizations could look on how they can use social media systems more effectively to communicate with the general public in GMOs. Furthermore, it was suggested that easy-accessible communication materials on GM for the public and journalists could be very useful.

Many participants indicated to consider the webinar very useful and requested to continue this effort in the future.

12 Next steps and follow up actions

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

- Available information on training of media will be shared among the organizers and participants.
 - CBD will share information on the fairs on Communication, Education and Public Participation that are organized on a biennial basis.
 - India will share the information of a contact point on the 'Awareness Workshops for Media Practitioners' that are organized by the ministry of Environment, Forest and Climate Change.
- Members/parties of the three databases will continue to populate the relevant databases.
- FAO, CBD and OECD will continue organizing more joint webinars in the future as feasible and appropriate.
- FAO will explore with CBD and OECD the possibility to develop a combined interface where the contact details of Focal/Contact Points of the various agencies can be exchanged.

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