



Food and Agriculture
Organization of the
United Nations

FAO GM Foods Platform:

Are we effectively evaluating food safety?

BACKGROUND PAPER
for the Platform
Community Meeting 2019

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Are we effectively evaluating food safety?



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Abstract

In order for Members of Codex Alimentarius (Codex, 2019a) to share information on Codex-aligned Genetically Modified (GM) food safety assessment, the Food and Agriculture Organization of the United Nations (FAO) maintains an online database entitled “FAO GM Foods Platform”. As of September 2019, 172 Codex Members out of 189 (91 percent) officially designated national focal points to the Platform to participate, however, only 28 percent¹ have been able to share the results of their own GM food safety assessments. Most of the remaining Members still struggle to conduct the assessment, mainly due to technical and institutional capacity and/or situational issues. This document aims to assist such focal points, particularly those in developing nations, as the document illustrates various Platform community members’ situations regarding the required knowledge and expertise, desired institutional set-ups, and effective communication mechanism. Some of the good practices are highlighted. The document serves as a fundamental basis for many key discussions to be held during the Global Community Meeting on the FAO GM Foods Platform to be held in Bangkok, Thailand from 10 to 13 September 2019. Together with the physical meeting, the paper provides a unique opportunity for both experienced and less-experienced Codex Members to understand the challenges that many countries face, and the opportunity to improve current situations. The annex of the document provides the contact information of all Platform community members, which is an invaluable resource for many focal points to establish technical networks and the community of practice together.

Keywords: food safety, risk assessment, safety assessment, Genetically Modified Organism (GMO), biosafety, regulatory framework, Food and Agriculture Organization of the United Nations (FAO), FAO GM Foods Platform

Year of publication: 2020

¹ The European Union is a Codex Member, in addition to its 28 Member States. The European Union shares its GM food safety assessment data on the FAO GM Foods Platform, and represents its current 28 European Union Member States (as of September 2019). Thus, the total number of countries that share their data on the Platform is 52 (24 non-European Union countries and 28 European Union Member States), and including the European Union as a Codex Member, the total becomes 53. Therefore, the calculation was made as 53 out of 189, which is 28 percent.



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Abbreviations and acronyms

CCAFRICA	FAO/WHO Coordinating Committee for Africa
CCASIA	FAO/WHO Coordinating Committee for Asia
CCEURO	FAO/WHO Coordinating Committee for Europe
CCLAC	FAO/WHO Coordinating Committee for Latin America and the Caribbean
CCNASWP	FAO/WHO Coordinating Committee for North America and South West Pacific
CCNE	FAO/WHO Coordinating Committee for Near East
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMO	Genetically modified organism
IT	Information technology
LLP	Low level presence
OECD	Organisation for Economic Co-operation and Development
r-DNA	recombinant-DNA



1 Introduction

Background

The Food and Agriculture Organization of the United Nations (FAO) hosts an online global database on Genetically Modified (GM) food, entitled “FAO GM Foods Platform”, (FAO, 2019a), where countries share information on official safety assessments of foods derived from Recombinant-Deoxyribonucleic Acid (r-DNA) plants conducted in accordance with the guidelines (Codex, 2008) developed by the Codex Alimentarius (Codex, 2019b), the international food standard-setting body. The Platform provides a reliable resource, and facilitates the effective utilization of GM food safety assessment results in situations regarding the Low Level Presence (LLP) of r-DNA plant materials in food.

Since the official launch of the Platform in July 2013, FAO has made significant progress towards fulfilling the requirements described by the Codex guidelines. As of September 2019, 91 percent (n=172) of all Codex Members (n=189) have joined the Platform community, and 28 percent² have been actively sharing their own GM food safety assessment results. Although the number may seem small in comparison to the total number of participating Codex Members, this represents the current reality in which only a small number of countries have the full capacity for conducting GM food safety assessments. The majority of Platform community members visit the Platform only to retrieve up-to-date information on safety assessments in order to utilize the gained knowledge for consideration to facilitate more effective national risk management decisions with regard to authorizations and LLP.

Many Platform community members have explained that their limited ability in sharing relevant data and information is directly connected to their limited capacity in conducting GM food safety assessments, and have expressed their need for assistance in capacity development on the relevant technical issues. To address these needs, FAO has been proposing the formation of a global community of practice that facilitates interactive communication and collaboration for capacity development. A few technical partnerships have been established among several Platform community members, but this has not yet become a global practice.

Scope

This document covers the technical and practical aspects of the effective risk-based GM food safety assessment and regulatory management. The document primarily targets focal points of the Platform as well as other governmental officers working in the area of biosafety. This document may also be useful for relevant stakeholders that are engaged in regulatory activities in the area of biosafety.

Objectives

This document was developed for Platform community members to:

² The European Union is a Codex Member, in addition to its 28 Member States. The European Union shares its GM food safety assessment data on the FAO GM Foods Platform, and represents 28 European Union Member States (as of September 2019). Thus, the total number of countries that share their data on the Platform is 52 (24 non-European Union countries and 28 European Union Member States), and including the European Union as a Codex Member, the total becomes 53. Therefore, the calculation was made as 53 out of 189, which is 28 percent.

- obtain good practices and lessons-learned on the GM food safety assessment process so that focal points can become more comfortable providing the results of science-based GM food safety assessments conducted by their national competent authorities, and so that policy-makers can make informed decisions; and
- better understand the various challenges that relatively inexperienced countries face in relation to conducting a GM food safety assessment, so that experienced countries and international organizations are better able to provide tailored assistance, information, experience and knowledge.

Methodology

In order to prepare this document, relevant data and information were collected and analysed through the Platform (FAO, 2019a). For the statistical country situational analyses, the set of data was extracted from the Global Outlook section of the Platform, which is automatically collected and synthesized through the country profiles. This data, therefore, refer to Platform community members, who are a large subset (91 percent) of Codex Members. Knowledge and capacity gaps, and communication issues were assessed through an online questionnaire that was prepared using SurveyMonkey (SurveyMonkey, 2019). Two separate sets of questionnaires (questionnaires A and B) were sent to all 189 Codex Members in July 2019: questionnaire A was sent to those 166 Codex Members who had not shared any GM food safety assessment result on the Platform, while questionnaire B was sent to those 23 Codex Members, who had already been sharing the GM food safety assessment data on the Platform.⁹ The purpose of having two separate sets of questionnaires was to obtain two different sets of responses from less-experienced countries and experienced countries. Questionnaire respondents were either Platform community members or other specifically designated people that could provide relevant and up-to-date information. The total response rate to the questionnaire was 61 percent (n=116, out of 189 Codex Members). Among those Codex Members who responded to the questionnaire, the regional response rate is presented in Table 1.

TABLE 1. Questionnaire response rates.

Region	Codex region (total number)	Response number	Response rate
Africa	CCAFRICA (49)	31	63%
Asia	CCASIA (24)	16	67%
Europe (including European Union)	CCEURO (52)	31	60%
Latin America and the Caribbean	CCLAC (33)	16	48%
North America and South West Pacific	CCNASWP (14)	8	57%
Near East	CCNE (17)	14	82%
Total	189	116	61%

⁹ In July, when FAO sent out the questionnaire, there were 23 Codex Members (22 non-European Union countries + the European Union) who had been uploading the records on GM food safety assessment. Questionnaire B was sent out to those who had had actual experience in sharing their results on the Platform, so not included are the 28 European Union Member States or two countries that started sharing their records in August/September 2019.



2

Current status of the FAO GM Foods Platform

Overview of the Platform structure

The Platform is owned by Codex Members and is administratively managed and maintained by FAO. Each Codex Member is responsible for the accuracy of their submitted information. While all the contents of the Platform are freely accessible by anyone, only focal points, who are officially nominated by the respective country's Codex Contact Point, can upload data and information to the Platform. As of September 2019, 91 percent of Codex Members have been registered as Platform community members.

Browsing of data and information sharing on GM food safety assessment

On the Platform, information can be browsed by referring to the: 1) Unique Identifier established by the Organisation for Economic Co-operation and Development (OECD), 2) Commodity, 3) Trait, or 4) Country. Figures 1–4 illustrate different ways to browse information.

FIGURE 1. “Browsing by OECD unique identifier” webpage on the Platform.

FAO GM Foods Platform

Browse information by OECD Unique Identifier

Each transformation event derived from recombinant-DNA techniques has a unique code. You may select an option from the list of **OECD Unique Identifier** (What is this?) below. Simply click on a code to reveal its information. You may also select a OECD Unique Identifier in the drop-down list below

To search information by commodity, trait, or country click the “Commodity”, “Trait” or “Country” in the main menu to the left.

OECD Unique Identifier: -- Select a OECD Unique Identifier --

« Previous 1 2 3 4 5 ... 14 Next »

OECD Unique Identifier	Commodity	Traits
BCS-GH005-8 x BCS-GH004-7 x BCS- GH005-8 x SYN-IR102-7	Cotton	Insect resistance

FIGURE 2. “Browsing by commodity” webpage on the Platform.

FAO GM Foods Platform

Browse information by Commodity · Potatoes

OECD Unique Identifier	Traits
NMK-89167-6	Coleoptera resistance, Kanamycin resistance
NMK-89175-5	Coleoptera resistance, Kanamycin resistance
NMK-89170-9	Coleoptera resistance, Kanamycin resistance
NMK-89185-6	Coleoptera resistance, Kanamycin resistance, Potato leaf roll virus resistance
NMK-89279-1	Coleoptera resistance, Kanamycin resistance
NMK-89367-8	Coleoptera resistance, Kanamycin resistance
NMK-89576-1	Coleoptera resistance, Kanamycin resistance
NMK-89593-9	Coleoptera resistance, Kanamycin resistance
NMK-89613-2	Coleoptera resistance, Kanamycin resistance
NMK-89653-6	Coleoptera resistance, Kanamycin resistance, Potato virus Y resistance

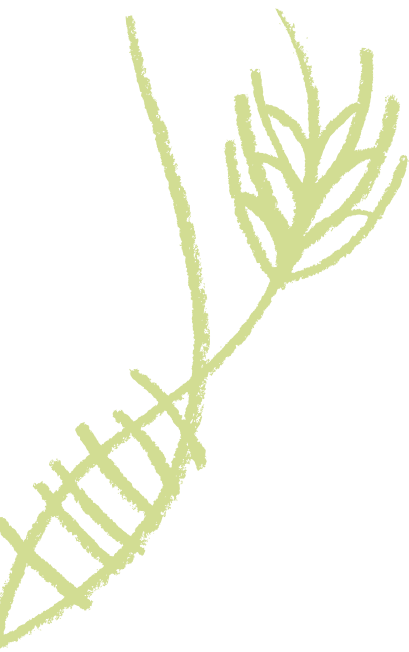
FIGURE 3. “Browsing by trait” webpage on the Platform.

OECD Unique Identifier	Commodity
MON-87460-4	Corn / Maize
MON-87460-4 x MON-89034-3 x MON-88017-3	Corn / Maize
MON-87460-4xMON-89034-3xMON-00603-6	Corn / Maize
MON-87460-4xMON-00603-6	Corn / Maize
IND-00410-5 x MON-04032-6	Soyabean / Soybeans
IND-00412-7	Wheat
MON-87427-7 x MON-87460-4 x MON-89034-3 x DAS-01507-1 x MON-87411-9 x DAS-59122-7	Corn / Maize

FIGURE 4. “Browsing by country” webpage on the Platform.

OECD Unique Identifier	Commodity	Traits	Latest entry uploaded on
ACS-GM006-4	Soyabean / Soybeans	Glufosinate tolerance	19/08/2013
BCS-GH811-4	Cotton	Glyphosate tolerance, Isoxafutole tolerance	14/02/2019
BCS-GH002-5 x BCS-GH004-7 x BCS-GH005-8 x SYN-IR102-7	Cotton	Glyphosate tolerance, Lepidoptera resistance, Glufosinate tolerance	08/03/2019
BCS-GH002-5xACS-GH001-3	Cotton	Glufosinate tolerance, Glyphosate tolerance	31/07/2018
BPS-CV127-9	Soyabean / Soybeans	Imidazolinone tolerance	31/07/2018
DAS-44406-6	Soyabean / Soybeans	Glyphosate tolerance, 2,4-dichlorophenoxyacetic acid (2,4-D) tolerance, Glufosinate tolerance	08/03/2019
DAS-40278-9	Corn / Maize	2,4-dichlorophenoxyacetic acid (2,4-D) tolerance, Aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor tolerance	19/02/2019
DAS-59122-7	Corn / Maize	Coleoptera resistance, Glufosinate tolerance	19/02/2019
DAS-68416-4	Soyabean / Soybeans	2,4-dichlorophenoxyacetic acid (2,4-D) tolerance, Glufosinate tolerance	19/02/2019
DAS-81419-2	Soyabean / Soybeans	Insect resistance	08/03/2019

Focal Point Information	
E-mail:	miema@magyp.gob.ar
Country:	Argentina
Organization/agency name (Full name):	Ministerio de Agroindustria



3 Global outlook in conducting a genetically modified (GM) food safety assessment

Countries that regularly conduct a GM food safety assessment

As of September 2019, 83 percent of all Codex Members (158 out of 189) have provided their country profiles on the conduct of the GM food safety assessment. According to the Global Outlook (FAO, 2019b), 69 Platform community members regularly conduct GM food safety assessments, including the European Union, which has 28 Member States. These Platform community members are listed by Codex regional classification (Codex, 2019c) in Table 2. Numbers next to the regions indicate how many Platform community members per region conduct safety assessments, and **bold** format indicates those that have shared the GM food safety assessment data on the Platform.

TABLE 2. Platform community members that regularly conduct a GM food safety assessment.

Codex region	Platform community members
CCAFRICA (6)	Kenya , Malawi, Nigeria, South Africa , Zambia, Zimbabwe
CCASIA (10)	China , India, Indonesia , Japan , Republic of Korea , Malaysia , Philippines , Singapore , Thailand, Viet Nam
CCEURO (36)	Belarus , European Union , ⁴ Kazakhstan, Norway, Russian Federation , Switzerland, Turkey , Ukraine
CCLAC (8)	Argentina , Brazil , Chile, Colombia , Mexico , Panama, Paraguay , Uruguay
CCNASWAP (4)	Australia , Canada , New Zealand , United States of America
CCNEA (5)	Iran (Islamic Republic of) , Israel, Qatar, Sudan, United Arab Emirates

Countries that do not regularly conduct GM food safety assessments, but have conducted at least once in the past

Table 3 shows that six Platform community members have conducted at least one GM food safety assessment. Country names are further formatted in **bold**, if they have shared their GM food safety assessment data on the Platform.

⁴ European Union has 28 Member States (as of August 2019).

TABLE 3. Platform community members who have conducted at least one GM food safety assessment.

Codex region	Platform community members
CCAFRICA (3)	Botswana, United Republic of Tanzania, Uganda
CCASIA (0)	
CCEURO (0)	
CCLAC (3)	Antigua and Barbuda, Bolivia (Plurinational State of) , Ecuador
CCNASWAP (0)	
CCNEA (0)	

Countries that have never conducted a GM food safety assessment but are planning to conduct one in the near future

Table 4 shows 59 Platform community members who have never conducted a GM food safety assessment but are planning to do so in the near future.

TABLE 4. Platform community members who plan to conduct their first GM food safety assessment soon.

Codex region	Platform community members
CCAFRICA (21)	Angola, Benin, Burkina Faso, Burundi, Cameroon, Chad, Comoros, Congo, Côte d'Ivoire, Cabo Verde, Ethiopia, Gabon, Ghana, Guinea-Bissau, Liberia, Madagascar, Mali, Mozambique, Senegal, South Sudan, Eswatini
CCASIA (7)	Bangladesh, Bhutan, Cambodia, Mongolia, Nepal, Sri Lanka, Timor-Leste
CCEURO (5)	Albania, Armenia, Azerbaijan, Iceland, Kyrgyzstan
CCLAC (13)	Belize, Cuba, Dominican Republic, Grenada, Guatemala, Guyana, Haiti, Jamaica, Saint Lucia, Saint Vincent and the Grenadines, Saint Kitts and Nevis, Suriname, Trinidad and Tobago
CCNASWAP (5)	Fiji, Kiribati, Samoa, Papua New Guinea, Tonga
CCNEA (8)	Bahrain, Egypt, Iraq, Lebanon, Saudi Arabia, Syrian Arab Republic, Tunisia, Yemen

Countries that have never conducted a GM food safety assessment and will not (be able to) conduct one in the near future

Table 5 shows 30 Platform community members who have never conducted a GM food safety assessment and will not (be able to) conduct such assessment in the near future.

TABLE 5. Platform community members who do not foresee the possibility of conducting a GM food safety assessment in the near future.

Codex region	Platform community members
CCAFRICA (12)	Algeria, Central African Republic, Djibouti, Niger, Democratic Republic of the Congo, Eritrea, Gambia, Mauritius, Rwanda, Sierra Leone, Somalia, Togo
CCASIA (4)	Afghanistan, Brunei Darussalam, Maldives, Myanmar
CCEURO (5)	Bosnia and Herzegovina, Georgia, North Macedonia, Montenegro, Uzbekistan
CCLAC (5)	Bahamas, Barbados, Costa Rica, Dominica, Venezuela (Bolivarian Republic of)
CCNASWAP (1)	Micronesia
CCNEA (3)	Kuwait, Mauritania, Morocco

Tables 2–5 have shown that 75 Platform community members have experience in conducting a GM food safety assessment, while 89 Platform community members do not have such experience. Many of the latter group have described their limited capacity and knowledge in the questionnaire, and therefore, they need to be equipped with relevant, yet tailored, information and skills in a timely and effective manner. On the other hand, experienced Platform community members can play a role by recognizing some technical areas in which they can provide support and can make use of bilateral and multilateral communication channels to share their knowledge.



4

Knowledge and capacity required for an effective Codex-aligned GM food safety assessment

Figure 5 shows that most respondents identified the process of a GM food safety assessment (n=69) as a major knowledge gap, followed by data interpretation in application dossiers (n=60), GM food safety assessment principles (n=54), and Codex guidelines on GM food safety assessment (n=53). These answers indicate that a holistic provision of knowledge on GM food safety assessment is still necessary, particularly in developing countries.

FIGURE 5. Areas of existing knowledge gaps in conducting a GM food safety assessment.

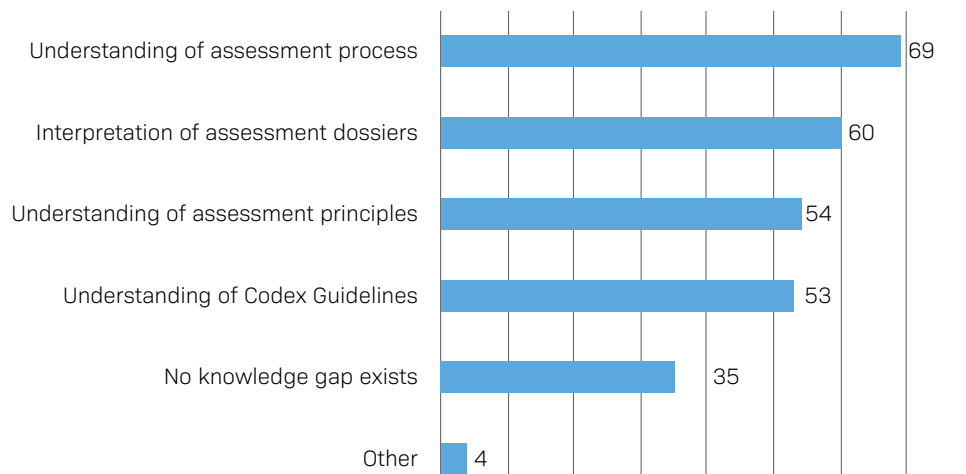
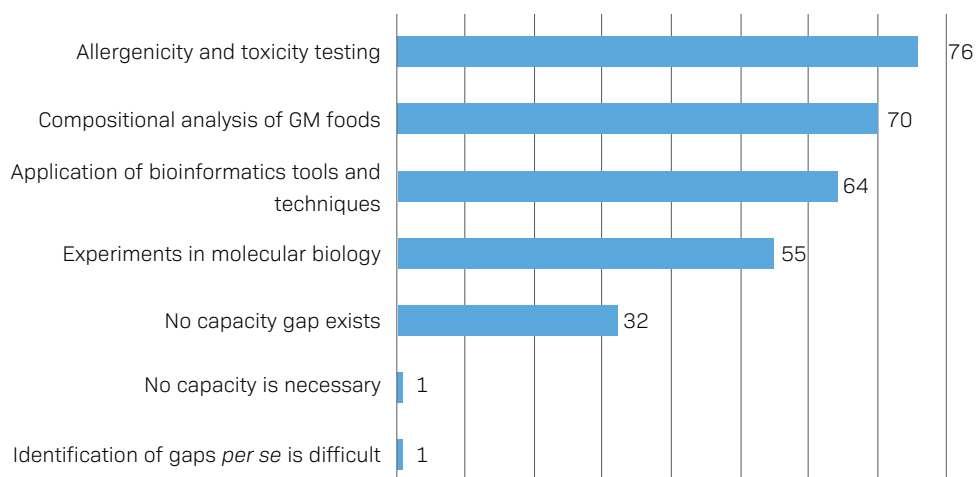


Figure 6 shows the capacity gaps that were identified through the questionnaire. The majority indicated allergenicity and toxicity (n=76) as the capacity area that mostly still needs to be developed. This was followed by compositional analysis (n=70), bioinformatics (n=64), and molecular biology (n=55) capacities. The identification of specific capacity gaps can help policy-makers understand the kind of expertise required to ensure an effective GM food safety assessment.

FIGURE 6. Areas of existing capacity gaps in conducting a GM food safety assessment.





5

Country practices on conducting GM food safety assessments

Overview of country approaches

Figure 7 illustrates the institutional set-ups for conducting GM food safety assessments in respondents' countries. While 39 percent of respondents answered that no framework exists, the majority reported that they have one competent authority that is tasked with leading the process of a GM food safety assessment. This can be captured as one of the good practices as the option would make the relevant roles and responsibilities clarified. On the other hand, where multiple authorities are involved, respondents reported that effective coordination and collaboration are essential.

Where an established mechanism to conduct food safety assessments exist, the institutional set-up was further investigated to understand if external experts or reviewers are involved during the GM food safety assessment. Results of such investigations are reported in Figure 8; 52 percent reported that external experts and/or reviewers are involved in GM food safety assessments in their countries. This can also be identified as a resource-effective practice that provides the opportunity to tap into different fields of expertise that are not available in the competent authority conducting the assessment. Various ways of engaging external experts during GM food safety assessments are described below and illustrated in Figure 9.

FIGURE 7. Institutional set-ups for conducting GM food safety assessments in respondents' countries.

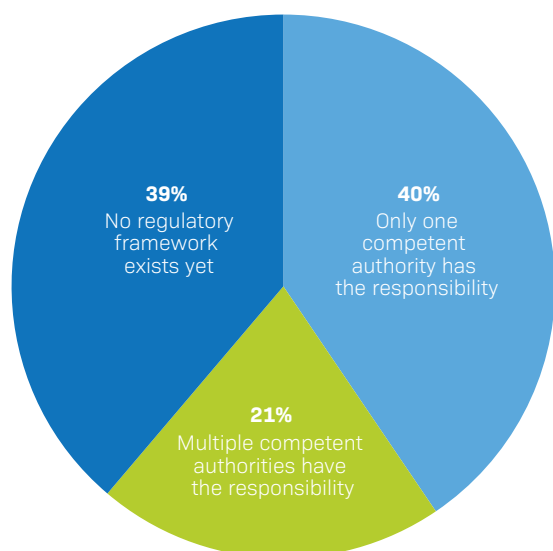
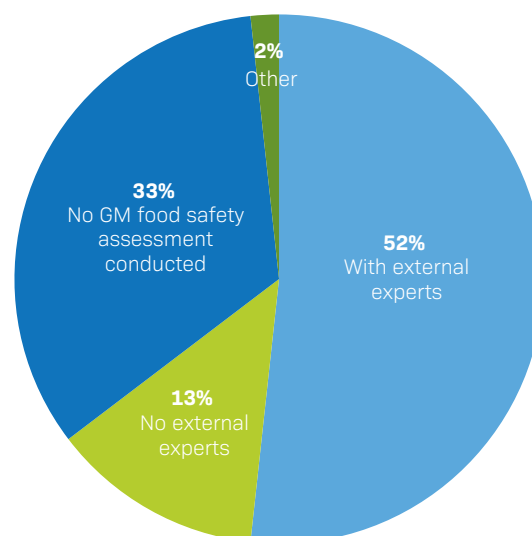


FIGURE 8. Engagement of external experts and/or reviewers during GM food safety assessments.



External experts are fully engaged in Kenya

Once an application dossier is submitted to the competent authority, technical staff members verify that the applicant has filled in the relevant sections. Thereafter, the application is sent to external reviewers in the roster of experts, depending on the type of application and expertise required for the review. For a GM food safety assessment, reviewers are asked to conduct the evaluation in line with the relevant Codex guidelines. Reviewers' comments are compiled into a report, which is discussed by the board's technical committee before a final decision is made by all board members.

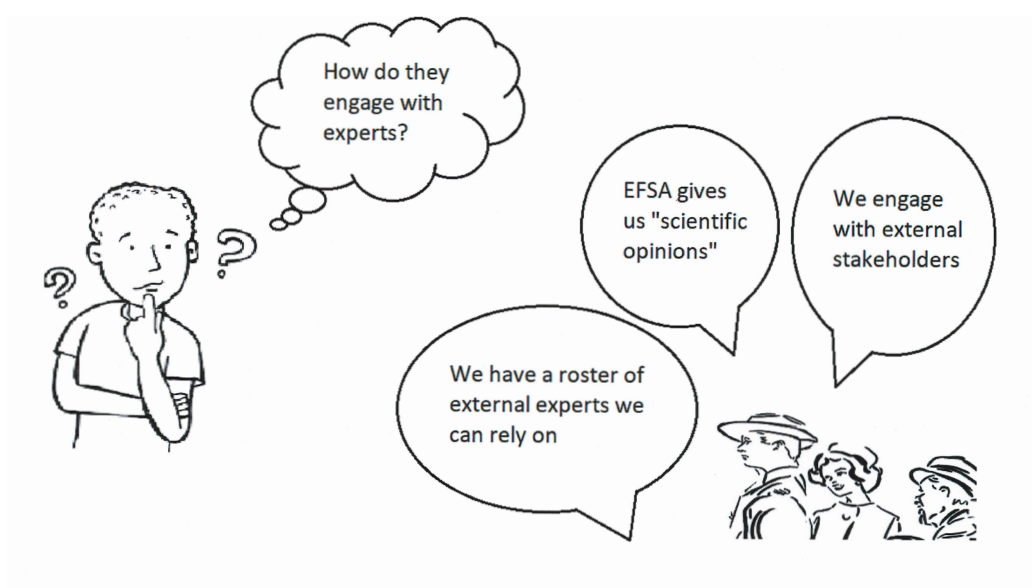
Australia consults stakeholders

Food Standards Australia New Zealand (FSANZ) does not engage experts outside of FSANZ for conducting or reviewing GM food safety assessments. Internal FSANZ officials often contribute specific expertise to the GM food safety assessment process. FSANZ does, however, consult stakeholders during the assessment process, which may include experts. During this consultation process, stakeholders may submit comments on a draft GM food safety assessment.

European Union/EFSA has official external expert panels producing scientific opinions

The European Union has a body tasked with conducting GM food safety assessments, called the European Food Safety Authority (EFSA). EFSA foresees the involvement of independent and highly qualified scientists who have the responsibility of assessing potential risks to human and animal health and the environment, of food and feed products in the European Union. EFSA has specific procedures for consulting national competent authorities of its Member States on every application of Genetically Modified Organisms (GMOs), and provides feedback on the scientific concerns raised by Member States during the GM food safety assessment process. The EFSA's scientific evaluation of GMO applications is made available in the form of "scientific opinions" that are publicly available on EFSA's website.

FIGURE 9. Engaging external experts for effective GM food safety assessment.



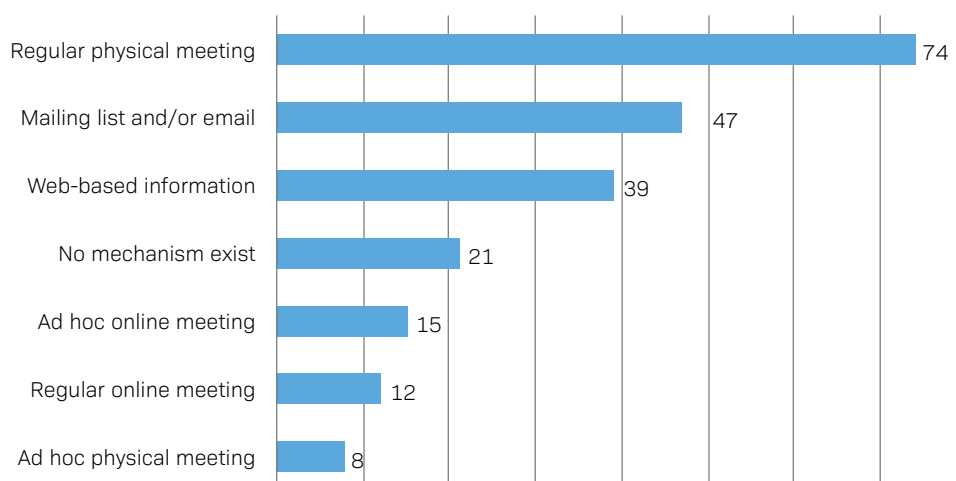


6 Country practices in communication mechanisms

Communications between GM food safety assessors and Platform focal points

Many respondents (n=74) reported that physical meetings regularly occur between GM food safety assessors and Platform focal points, in addition to other communication methods as seen in Figure 10 (particularly email, and web-based and online meetings). This result suggests that, having regular physical meetings can be considered an effective practice for discussing the results of GM food safety assessments with focal points.

FIGURE 10. Communication mechanism between risk assessors and Platform focal points.



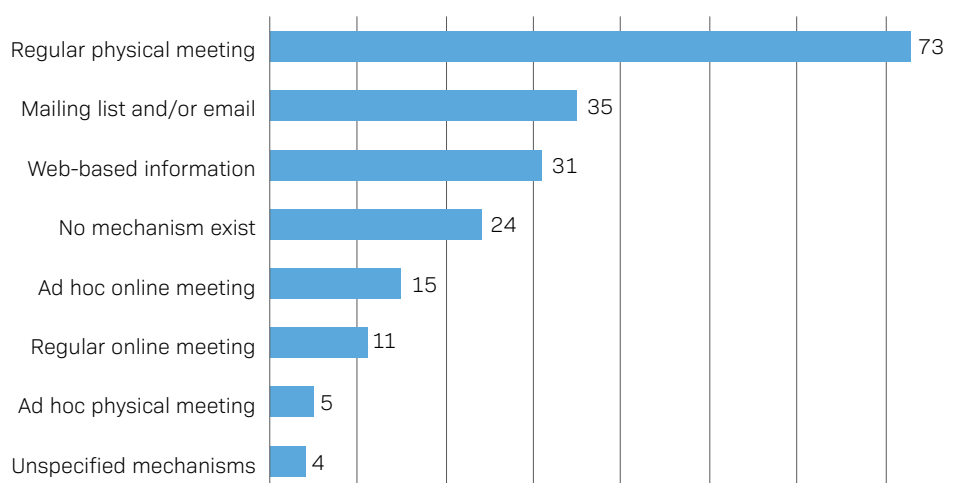
Some Platform community members utilize formal working groups to discuss various issues on GM food safety assessments. It is also notable that one respondent stated that relevant information is often shared in an informal way through personal contacts, and that results are presented during workshops, but consistency and transparency could be a challenge with this approach.

Between GM food safety assessors, focal points and decision-makers

As Figure 11 indicates, regular physical meetings (n=73) are the most common mechanism for communicating between GM food safety assessors and decision-

makers. The results of GM food safety assessments are documented and shared, but verbal discussions on the results seem to be a good practice. A similar result was obtained on the communication mechanisms between focal points and decision-makers.

FIGURE 11. Communication mechanisms between risk assessors and decision-makers.



One respondent reported that one effective way to communicate with decision-makers is represented by regular monthly meetings that are held among high-level groups of people belonging to different organizations such as ministries of agriculture, health, finance, produce chemist laboratory, bureau of standards, customs and port authority, farmers, and consumers organizations. These regular meetings are the opportunities for risk assessors to discuss technical issues with policy-makers.

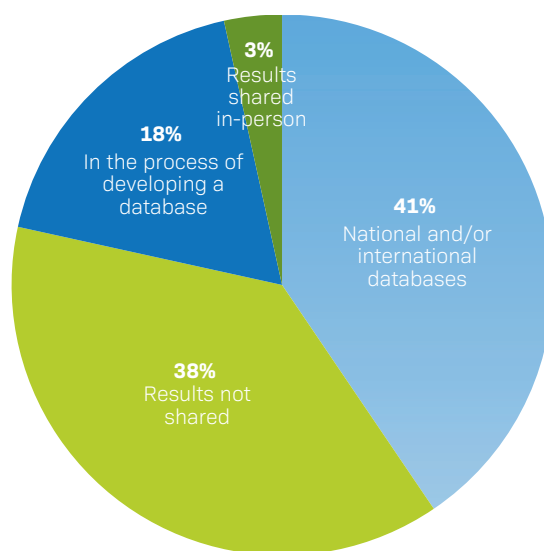
7

Data sharing of results on GM food safety assessments

Country practices in documenting and registering the results of GM food safety assessments

Figure 12 shows how GM food safety assessment results are shared by countries. The most popular (41 percent) answer was that they use national websites and/or international databases to share assessment results. To this extent, having national repository systems to document all GM food safety assessment results can be considered the ideal situation, but for those countries with limited Information Technology (IT) infrastructure, international database(s) represent a cost-effective

FIGURE 12. How/where to store results of GM food safety assessment.

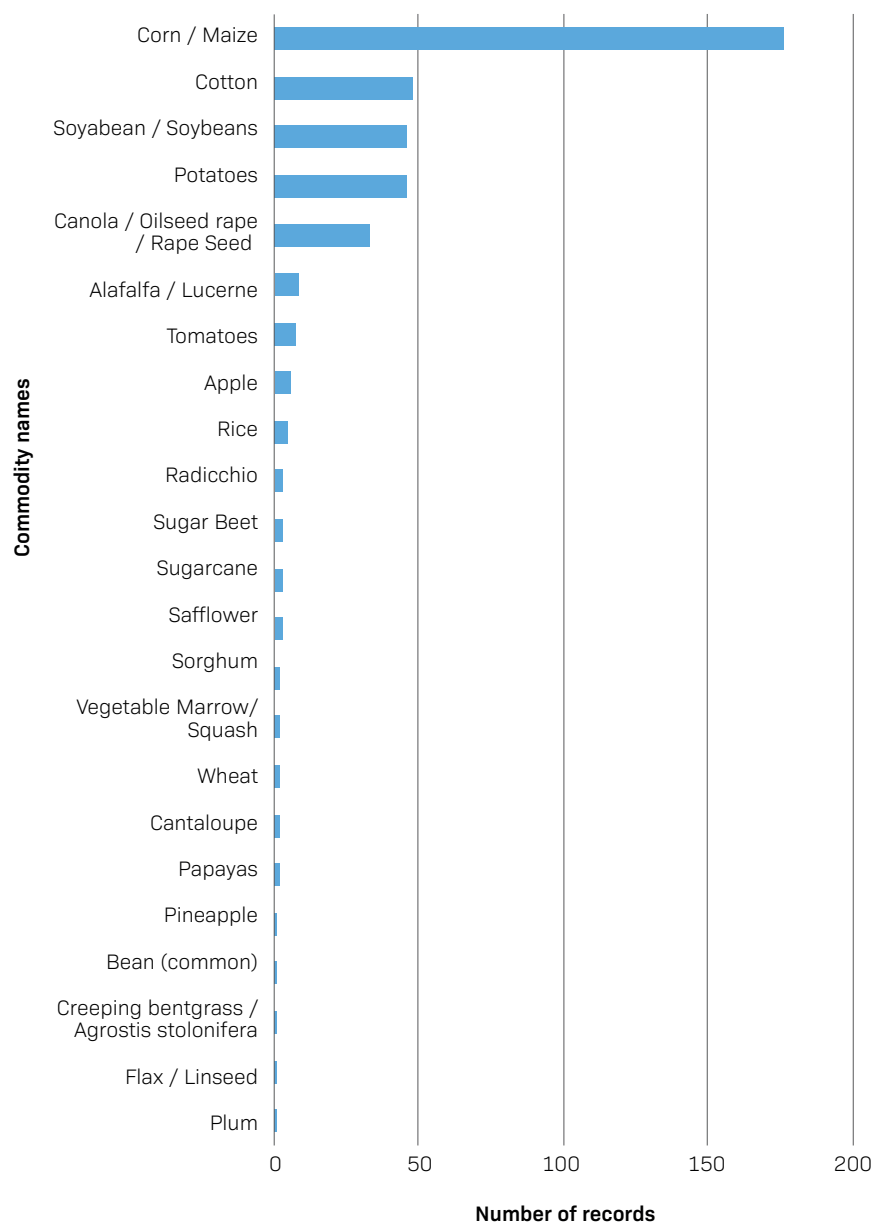


and maintenance-free option. The FAO GM Foods Platform serves the purpose of providing many developing nations with an external database and source of information to rely on.

GM food safety assessment results by commodity

Figure 13 shows the number of Platform records by commodity (FAO, 2019c). As of October 2019, maize has the largest number of records (n=176), followed by cotton (n=47) and soybeans (n=46).

FIGURE 13. Shared GM food safety assessment records, by commodity.



By clicking on each single bar, Platform users are re-directed to the commodity page indicated by that bar. For example, clicking the bar labeled “Rice” leads to a page where five different OECD Unique Identifiers are listed, indicating five different GM rices whose traits include glufosinate tolerance, insect resistance and increased levels of provitamin A.

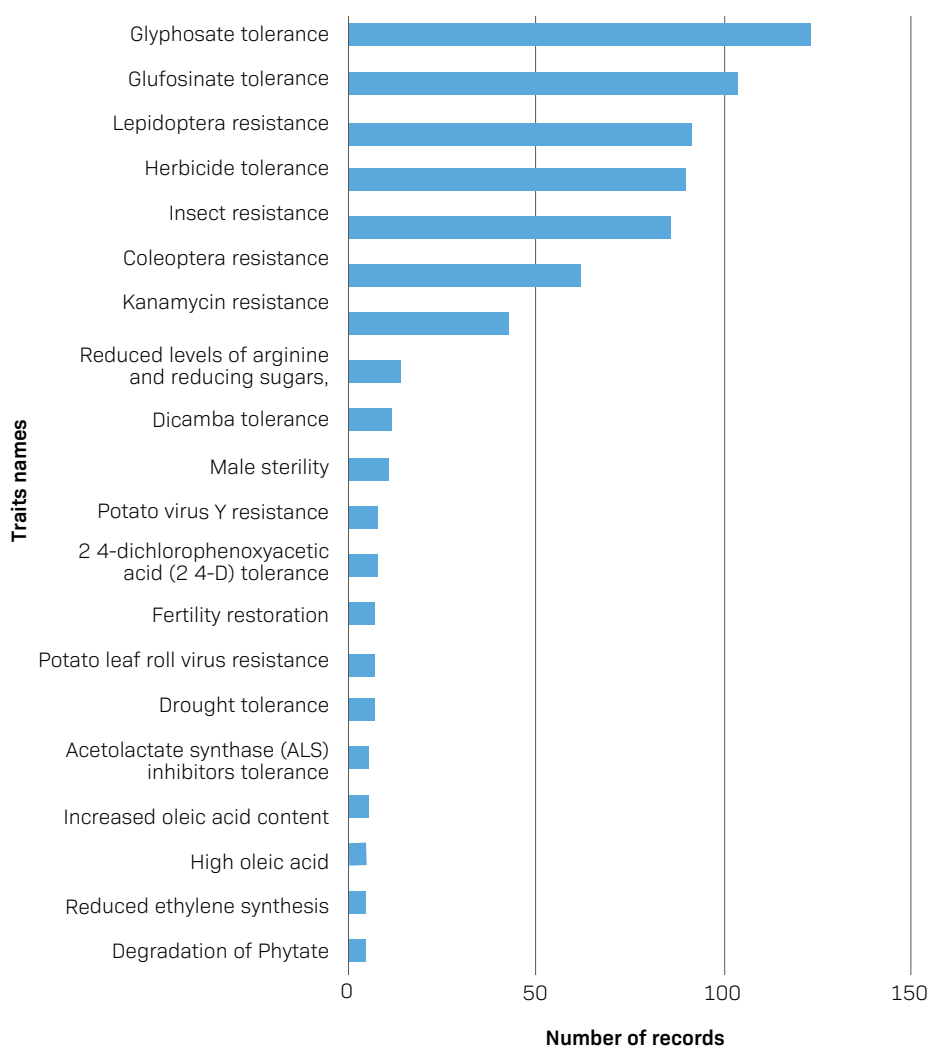
FIGURE 14. Shared GM food safety assessment records, by OECD unique identifier.

OECD Unique Identifier	Traits
ACS-OS001-4	Glufosinate tolerance
ACS-OS002-5	Glufosinate tolerance
BGH-00827-7	Insect resistance
HZU-HHU 0 01-9	Insect resistance
IR-00GR2E-5	Rice with increased levels of provitamin A

GM food safety assessment results by traits

Figure 15 shows the number of the Platform record by traits (FAO, 2019d). Currently, the Platform has 52 different traits registered.

FIGURE 15. Shared GM food safety assessment records, by trait.





8

Challenges in conducting GM food safety assessments

Overview of country challenges

Possible challenges experienced by countries in conducting GM food safety assessments were also investigated through the questionnaire described in the Methodology section through an open-ended question. Answers were then categorized, indexed and charted to obtain the results reported on in Table 6.

TABLE 6. Main challenges in conducting GM food safety assessments.

Challenges	Response
Decision-makers have limited knowledge about GM food safety assessment	18
Country does not have necessary legislations and/or regulations	17
Coordination of multiple agencies is challenging	12
Limited experience in conducting GM food safety assessments	14
Capacity challenge exists on data collection, analysis and sharing	12
Communication to the public about GMOs is challenging	10
Relevant regulations are difficult to implement in reality	7
Public perception makes regulators to conduct GM food safety assessment difficult	6
Capacity challenge exist on LLP detection and management	2
No challenges	15

Challenge in Bangladesh to coordinate different agencies

The coordination of different national agencies was listed as a challenge by 12 respondents in cases where multiple government agencies are involved in GM food safety assessments. This may be due to conflicting or possibly overlapping mandates among the agencies, or practical feasibility in getting consensus from all agencies involved. The respondent from Bangladesh listed this as a challenge as all food safety issues, including GM food safety, are dealt by different ministries, agencies or departments, as illustrated in Figure 16.

FIGURE 16. Too many chefs to cook?



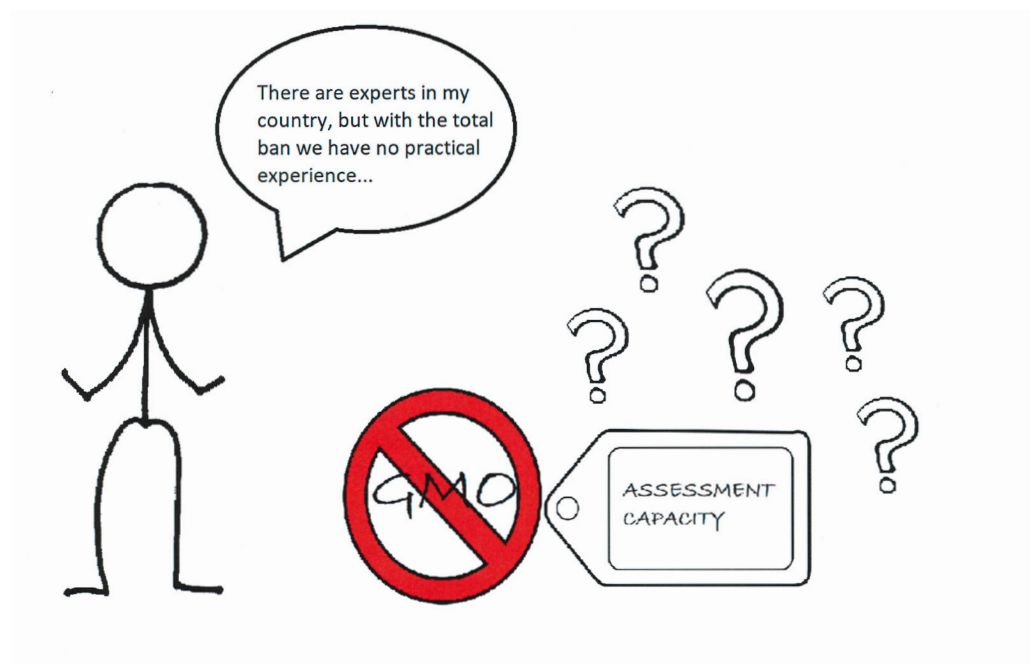
Decision-makers' technical knowledge can be improved in Zambia

A number of countries indicated that they have experienced the situation where decision-makers need to be further sensitized about the technical aspects of GM food safety assessments. The respondent from Zambia explained that the absence of a contingency plan to maintain knowledge after members of the current board and scientific advisory committee rotate when their term of office ends, may affect decision-making. This may be because most of members of boards and decision-making committees are political appointees who may not necessarily have a scientific background. It is, therefore, important for them to put measures in place to ensure they are sensitized and advised by scientific experts before decision-making occurs.

Impact of a total ban on GMOs for capacity development in Serbia

Countries where no regulations exist or where bans on GMOs are in place, reported that the regulatory framework itself, or the lack of one, is a challenge in conducting GM food safety assessments. Serbia reported that it has put a ban on GMOs over the last 10 years and no capacity development has been needed in the area of GM food safety assessments. Now country expects a drastic change to harmonize its regulatory framework with that of the European Union, and the major challenge is the limited practical experience in conducting GM food safety assessments. The country believes that it has a sufficient number of qualified experts with the necessary expertise required, but it is a challenge to seek a starting point with the current situation of a total ban (Fig. 17).

FIGURE 17. Does a ban on GMOs close the door for scientific capacity development?



Challenges to identify challenges in Libya

In some case, the challenge is to identify national challenges, which is illustrated in Figure 18. A respondent from Libya expressed his limited awareness about any possible difficulty that his country currently faces in conducting GM foods safety assessments. Other countries could also be facing a similar predicament, suggesting that competent authorities need a basic understanding of concepts related to GM food safety assessments, even before the draft guidelines or discussion on how the process should be conducted.

FIGURE 18. The biggest challenge is to identify challenges.

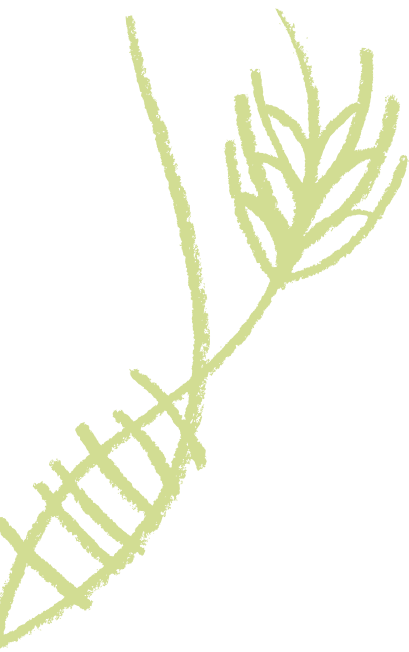


Areas where countries can provide technical support

Platform community members that already share their results of GM food safety assessments on the Platform were asked to choose areas of expertise for which they can provide technical support to less-experienced countries. Multiple answers were allowed and responses are summarized in Table 7.

TABLE 7. Areas of expertise and countries offering support.

Area of expertise	Platform community members willing to offer technical support
Allergenicity and toxicity testing	Australia, Argentina, Canada, China, European Union, Indonesia, Iran, Kenya, Philippines, Turkey, New Zealand, United States of America
Experiments in molecular biology	Australia, Argentina, Belarus, Canada, China, European Union, Indonesia, Iran, Kenya, Philippines, Turkey, United States of America
Compositional analysis of GM foods	Australia, Argentina, Canada, China, European Union, Indonesia, Iran, Kenya, Philippines, United States of America
Application of bioinformatics tools and techniques	Australia, Argentina, Canada, China, European Union, Indonesia, Iran, United States of America



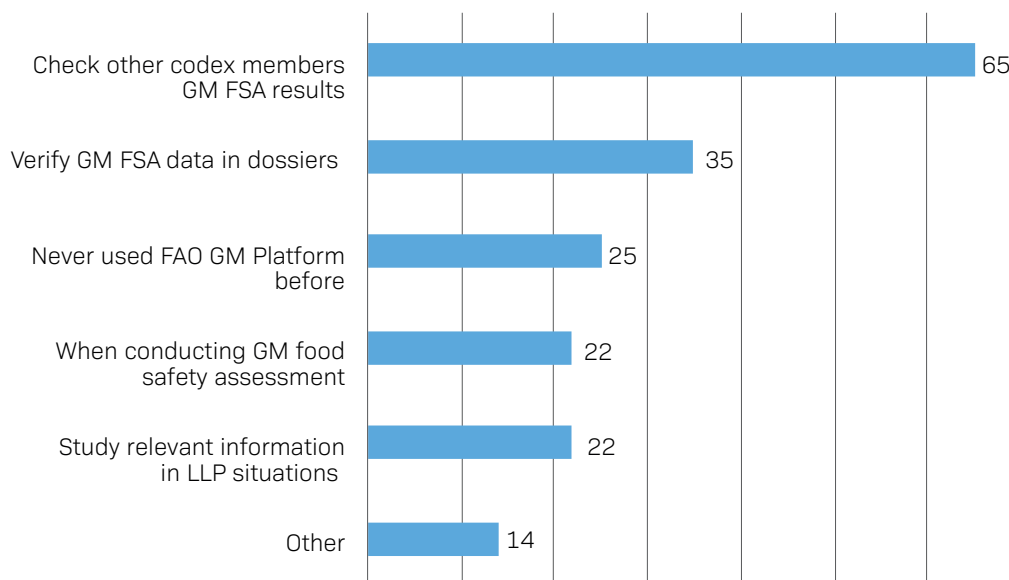
9

Towards effective risk-based GM food safety assessments and regulatory management

Country practices of the effective use of the Platform

How the Platform is used by Codex Members was also investigated through the questionnaire, and results are shown in Figure 19. Multiple answers were allowed for the questions, and many respondents (n=65) indicated that they use the FAO GM Foods Platform to review GM food safety assessment results from other countries. Although Codex Members agreed to have FAO maintain the Platform for possible LLP situations, only 22 respondents reported that they use the database for this purpose, indicating that there is a need to increase awareness of the usefulness of the Platform and its data for LLP situations.

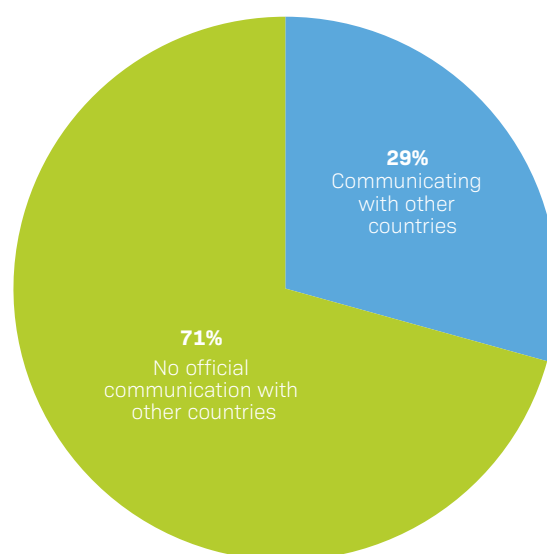
FIGURE 19. Main purposes for using the FAO GM Foods Platform.



Partnerships and collaborations with other countries on GM food safety assessments

Figure 20 shows that the majority of the respondents (71 percent) stated that they do not have good communication mechanisms with other countries to discuss issues pertaining to GM food safety assessments. Communication among trading partners and neighbouring countries would possibly improve the understanding, quality and effectiveness of GM food safety assessments through positive collaborations. Many countries have requested FAO to provide various technical fora for dialogues on GM food safety assessments.

FIGURE 20. Partnerships and collaborations with other countries on GM food safety assessments.



List of countries that share data on GM food safety assessments and the languages they use

Table 8 shows the languages that experienced countries use to share results of GM food safety assessments on the Platform (FAO, 2019e). This can be useful for countries to look up data and information, and to develop technical collaborations and partnerships.

TABLE 8. List of countries sharing data on the Platform.

Country (number of records shared)	Codex region	Languages can be used
United States of America (177)	CCNASWAP	English
Republic of Korea (152)	CCASIA	English
European Union (137)	CCEURO	English, Spanish, French
Colombia (137)	CCLAC	English, Spanish
Japan (135)	CCASIA	English
Mexico (132)	CCLAC	English, Spanish
Canada (125)	CCNASWP	English, French
Australia (106)	CCNASWP	English
New Zealand (98)	CCNASWP	English
Philippines (90)	CCASIA	English
Argentina (61)	CCLAC	English, Spanish
Brazil (60)	CCLAC	English, Spanish
Malaysia (38)	CCASIA	English
Turkey (36)	CCEURO	English
Russian Federation (27)	CCEURO	English, Russian



10

Conclusion and way forward

Ensuring the safety of any type of food is a challenging task, both in developing and developed nations. Food safety in general requires the development and implementation of effective regulatory frameworks to establish the multi-faceted approach necessary to protect the public's health and to facilitate fair trade. The necessary elements are not unique to GMOs, but are discussed in the following paragraphs under the lens of a GM food safety assessment.

Good practices: Involving external experts and/or reviewers in national GM food safety assessments is not only resource-efficient but also provides the opportunity to tap into many different fields of expertise that may not be available in the competent authority conducting the assessment, thus ensuring the robustness of the evaluation. Regular communications among Platform focal points, policy-makers, risk assessors and risk managers are extremely beneficial to ensure that all aspects of the risk assessment are well understood during the whole process. In addition to digital-based communication channels (email, web-based and online meetings), regular physical meetings are also useful.

Challenges: To set up processes and policies for GM food safety assessments can be a daunting task. Existing or suspected knowledge gaps are often difficult to fill and the challenges remain, in particular, around the boundaries of the process and the scientific questions to be answered during a GM food safety assessment. Having access to relevant yet tailored information and knowledge in a timely and effective manner can be especially helpful to address these questions during the establishment of a GM food safety assessment. The Platform provides information that gives a look at assessments performed by various countries, and thereby aids in developing a more holistic understanding of the GM food safety assessment process. However, the political reality can pose challenges that may be hard to overcome, for example, a political ban on GMOs usually prevents technical officers from developing their capacities to conduct effective GM food safety assessments, and may render an administration uninformed about the current science in GM food safety assessment processes. This is particularly concerning as such knowledge gaps are more difficult to fill over time, and as new science and technologies emerge elsewhere, this gap can only widen.

Documentation of GM food safety assessments: Ideally, countries have their own national repository system to document all GM food safety assessment results; however, where a stable IT infrastructure is not readily available, international database(s) can provide an alternative and serve as a cost-effective, maintenance-free national data repository system. The FAO GM Foods Platform is serving such a purpose for many developing nations. The initial purpose of the FAO GM Foods Platform was to facilitate the decision-making process with regard to possible LLP situations, yet only 22 survey respondents (19 percent of all responses) reported that they use the Platform for this purpose. There is a need to increase awareness among community members on the usefulness of the Platform for LLP situations.

This document can be used as a trigger to initiate open dialogue among community members to discuss how best to utilize the Platform to improve GM food safety assessments in their respective countries and/or country groups. Experienced countries can identify in the document specific areas of expertise, so as to offer their technical support to less-experienced countries to help improve efficiency of GM food safety assessments. It is often beneficial to consider deepening and lengthening the learning experience about good practices in the context of bilateral and/or multilateral collaborations and partnerships in order to conduct effective GM food safety assessments. To overcome the lack of world-class scientific expertise in all the necessary faculties, country groups may wish to consider establishing mutual reference or recognition of the respective GM food safety assessment results, or to at least create a pool of experts for reviewing applications. Twenty nine percent of the survey respondents reported that they have effective communication mechanisms with other countries, and Platform community members can learn from their experience to establish their own partnerships.

The Platform is a good reference point for fully understanding the GM food safety assessments that other countries have conducted. FAO will continue to support this Platform in order to facilitate the establishment of a community of practice that will empower countries to understand modern technologies to ensure food safety and food security in their countries, with the confidence that they have sufficient knowledge and expertise to conduct GM food safety assessments.

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List of FAO GM Foods Platform Focal Points

Asterisks next to names (*) indicate that the focal point nomination has not yet been formalized through a nomination form. For contact information of the focal points and alternate focal points, visit the resource section of the Platform at <http://www.fao.org/food/food-safety-quality/gm-foodsplatform/resources/>.

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The reality of GM food safety: Are we effectively evaluating it?

Many countries have made significant efforts, often with technical assistance from FAO and Codex Alimentarius, to regulate and manage GM food safety issues. However, as of September 2019, fewer than 30 countries have been able to conduct a full GM food safety assessment. The big question remains as to whether this is an effective safety evaluation of GM food, with only some countries technically capable of relevant risk assessment.

A global survey including 116 countries was administered to collect information on good practices and specific challenges that countries are facing. The findings revealed that in any country, the government's risk assessment team alone will not be sufficiently able to develop the full assessment conclusions, as 52 percent of the respondents are involving external non-government experts in the national GM food safety assessment process. If the decision makers request the government experts to perform the entire risk assessment process, it would require additional financial and human resources. More than 60 percent of the respondents stated regular communications between risk assessors and risk managers through physical meetings are beneficial for the policy-makers to make science-based and informed decisions. While some respondents stated that the limited understanding of the topic for policy-makers (18 percent) and the difficulty to coordinate across multiple relevant agencies (12 percent) are still the biggest barriers, many stated that learning from the experienced countries with their good practices would improve their capacity. This document has compiled the results of the survey, as well as the statistics collected from the data on the FAO GM Foods Platform to provide countries with practical options to solve the issues they face, and to promote collaborative approaches among countries to develop their capacities in GM food safety assessment.