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Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants – Consensus Document

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Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants

- Consensus Document -

Environment Directorate

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Also published in the Series on the Safety of Novel Foods and Feeds:

[No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001) – ***REPLACED with revised Cons. doc. No. 24 (2011)***]

[No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001) – ***REPLACED with revised Cons. doc. No. 25 (2012)***]

No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-nutrients (2002)

[No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2002) – ***REPLACED with revised Cons. doc. No. 33 (2020)***]

No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)

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No. 19, Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [*Sorghum bicolor* (L.) Moench]: Key Food and Feed Nutrients and Anti-nutrients (2010)

No. 20, Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [*Ipomoea batatas* (L.) Lam.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)

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The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 38 Member countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working parties composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working parties are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in twelve different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides; Biocides**; **Risk Management; Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds**; **Chemical Accidents**; **Pollutant Release and Transfer Registers**; **Emission Scenario Documents**; **Safety of Manufactured Nanomaterials**; and **Adverse Outcome Pathways**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication is available electronically, at no charge.

For the complete text of this and many other Biosafety publications, consult the OECD's World Wide Web site (www.oecd.org/env/ehs/biotrack/)

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FOREWORD

The Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) aims to assist countries in evaluating the potential risks of novel foods and feeds derived from genetically-engineered organisms, foster communication and mutual understanding of relevant regulations in countries, and facilitate harmonisation in risk/safety assessment of products from modern biotechnology. This programme encourages information sharing, promotes harmonised practices and contributes to prevent duplication of efforts among countries, while consolidating high food and feed safety standards. The WP-SNFF's activities and outputs are complementary to those of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, which deals with environmental safety (biosafety) of genetically-engineered organisms.

The WP-SNFF's main outputs are the science-based ***consensus documents on compositional considerations***, which are mutually acceptable among member countries and partners. These practical tools contain information for use during the regulatory safety assessment of a particular food/feed product. Already covering 22 different crop species, these consensus documents provide key elements on the nutrients, anti-nutrients or toxicants of the considered product, information of its use as a food/feed and other relevant information. Additional guidance documents are also published by the WP-SNFF, available together with the consensus documents at www.oecd.org/env/ehs/biotrack/.

Of different content, this consensus document was drafted by an Ad-hoc drafting group consisting of experts from Argentina (Mr. Facundo Simeone), Australia (Dr. Lisa Kelly), Canada (Mr. Jordan Bean, Ms. Annie Savoie, Ms. Lynne Underhill), BIAC (Mr. Luis Luque), the AUDA-NEPAD African Biosafety Network of Expertise (Ms. Modupe Adeyemo, Mr. Samuel Timpo) and AFSI (Dr. Bhavneet Bajaj). Canada and Australia served as co-lead countries in the preparation of the document. The draft has been revised on a number of occasions based on the input from other member countries and stakeholders.

This document is the first publication in the Series to address collaborative work in novel food and feed safety assessment. It serves as a resource for regulatory agencies seeking to collaborate on the safety assessment of foods and feeds derived from transgenic plants. It describes various types of collaborative work among agencies, potential benefits and challenges of implementing such activities, underlying principles and foundations that may facilitate collaboration, aspects to consider when preparing and evaluating such work. It also provides real-world examples of collaborative work between agencies.

The WP-SNFF endorsed this document, which is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

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1 Preamble

Cooperation among regulatory agencies continues to be encouraged by many governments around the world, in various areas of pre-market assessment including pharmaceuticals, pesticides and more recently, the possibility of collaboration is being explored for plant products developed via biotechnology.

Collaboration on the safety assessment of foods and feeds derived from recombinant DNA (rDNA) plants has the potential to benefit all involved participants, from the regulatory agencies[1] to the applicant submitting a product for review. For agencies, it offers opportunities for harmonising or aligning assessment processes, sharing the burden of work, increasing the acceptance and legitimacy of findings and recommendations, and mutual capacity building and learning. Exchange of knowledge and expertise can result in enhanced efficiency and effectiveness in assessment processes of the agencies.

The present OECD publication entitled *Considerations for Collaborative Work on the Safety Assessment of Foods and Feeds Derived from rDNA Plants – Consensus Document* serves as a resource for regulatory agencies seeking to collaborate on the safety assessment of foods and feeds derived from rDNA plants. This document describes various types of collaborative work that may be undertaken and highlights the potential benefits and challenges of implementing such work. Furthermore, this document addresses the underlying principles and foundations that may facilitate collaborative work related to the safety assessment of foods and feeds derived from rDNA plants, highlighting certain aspects to consider prior to implementing any collaborative process, and how collaborating agencies may evaluate the success of their work. Where applicable, the document provides real-world examples of collaborative work between agencies.

When referring to rDNA plants, various terminologies are used in different agencies, organisations for designating the same products: ‘rDNA plants’, ‘genetically modified organisms’, ‘living modified organisms’, ‘genetically engineered organisms’, and others. This diversity is reflected under Section 9 of the document providing collaborative work examples, leaving individual agencies to use the terms they prefer in the description of their collaborations.

This document is not prescriptive nor is it an exhaustive list of how agencies may choose to collaborate. Any arrangement between agencies continues to be voluntary and not legally binding. While this document is supportive of collaborative work between regulatory agencies around the world, it does not suggest any change in the regulatory sovereignty of any agency.

[1] Within the context of this document, the term “agency” refers to all regulatory groups involved in a collaborative arrangement. It is acknowledged that different regulatory groups identify as departments, agencies, administrations, etc., however for simplicity this document refers to all these groups as “agencies”.

2 Scope

For the purposes of this document, the scope of collaborative work is the safety assessment of foods and feeds derived from rDNA plants. In any collaborative work among the responsible agencies, each jurisdiction maintains its sovereignty in the risk management steps to be taken once the safety assessment is completed. Even in collaborations involving acceptance or recognition by one agency of the safety assessment conclusion of another agency, the final authorisation decision remains the responsibility of each jurisdiction. Risk management/authorisation is not addressed in this document.

Among the various types of collaboration described in Section 4., agencies have flexibility to determine if they will work together on a few or all elements of the safety assessment.

3 Benefits and challenges of collaborative work

3.1 Benefits from collaborative work

Collaboration on the safety assessment of foods and feeds derived from rDNA plants has the potential to directly benefit both the agencies involved in the assessment of products, and to the applicants bringing forward products for review. Depending on the type and breadth of collaborative work, there may also be wider-reaching indirect benefits for both the regulatory and regulated communities.

The benefits that may arise from collaborative work include:

(i) *Efficiency gains in assessment processes*

Collaborative activities may reduce the time as well as the amount of resources required for a safety assessment. For the agencies, this may allow for the reallocation of resources to new and/or future needs. Reducing the time taken to complete an assessment may also enable faster authorisations, allowing innovative products to be brought to market faster which benefits users and consumers.

(ii) *Improved synchronisation of food and feed authorisations*

Certain types of collaboration have the potential to improve the synchronisation of authorisations within geographical regions or among trading partners. This can lead to greater predictability for applicants as well as indirectly provide benefits for trade, for example, reducing the potential for non-tariff trade barriers.

(iii) *Mutual capacity building and learning*

Collaboration, no matter what form it takes, provides the opportunity to share knowledge and learn from each other. This can enhance the professional development of staff within agencies, as well as directly improve the efficiency and effectiveness of assessment processes. This benefit can be derived irrespective of the level of assessment experience of individuals or the agency.

(iv) *Stronger working relationships between agencies*

The process of collaboration builds stronger working relationships between agencies, leading to improved knowledge and information sharing, as well as enabling the leveraging of each other's expertise for mutual benefit. Ultimately, this may open up further opportunities for collaboration.

(v) *Increased public confidence in regulatory decisions*

Working together on safety assessments and sharing knowledge and expertise can improve the rigor of assessments and, with it, public confidence in the assessment outcomes.

(vi) *Increased harmonisation, including alignment of assessment approaches*

Collaborative work between agencies on the safety assessment of foods and feeds derived from rDNA plants may facilitate consistency in the adoption of international guidelines and best practices, leading to increased harmonisation.

(vii) *Potential to reduce regulatory burden*

Measures that improve the efficiency of assessment and authorisation processes may reduce the regulatory burden on both agencies and applicants.

(viii) *Provide a regulatory environment that supports innovation*

Gains in efficiencies can ultimately result in a clearer and more predictable assessment process. This in turn provides a regulatory environment that is supportive of innovation, which can benefit both consumers and the environment in terms of health, nutrition, food affordability/access, etc.

3.2 Challenges in undertaking collaborative work

While significant benefits may be derived through collaboration, agencies may face some challenges in undertaking collaborative work. These may include:

(i) *Legal issues*

Some legislative frameworks may preclude certain types of collaborative work. Before commencing collaboration, it will be important for agencies to confirm what types of collaboration are permissible under their existing legislative frameworks. Collaboration that requires a change to legislation, for example, may be too difficult or costly to put in place and alternative forms of collaboration may need to be considered.

(ii) *Demand on resources*

Collaborative work may be resource-intensive to begin with as different models for collaboration are explored. It may also require a commitment of resources for some time before any benefits may be realised. In deciding the type of collaboration to undertake, agencies must weigh up whether the potential benefits are worth the investment of resources.

(iii) *Operational differences between agencies*

Operational differences between agencies, such as differences in assessment and authorisation processes and timelines, data and information requirements, confidentiality requirements etc. may make some forms of collaboration more difficult to undertake. This will need to be taken into account when deciding on the type of collaboration to pursue.

(iv) *Logistical and practical challenges*

Differences in time zones, languages, or even communication technologies may make it more difficult or time-consuming to work together. This will need to be taken into account in deciding how the collaborating agencies should communicate with each other.

(v) *Level of commitment*

In some instances, the level of commitment to collaborative work may vary between collaborating agencies or diminish over time. This may be driven by changes in the resource levels of agencies, a change in leadership or key staff of an agency, or simply a product of the length of time it takes to establish effective collaboration.

While these challenges can make it more difficult to undertake collaborative work, they are not necessarily insurmountable, particularly if the level of commitment is there and the potential benefits to be realised outweigh the costs.

4 Types of collaborative work

The types of collaborative work described in this document, as distinguished from more formal arrangements between governments, can be largely accomplished without complex, legally binding agreements among agencies.

Collaborative work refers to any collaboration between agencies whose remit is the safety assessment of foods and/or feeds derived from rDNA plants. This work could include inter-agency peer review of assessments, parallel or concurrent assessment, sharing of safety assessments, joint safety assessments, recognition/acceptance of conclusions of assessments or parts of assessments conducted by one or more agencies, or recognition of, or reference to previous safety assessments conducted by one or more agencies. These types are further outlined in the following sections.

Certain types of collaborative work can often serve as a foundation to support further work between agencies. The different types of collaborative work described below have been ordered where possible to illustrate this concept.

Each type of collaborative work offers certain benefits and challenges to agencies. While this document highlights some of these benefits and challenges, it is recognised that they may vary depending on the agencies involved. Within the context of their unique situation, it will be up to collaborating agencies to determine the type of work that will provide the most benefit.

4.1 Inter-agency peer review

Peer review is an element of many types of collaboration but could also be performed as an exercise in its own right, without the peer-reviewing agency using the assessment themselves for the authorisation process. This collaboration may be useful in training or capacity building (Section 4.7). It may also be a way to ensure and maintain the rigour of an agency's safety assessments. Depending on an agency's legislative requirements, consent to disclose certain information may be required from an applicant.

Benefits

- Mutual capacity building and learning
    - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
- Stronger working relationships between agencies
    - Can build trust between agencies/facilitate other types of collaborative work (e.g., sharing of safety assessments)
- Increased public confidence in regulatory decisions
    - Can improve the rigour of an agency's assessments (i.e., by ensuring that their assessments consider all relevant endpoints regarding the safety of the product). This in turn can increase public confidence in the assessment outcomes

Challenges

- Legal issues
  - Collaborating agencies may need to consider if their respective existing legislative frameworks can facilitate the peer-review of another agency's assessments

4.2 Parallel/Concurrent assessment

Two or more agencies complete their own safety assessment of an application but in a coordinated fashion according to a mutually agreed timeline. The agencies would need to receive simultaneous applications for the same product from an applicant. The agencies would hold scheduled check-ins and ad hoc discussions of any aspects of the submission during the course of the assessment.

Benefits

- Mutual capacity building and learning
  - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
  - Professional development can be particularly effective if one of the agencies has more experience conducting assessments
- Stronger working relationships between agencies
  - Can build trust between agencies/facilitate other types of collaborative work (e.g., sharing of safety assessments)
- Increased public confidence in regulatory decisions
  - May improve/maintain positive public confidence in the assessment process of a less-experienced agency if collaborating with a more experienced agency
- Increased harmonisation, including alignment of assessment approaches
  - Can be used as a first step to more aligned safety assessments
  - Synchronised submissions and assessments with two or more agencies at the same time could promote more synchronised decision-making

Challenges

- Operational differences between agencies
  - To perform parallel/concurrent assessments, agencies may need to accommodate differences in assessment and authorisation processes and timelines. There may also be differences in confidentiality requirements between agencies that must be considered
- Logistical and practical challenges
  - To perform parallel/concurrent assessments, agencies may need to accommodate for differences in time zones, languages, or even communication technologies

4.3 Safety assessment sharing

Safety assessment sharing refers to one lead agency completing a safety assessment, which is then shared with collaborating agencies for peer review and collaborative finalisation of the assessment. The final assessment is used by each agency in their respective authorisation process. The sharing of safety

assessments can serve as a trust building exercise, establishing a foundation for the recognition and acceptance of assessments by other agencies without peer review (Section 4.5).

Benefits

- Efficiency gains in assessment processes
    - Can reduce resources and time required for conducting assessments between the collaborating agencies, compared to agencies completing separate safety assessments for the same product
    - Freeing resources should enable increased capacity for agencies to review additional applications at the same time, thus reducing the time spent in queued applications, therefore reducing overall timelines
    - Applicants of foods or feeds derived from rDNA plants may benefit from more timely authorisations by multiple agencies
- Improved synchronisation of food and feed authorisations
    - Promotes synchronised authorisations based on a single safety assessment
    - Serves as an opportunity to harmonise assessment information requirements between agencies
- Mutual capacity building and learning
    - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
    - Professional development can be particularly effective if one of the agencies has more experience conducting assessments
- Stronger working relationships between agencies
    - This type of collaboration requires trust-building between agencies, which in turn will build a stronger working relationship
- Increased harmonisation, including alignment of assessment approaches
    - Through discussing and sharing the assessment outcomes performed by the lead agency with the peer-reviewing agency, there is the potential for increasing harmonisation of the respective assessments between agencies
- Potential to reduce regulatory burden
    - Improving the efficiency of the assessment process may reduce the regulatory burden for both collaborating agencies and applicants
- Provide a regulatory environment that supports innovation
    - Recognition/acceptance of assessments (or parts thereof) between two or more agencies can provide a regulatory environment that is supportive of innovation, which can benefit both consumers and the environment in terms of health, nutrition, food affordability/access, etc.

Challenges

- Legal issues
    - Collaborating agencies may need to consider if their respective existing legislative frameworks can facilitate safety assessment sharing
- Demand on resources

  - Establishing a safety assessment sharing process initially requires extensive project planning to assign tasks and establish timelines. This type of collaboration also likely requires preliminary exercises of trust-building between agencies (e.g., see Sections 4.1 and 4.2) prior to conducting such work
- Operational differences between agencies
  - To share safety assessments, agencies may need to accommodate differences in assessment and authorisation processes and timelines
- Logistical and practical challenges
  - To share safety assessments, agencies may need to accommodate for differences in time zones, languages, or even communication technologies between agencies
- Level of commitment
  - This type of collaboration requires a continued level of commitment by all collaborating agencies

4.4 Joint safety assessments

Joint safety assessments are a form of collaborative work where two or more agencies share resources to complete a single safety assessment. Each agency takes responsibility for completing specific elements or sections of the assessment. Once the draft assessment is completed, it is peer reviewed by all agencies. Once all agencies are satisfied with the overall assessment, the final, single assessment is used for each agency's authorisation process.

Benefits

- Efficiency gains in assessment processes
  - Saves resources and time for all agencies as each agency is responsible for completing only part of the assessment
  - Freeing resources should enable increased capacity for agencies to review additional applications at the same time, thus reducing the time spent in queued applications, therefore reducing overall timelines
  - Applicants of foods or feeds derived from rDNA plants may benefit from more timely authorisations by multiple agencies
- Improved synchronisation of food and feed authorisations
  - Promotes synchronised authorisations based on a single safety assessment
  - Serves as an opportunity to harmonise assessment information requirements between agencies
- Mutual capacity building and learning
  - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
  - Professional development can be particularly effective if one of the agencies has more experience conducting assessments
- Stronger working relationships between agencies

  - This type of collaboration requires agencies to work together to complete assessments, which in turn will build a stronger working relationship
- Potential to reduce regulatory burden
  - Improving the efficiency of the assessment process may reduce the regulatory burden for both collaborating agencies and applicants
- Provide a regulatory environment that supports innovation
  - A clear and predictable joint assessment process between two or more agencies can provide a regulatory environment that is supportive of innovation, which can benefit both consumers and the environment in terms of health, nutrition, food affordability/access, etc.

Challenges

- Legal issues
  - Collaborating agencies may need to consider if their respective existing legislative frameworks can facilitate joint safety assessments
- Demand on resources
  - Establishing a joint assessment process initially requires extensive project planning to assign tasks and establish timelines. This type of collaboration also likely requires preliminary exercises of trust-building between agencies (e.g., see Sections 4.1 and 4.2) prior to conducting such work
- Operational differences between agencies
  - To conduct joint safety assessments, agencies will need to accommodate differences in assessment and authorisation processes and timelines (possibly resulting in the harmonisation of both information requirements and/or assessment/authorisation process timelines)
- Logistical and practical challenges
  - To conduct joint safety assessments, agencies may need to accommodate for differences in time zones, languages, or even communication technologies between agencies
- Level of commitment
  - This type of collaboration requires a continued level of commitment by all collaborating agencies

4.5 Recognition/Acceptance of an assessment or parts of an assessment

Recognition or acceptance of an assessment is an advanced form of collaboration in which one agency would recognise and accept the outcomes of another agency's assessment of a specific product for the purposes of their own authorisation process of the same product. A variation of this type would be the recognition and acceptance of a part of another agency's assessment of a specific product (e.g., a toxicological assessment) to include in or supplement their own assessment of the same product.

Benefits

- Efficiency gains in assessment processes
  - Substantial resource and time savings for those agencies recognising/accepting assessments conducted by other agencies

  - Freeing resources should enable increased capacity for agencies to review additional applications at the same time, thus reducing the time spent in queued applications, therefore reducing overall timelines
  - Applicants of foods or feeds derived from rDNA plants may benefit from more timely authorisations by multiple agencies
- Improved synchronisation of food and feed authorisations
  - Improved synchronisation of assessments between agencies
- Mutual capacity building and learning
  - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
  - Professional development can be particularly effective if one of the agencies has more experience conducting assessments
- Stronger working relationships between agencies
  - This type of collaboration requires agencies to recognise/accept another agency's assessments. By default this requires a strong working relationship between collaborating agencies
- Increased harmonisation, including alignment of assessment approaches
  - Recognition/acceptance of an assessment (or parts thereof) can facilitate the adoption of assessments conducted according to international guidelines and best practices, leading to increased harmonisation between agencies
- Provide a regulatory environment that supports innovation
  - Recognition/acceptance of assessments (or parts thereof) between two or more agencies can provide a regulatory environment that is supportive of innovation, which can benefit both consumers and the environment in terms of health, nutrition, food affordability/access, etc.

Challenges

- Legal issues
  - Collaborating agencies will likely need to consider if their respective existing legislative frameworks can allow for the recognition/acceptance of assessments conducts by other collaborating agencies
- Demand on resources
  - Establishing a collaborative arrangement whereby agencies can recognise/accept assessments conducted by other collaborative agencies initially requires extensive preliminary exercises of trust-building between agencies (e.g., see Sections 4.1 and 4.2, and possibly Sections 4.3 and/or 4.4)
- Operational differences between agencies
  - To recognise/accept safety assessments conducted by other collaborating agencies, agencies will need to accommodate differences in assessment processes, likely resulting in the harmonisation of assessment information requirements between agencies

- Level of commitment
    - This type of collaboration requires involved agencies keeping each other informed of any changes relevant to their respective safety assessment processes such that it may change an agency's ability to recognise/accept another collaborating agency's assessments
- Public confidence in regulatory decisions
    - May require greater efforts in public education to maintain public confidence in the safety assessment process between collaborating agencies

4.6 Referencing another agency's assessment/application of a product to inform an agency's own assessment/application of the same or similar product

For this type of collaboration, an agency is still conducting their own assessment of a specific product. However, an agency may recognise/reference the outcomes of another agency's assessment of that product as part of the 'weight of evidence' in coming to their own conclusions regarding the safety of that specific product. Likewise, this type of collaboration could be applied to inform an agency's own assessment of a similar/comparable product (e.g., products of retransformation or breeding stacks).

Benefits

- Mutual capacity building and learning
    - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
    - Professional development can be particularly effective if one of the agencies has more experience conducting assessments.
- Increased harmonisation, including alignment of assessment approaches
    - Referencing of another agency's assessment/application of a product is an acknowledgement of that agency's assessment process as robust. In agreement with their process, it is likely that there is increased harmonisation and alignment between the assessment approaches of each agency.

Challenges

- Demand on resources
    - Initially requires investment in time and trust-building among agencies such that one agency is confident in referencing and applying another agency's assessment as part of the 'weight of evidence' of their own respective assessment.

4.7 Capacity building

This type of collaboration could involve any of the above-mentioned types of collaboration in which one agency takes the lead on one or more parts of an assessment, with the objective of training or mentoring assessors in the collaborating agency.

Benefits

- Efficiency gains in assessment processes
    - Gain efficiency in conducting safety assessments

- Mutual capacity building and learning
  - Opportunity for sharing knowledge between agencies and enhancing professional development of staff using actual submissions
  - Professional development can be particularly effective if one of the agencies has more experience conducting assessments
- Stronger working relationships between agencies
  - Potential to serve as a foundation for further collaborative work

Challenges

- Demand on resources
  - Initially requires investment and trust-building in relationships among agencies

4.8 Enabling regional harmonisation through collaboration

This type of collaboration would involve deliberation towards a regional harmonised approach to safety assessment of food and/or feed derived from rDNA plants. This collaboration could promote consistent standards, regulatory requirements, and processes. An approach to regional harmonisation could stem from leveraging experience in safety assessments to build appropriate guidelines upon the common elements in national guidelines for food safety assessment.

Benefits

- Improved synchronisation of food and feed authorisations
  - Facilitation of regional trade and minimise trade distributions
- Increased harmonisation, including alignment of assessment approaches
  - Reduction of regulatory disparities through promoting consistent guidance
- Potential to reduce regulatory burden
  - Reduction of resource burden on agencies and applications by streamlining the process for multi-agency safety assessments

Challenges

- Demand on resources; Level of commitment
  - Investment of significant resources – monetary, personnel, and trust-building in relationships among agencies from countries in the region
- Operational differences between agencies
  - Establishing an aligned regulatory process has the potential risk of aligning to the agency with the longest timelines
  - May be difficult to establish alignment on safety assessment/policy modernisation among multiple agencies

5 Foundations and principles of collaborative work

There are several principles upon which successful collaborations can be founded. The following concepts should be given consideration, as they will affect the types of work that are possible between agencies.

5.1 Information sharing

At its core, collaborative work involves the sharing of available resources between agencies typically for achieving a mutually beneficial outcome. These resources can include available work time, staffing, but perhaps most importantly, access to information relevant to the work at hand. The safety assessment of foods and feeds derived from rDNA plants involves the review of a significant amount of information and thus any collaborative work in this area must first be founded on the ability to share information between agencies.

Collaborating agencies can choose the type of agreement for sharing information that is most appropriate for their arrangement and is legally permissible by all collaborating agencies. Whether it be a legally enforceable agreement or a Memorandum of Understanding (MoU), collaborating agencies should establish a written document, which describes in detail the types of information that can/will be shared between agencies, and under what conditions this information can be shared. The safety assessment of foods and feeds derived from rDNA plants sometimes involves the use of Confidential Business Information (CBI) provided by the applicant. Therefore, any agreement should address by what mechanism such information can be shared between agencies if possible. The greater the latitude of information exchange between agencies, the more possibilities/options to collaborate.

5.2 Safety assessment based on internationally accepted guidance

Collaborative work is also made possible where agencies conduct safety assessments which are based on internationally accepted guidance, such as the Codex Alimentarius Commission's Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003) and the Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003).

Such guidance has been established by many contributors in the international fora, resulting in a robust, science-based approach to assessing the safety of these products. Where assessments are based on such guidance, collaborating agencies can have higher confidence that the outcome of one agency's safety assessment of a product would reliably be similar to the outcome of another's assessment. Depending on the degree of similarity between assessments, certain agencies may have the option of using/recognising another agency's assessment to inform their own regulatory decision-making processes.

5.3 Independent regulatory decision-making

The scope of collaborative work as described in this document focuses on the process of conducting a safety assessment for a food and/or feed derived from a rDNA plant and not subsequent decisions made regarding the risk management and/or risk communication related to that product. Limiting the scope of the work to the assessment of the product allows involved agencies to focus on the mutually recognised science that supports the product's safety without having to address other factors (e.g., political, socio-economic, etc.) which may influence the decision-making processes specific to an agency. Maintaining regulatory independence can allow for possible collaborations between agencies with different regulatory frameworks.

5.4 Coordination of regulatory timelines

For a collaboration to be successful, agencies should examine if their individual timelines for the completion of a safety assessment are compatible such that all agencies can continue to meet their required timelines (i.e., service standards).

5.5 Transparency

Any collaborative venture undertaken should be conducted in an open and transparent manner to the fullest extent possible while also protecting an applicant's CBI and privacy in accordance with the national legislation of all involved agencies. A collaborative process that is transparent will benefit from greater understanding by applicants and the public which in turn will instil greater confidence in the process. This transparency can be achieved through the publication of communication outputs appropriate for the process (e.g., guidelines).

Where possible, agencies should develop publicly available materials, which generally describe the collaborative arrangement (e.g., its purpose, its outcomes, etc.) and guidance, which will help potential applicants decide if they wish to participate in the process.

5.6 Applicant engagement and agreement

When developing a collaborative arrangement, agencies should actively engage with those applicants who would be directly impacted by such a process. This engagement will allow applicants to not only understand the requirements to participate in the process, but also the tangible benefits for both applicant and agency (e.g., savings in time, application cost, resources, etc.). This can be achieved by scheduled meetings between the agency and the applicant to introduce the product and to check on the status of the application. A collaborative process for the safety assessment of foods and feeds derived from rDNA plants is likely to be more beneficial to both agencies and applicants where: the product is regulated and requires pre-market assessment in all relevant jurisdictions; the applicant typically seeks authorisation in all relevant jurisdictions; and the process is voluntary.

6 Points to consider when planning the collaborative work

When embarking on collaborative work, it is important that attention is paid to early conceptualisation and planning, as well as the lessons learned from any previous successful and unsuccessful collaborations. This can be used to inform the development of appropriate collaboration approaches and maximise the potential for success.

When planning collaborative work, some of the points to consider are:

(i) *Interagency agreements*

Before any collaboration can commence it is typical for the agencies to establish a formal agreement (e.g., MoU) providing a framework under which collaboration may occur. Such agreements generally do not provide details of specific collaborative projects, but set out the various terms under which such projects can be undertaken, for example how information is to be shared, high level goals and vision for collaboration etc. MoUs are typically not legally binding.

(ii) *Objectives for the collaboration*

Before commencing any work, it is important for the agencies to clearly define the purpose of the collaboration and what the agencies wish to achieve. Consideration should also be given to establishing appropriate metrics against which success can be measured. These will depend on the type of collaboration being undertaken and its objectives. For example, reduced assessment time, faster authorisations, less resources required for an assessment, improved information sharing, positive feedback from stakeholders, number of assessments completed in a defined period, number of staff trained in safety assessments, reduced fees, increased communication with applicants regarding agency processes, supporting innovation and trade, etc.

(iii) *Compatibility of safety assessment approaches*

As safety assessment of foods and/or feeds derived from rDNA plants is the focus of the collaborative work, an important starting point will be for the agencies to compare their safety assessment approaches to ensure their compatibility. While it is expected that safety assessments will be conducted according to Codex principles and guidelines, some differences may exist between agencies in terms of how these are interpreted or implemented in practice within each agency's legislative framework. An early comparison of assessment approaches will serve to identify what differences, if any, exist and whether those differences affect the ability of the agencies to undertake collaborative work. While some differences would be expected to occur, it may be possible to find a way to work around them, particularly if the differences are relatively minor.

(iv) *Collaborative outputs*

Agreement needs to be reached on the outputs from a collaboration. This will depend on the type of collaboration being undertaken, but where the collaboration is focussed on a shared or joint safety assessment there will need to be agreement on the type and format of the assessment

report to be produced, taking into account the reporting requirements of each agency. For example, whether to use the existing report format of one of the agencies, or whether to develop a new format. In making this decision, it will be important to consider how the report is used by each agency, including whether it is released for a public consultation process.

(v) *Project planning*

As with any new project, it will be important to establish a project plan for the collaboration, its establishment as well as its implementation. The project plan should itemise the individual tasks and milestones to be completed and by whom, timelines, review processes, and when the final deliverables are due. The project plan may need to be revised and timelines adjusted from time to time.

(vi) *Communication between agencies, applicants*

Frequent communication between all collaborating agencies and the applicant is essential for a successful collaboration. These can take the form of regular emails, videoconferencing, face-to-face meetings, etc. Frequent communication also helps to strengthen the relationship between the work units involved in a particular collaboration and build trust.

(vii) *Building trust*

Trust is an important component of a successful collaboration. This is particularly so if the agencies have not previously collaborated, and where there will be shared or joint safety assessments where one agency will need to trust and rely on the work of another agency. To build trust, it will be important for the individuals and work units involved in the collaborative work to get to know each other and learn how each agency operates. This can be facilitated by sharing and peer reviewing examples of each other's work, discussing and sharing experiences from previous safety assessments, and undertaking parallel/concurrent safety assessment exercises. It is recommended that trust-building exercises are incorporated in the project plan.

(viii) *Consider conducting a pilot project*

This will be more suitable in the case of shared or joint assessments and can be used to test the viability of a particular collaboration model, including identify any issues, before proceeding to full implementation and commitment of resources.

7 Implementation of collaborative work

Once agencies have established the framework for their collaboration and the logistics of the process the following steps should be considered when implementing the work.

(i) *Develop guidance for the collaborative process*

Where relevant, agencies should develop guidance aimed at describing the nature of the collaborative process and the expectations between regulators and applicants (e.g., timelines, submission information requirements, outcomes, etc.). This guidance should be made publicly available if possible or provided to applicants upon request.

(ii) *Establish internal operating procedures*

At the same time, agencies will benefit from revising or establishing their own internal operating procedures that detail the roles and responsibilities of each agency. Having internal operating procedures can allow collaborative agencies to examine each step of the process in significant detail and may help to identify challenges to implementation (if any).

(iii) *Conducting the work and documentation*

While conducting the work associated with the collaborative process, agencies should take care to document how and when specific tasks are accomplished. This documentation will not only serve as a means of evaluating the success/benefits of the collaboration against the established goals, but will give relevant agencies the opportunity to explore areas in which the process can be improved.

It is likely that any collaborative process will involve multiple individuals who will work on different steps throughout. For the purposes of organisation, time management, and proper documentation, collaborative agencies may consider using a project management tool, which will allow all agencies to visualise the progress of work and the required input of all involved individuals.

8 Evaluation of collaborative work

When collaborating agencies have completed the activities of their work, it is important to evaluate and discuss how the process performed (e.g., what aspects worked well, what aspects were challenging to implement, etc.).

(i) *Evaluate the success of the collaborative process against the established objectives*

The success of any collaborative process will depend on what the collaborating agencies identified as the objectives/goals of the work. For example, if the goal of the process is to reduce the amount of time required for an agency to conduct a safety assessment, how much of a reduction in time is considered a success for the involved agencies? If the goal of the process is to ensure that completion of all safety assessments of foods and feeds derived from rDNA plants is synchronised between agencies, success may be defined as having the assessments for a specific product completed by all agencies within an established time.

(ii) *Obtain feedback from all agencies and the applicant*

Ensure that all agencies and the applicant involved in the collaborative process have the opportunity to provide feedback during the evaluation process. Based on their own regulatory framework, agencies will likely experience different challenges and benefits throughout the process that should be considered.

Likewise, it is important to hear the perspectives of the applicant and their experience during the collaborative process. For example, did they experience a benefit through participation in the process or do they have any suggestions for how to improve the process?

(iii) *Identify areas for improvement and next steps*

Based on the perceived success of the process and the feedback received, collaborative agencies should consider ways in which the process can be improved and how this will be achieved. Agencies should not hesitate to re-evaluate the objectives/goals of their work or even the type of collaborative arrangement if their evaluation shows that such changes can be made to realise greater benefits for the involved agencies and applicants.

(iv) *Publicly communicate the outcome(s) of the collaborative work*

Lastly, while protecting CBI, agencies should consider communicating the outcome(s) of their work for public access (e.g., on the agency website, in a scientific journal, etc.). Communicating the outcome(s) of the process can serve as an opportunity to highlight the value of this work to stakeholders, provide a useful example to other agencies considering collaborative work, and encourage other applicants to participate.

9 Examples of collaborative work

The following section contains real world examples (either ongoing or completed) of collaborative work regarding the safety assessment of foods and/or feeds derived from rDNA plants.

Where applicable, each example includes information relevant to the topics presented in this consensus document. The purpose of presenting these examples is to demonstrate how the concepts and considerations presented in this document have been applied by various collaborative agencies. The format for these examples remains flexible to allow individual agencies choice in how best to describe their work.

Further information about the agencies, organisations, and other materials referenced in the following examples can be accessed in Annex A: Further readings and websites.

9.1 Health Canada and Food Standards Australia New Zealand (FSANZ) Safety Assessment Sharing Initiative

9.1.1 Type of collaborative work

This initiative is a form of "Safety Assessment Sharing" as described in Section 4.3. To arrive at this collaborative arrangement, two other forms of collaboration were initially used: inter-agency peer review and parallel/concurrent assessments. These other forms of collaboration were a key part of developing the relationship and building trust between the two agencies as well as investigating the feasibility of safety assessment sharing. Inter-agency peer review remains a key element of the current Safety Assessment Sharing Initiative between Health Canada and FSANZ.

The initial inter-agency peer review involved reviewing and comparing each agency's data requirements and safety assessment approach, as well as historical safety assessments of products that had been previously assessed by both agencies. These exercises enabled Health Canada and FSANZ to confirm their similarity in terms of assessment approach as well as the conclusions that are reached. It also provided the opportunity to consider a number of practical and operational aspects between the two agencies, and whether this would impede the ability to work collaboratively.

Health Canada and FSANZ also conducted two parallel/concurrent assessment exercises. The first, conducted in 2015, was for a herbicide tolerant corn line, and the second, in 2017, was for provitamin A enriched rice line. Cooperation from the applicants was a key factor in the success of these simultaneous review exercises. Simultaneous submissions were provided to Health Canada and FSANZ as well as agreement from the agencies to freely exchange information relating to the safety assessment. Inter-agency peer review was also a component of these exercises.

While these earlier collaborative exercises were time consuming, they were critical to establishing and finalising the details of the Safety Assessment Sharing Initiative between Health Canada and FSANZ. The earlier work also provided the foundation for a successful first shared safety assessment (i.e., a first pilot) between the two agencies.

9.1.2 Benefits and challenges of the collaborative work

Through the Safety Assessment Sharing Initiative, Health Canada and FSANZ have experienced the following benefits of collaborative work:

- *Efficiency gains in assessment processes*. From an agency perspective, the peer-reviewing agency has typically experienced a reduction in the time required to complete their safety assessment by several months as a result of using the shared assessment report of the lead agency.
- *Improved synchronisation of food authorisations*. Products that have undergone a pre-market safety assessment through the Safety Assessment Sharing Initiative have received authorisation from both Health Canada and FSANZ within a short amount of time of each other.
- *Mutual capacity building and learning*. While Health Canada and FSANZ have an established capacity for pre-market safety assessment, this collaborative work provides an opportunity for continued learning between the agencies.
- *Stronger working relationships between agencies*. The Safety Assessment Sharing Initiative has strengthened the working relationship between Health Canada and FSANZ, promoting both agencies to explore other areas of product assessment collaboration (e.g., pre-market assessment of enzyme preparations for food use).
- *Increased harmonisation, including alignment of assessment approaches*. While Health Canada and FSANZ are already well aligned in their respective assessment approaches, this collaborative work has prompted both agencies to review the endpoints of their assessments and the information required to address them.

However, both agencies have also experienced some challenges in this work:

- *Operational differences between agencies*. Both Health Canada and FSANZ recognise that their service standards for the pre-market assessment of food products are different. As such, both agencies must consider their respective workloads and available resources at any given time to ensure that any product assessed under the collaborative arrangement can meet both service standards. At present, this requires a degree of preparation, both between agencies and with the applicant of the assessed product to establish a mutually recognised timeline for the assessment of that specific product (including submission coordination to each agency, identification of lead and peer-reviewing agency, etc.).
- *Logistical and practical challenges*. Situated on opposite sides of the globe, Health Canada and FSANZ have the practical challenge of working in different time zones. Meetings between agencies often have to take place either in the very early or late hours of a typical workday. Email is a typical method of communication, which places an emphasis on clear communication between both agencies. Furthermore, there is an inherent latency in responses due to the difference in time zones.

9.1.3 Foundations and principles of the collaborative work

Information Sharing

Health Canada and FSANZ entered into a Memorandum of Understanding (MoU) in May 2001. The MoU established an arrangement for the exchange of information about the applications each agency received for approval of genetically modified (GM) foods (including foods derived from rDNA plants), in order to enhance the capacity of each agency in the safety assessment of GM foods. The MoU was renewed and expanded in 2004 to address other areas of mutual interest and again reaffirmed by both agencies in 2017. The MoU does not compromise the regulatory or legal authority of either agency to carry out their

respective responsibilities (i.e., mandates) and does not create legally binding obligations on either agencies or between them, including an obligation to share information with each other (i.e., the arrangement is entirely voluntary).

The MoU acts as a mechanism for early information exchange on upcoming food safety issues and food regulatory problems that may affect Australia, New Zealand, and/or Canada. It also allows for participation in joint projects between the two agencies, and the development of education and communication materials for use by the agencies individually and/or jointly. The MoU identifies the types of information that both agencies can (and more importantly cannot) disclose to one another (e.g., third party information that is considered CBI must not be disclosed without permission from the owner of the information, information received in confidence from other governments cannot be disclosed, etc.). The MoU also identifies each agency's respective 'Access to Information' laws and the responsibilities of each agency to disclose or publish information provided to them by the other agency. In addition, the agreement stipulates what access employees of each agency have to information that is shared. Lastly, the MoU describes the administrative mechanisms by which the two agencies can manage this agreement (e.g., through scheduled meetings and periodic review of the document). From these elements, the MoU laid the foundation for the collaborative options available to both agencies.

Safety assessment based on internationally accepted guidance

The Governments of Canada, Australia, and New Zealand are all signatories to the Codex Alimentarius Commission (CAC) and as such Health Canada and FSANZ both conduct the safety assessment of foods and feeds derived from rDNA plants according to the CAC guidance documents. Furthermore, all three governments actively participated in the formation of this guidance through the Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (TFFBT). As part of developing a collaborative arrangement between Health Canada and FSANZ regarding the safety assessment of these products, it was observed that the assessments of both agencies were sufficiently similar such that the assessment outcome of one agency could be used to inform the regulatory decision-making processes of the other agency for a particular product.

Independent regulatory decision-making

The Safety Assessment Sharing Initiative between Health Canada and FSANZ allows both agencies to use the outcomes of a safety assessment conducted by each other for the purposes of informing their regulatory decisions regarding the product of interest. However, the post-assessment processes and decisions of each agency remain separate and independent of each other.

Coordination of regulatory timelines

Health Canada has a service standard of 410 calendar days from the date of receiving a submission to the date of authorisation for the completion of the pre-market assessment process of a GM food. This timeline not only includes the time to complete the actual assessment itself, but also the post-assessment, decision-making processes.

FSANZ has a typical service standard by which applicants incur a set fee for the assessment and authorisation of a GM food within a 9-month period (i.e., for a General Procedure to amend the Australia New Zealand Food Standards Code).

Health Canada and FSANZ recognised that, when Health Canada conducts the assessment, this would either need to be completed within the 9-month period of FSANZ's standard or the Applicant could make their official submission to FSANZ at a later time (i.e., months after submitting to Health Canada) in order for both agencies to complete their processes on time.

Transparency – Process and outcomes

Health Canada and FSANZ are co-developing materials that describe the Safety Assessment Sharing Initiative (i.e., an overview of the collaboration), which will be published on their respective websites. Furthermore, both agencies have published the general outcomes/lessons learned from their first pilot project, and the next steps that will be undertaken for their second pilot project.

Both agencies are co-developing guidance that describes the information requirements/criteria to participate in this collaborative arrangement (aimed at potential applicants), and a more in-depth (i.e., compared to what is currently available) description of the initiative for the public.

Applicant engagement and agreement

In the development of the Health Canada/FSANZ Safety Assessment Sharing Initiative, both agencies reached out to stakeholder associations representing developers of rDNA plants (e.g., CropLife Canada/CropLife Australia) to describe the proposed collaborative arrangement. Through this engagement, stakeholders understood that this initiative was for the pre-market safety assessment of food derived from rDNA plants whereby if they apply to this initiative, applicants would submit applications containing the same information (though not necessarily in the same format/organisation) to both agencies, satisfying the information requirements of both Health Canada and FSANZ. Either Health Canada or FSANZ would conduct the assessment of their product and provide the other agency with the outcome of their assessment. As a result, applicants would experience a shorter assessment process time with the second agency (and potentially a reduced assessment fee with FSANZ).

9.1.4 Considerations when planning the collaborative work

In the development of the Safety Assessment Sharing Initiative, Health Canada and FSANZ made a number of considerations:

(i) *Interagency agreements*. In considering what type of collaborative work that both agencies could undertake, Health Canada and FSANZ acknowledged and reviewed the existing MoU between the agencies, including what information could be shared pertaining to the pre-market assessment of foods derived from rDNA plants.

(ii) *Objectives for the collaboration*. As Health Canada and FSANZ already have well-established pre-market assessment processes, both agencies identified that the primary objectives of the collaborative arrangement were to reduce the time and resource requirements necessary for the pre-market assessment of foods derived from rDNA plants.

(iii) *Compatibility of safety assessment approaches*. Health Canada and FSANZ conducted an in-depth review of each agency's safety assessment approach. From this review, it was recognised that overall, the approaches of both agencies are highly compatible (both based on Codex principles and guidelines), with the exception of a few specific pieces of assessed information (i.e., endogenous allergens for Health Canada, and herbicide residues for FSANZ).

(iv) *Collaborative outputs*. Once it was agreed upon that Health Canada and FSANZ would establish a Safety Assessment Sharing Initiative, both agencies determined how the shared assessment document would be written (i.e., both in content and organisation). The output document has to be written in a format that can be easily used by both agencies and allow each to address their respective endpoints of their assessment.

(v) *Project planning*. Prior to conducting the Safety Assessment Sharing Initiative, Health Canada and FSANZ had several discussions regarding how the collaborative arrangement would work,

including the roles and responsibilities of each agency (i.e., for the lead and peer-reviewing agencies), and how the required milestones of the arrangement would be met.

(vi) *Communication between agencies, applicants*. Health Canada and FSANZ maintain frequent communication between the agencies, using a variety of tools including videoconferencing and email. Prior to assessing a specific product through the Safety Assessment Sharing Initiative, both agencies meet with the applicant to discuss the process, expectations, and timelines. The discussion will also consider the benefits and challenges for the applicant depending on which agency is chosen as the lead and peer-reviewer.

(vii) *Building trust*. As mentioned in Section 9.1.1, Health Canada and FSANZ engaged in a number of collaborative activities (e.g., inter-agency peer-review, parallel/concurrent assessment), each further increasing trust between the agencies. Through successful forms of collaboration, Health Canada and FSANZ were able to establish the confidence in each other such that sharing safety assessments became a possible type of collaborative work for both agencies.

(viii) *Consider conducting a pilot project*. Once the Safety Assessment Sharing Initiative was established, the agencies conducted their first pilot project, involving the pre-market assessment of a food derived from a rDNA plant with a familiar dicamba herbicide tolerance characteristic. A product of high familiarity to both agencies was intentionally chosen such that the pilot could focus on the logistics of the process, rather than the nuances of the specific product. For the first pilot, Health Canada acted as the lead agency, conducting the initial assessment of the product, and through discussion with FSANZ as the peer-reviewing agency, produced the shared assessment document that was used by both agencies to inform their respective and independent decision-making processes regarding the specific product. Overall, the first pilot was a success, with FSANZ benefiting from a significant reduction (about 5 months) in the time required to complete their assessment process.

9.1.5 Implementation of the collaborative work

For their Safety Assessment Sharing Initiative, Health Canada and FSANZ are co-developing guidance for applicants regarding this arrangement to be completed in the near future. This guidance includes a detailed description of the process (i.e., objectives, stages, timelines, etc.) the criteria for a GM food product to qualify for this process (e.g., must be food derived from a GM plant regulated by both agencies), and what the applicant must provide to both agencies (i.e., the contents of their application). This guidance will be available on the respective websites of each agency. Health Canada and FSANZ have also individually developed operational procedures for their own assessors regarding how to conduct a GM food assessment under the collaborative arrangement. These procedures have been shared between the agencies.

9.1.6 Evaluation of the collaborative work

For the Safety Assessment Sharing Initiative, it was acknowledged by both Health Canada and FSANZ that the main benefit of this collaborative arrangement would be a reduction in time to conduct the assessment of a GM food (for the agency accepting the shared assessment document of the lead agency), both agencies measure the success of their collaboration by the amount of time saved relative to the average amount of time it takes to conduct the assessment outside of the collaborative arrangement. Additionally, as there is an assessment fee for applicants to submit their GM food product to FSANZ for pre-market assessment, the reduction in processing time may also result in a reduced fee for applicants as it is calculated by the amount of time required to complete the application.

After conducting a GM food assessment through the collaborative arrangement, both agencies together discuss the outcomes of the process for that product (e.g., were there any challenges with this particular product?). Feedback from the applicant regarding their experience with the process is also solicited.

As for the outcomes of the process, both Health Canada and FSANZ individually publish the outcomes of the GM food assessment on their respective websites (in FSANZ's case for public consultation). The published summaries of the assessment indicate that the product was assessed through the collaborative arrangement including which agency was the lead and peer-reviewing agency.

9.2 Harmonisation initiative in South Asia

9.2.1 Type of collaborative work

This approach involves working with countries in South Asia including Bangladesh, Bhutan, India, and Sri Lanka that are Codex members and have already agreed to Codex standards/guidelines pertaining to the safety assessment of foods and feeds derived from rDNA plants. These countries are World Trade Organisation (WTO) members (except for Bhutan, which is currently going through the process for accession) and are trading partners in the region with trade in food being most prominent. Discussion on harmonisation of food safety assessment for foods derived from rDNA plants began in 2014 in the form of peripheral informal consultations during the South Asia Biosafety Conference. The need for harmonisation of genetically engineered (GE) food safety standards and the potential benefits of doing so are well recognised by the above countries, all of which have participated in regional consultations and workshops on this topic, including efforts organised under the South Asia Biosafety Programme (SABP). The harmonisation initiative in South Asia was formally undertaken by Agriculture & Food Systems Institute (AFSI) as part of the SABP in partnership with Biotech Consortium India Limited (BCIL) in 2020.

The work began by engaging with a small subset of experts, identified from agencies from the above countries, that are relevant to safety assessment of foods derived from rDNA plants, in the initial stages and will continue to expand the outcomes of the engagements to a larger group of stakeholders in each participating country to enable regional alignment of safety assessment processes for food derived from rDNA plants.

9.2.2 Benefits of harmonisation

There are several benefits to promoting a harmonised approach for safety assessment of food derived from rDNA plants across South Asian countries that is consistent with international standards and best practices. Having assessment criteria anchored to internationally agreed standards will contribute to improved transparency. It will also enable predictability of the process. As food and food products move between South Asian markets, streamlined safety assessment processes will decrease chances for asynchronous approvals facilitating regional trade and minimise trade disruptions.

9.2.3 Priming of stakeholders

To raise awareness of the topic AFSI prepared a two-part series of articles on 'Harmonisation of International Standards for Food Safety' to reach out to a wider audience in South Asia. The articles were published in the SABP Newsletter, which is a monthly publication under the SABP and is circulated to over 25000 subscribers in the region.

9.2.4 Establishment of an expert working group

The work towards harmonisation began with convening of an Expert Working Group (EWG) to discuss the technical aspects of safety assessment of food derived from rDNA plants. Experts with the appropriate background and role from respective regulatory agencies were officially invited to participate in the meetings with the objective to undertake the development of: (a) a guidance document that describes a consensus approach to the safety assessment of foods derived from rDNA technology for application across the participating countries, based on the Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA*; and (b) a plan for adoption and operationalisation of the regional guidance in each of the respective countries. The experts participated in their individual capacity with full support of their affiliated office. All EWG Meetings were facilitated by AFSI in partnership with BCIL.

In addition to the EWG meetings, several 'Discussion Sessions' were held as a knowledge sharing exercise, during which the EWG interacted with regulators from other regulatory agencies including FSANZ and US Food and Drug Administration and intergovernmental organisations such as the OECD and the South Asian Regional Standards Organisation. Topics discussed included examples of collaborative work.

9.2.5 Basis of consensus statement and other documents

The countries in South Asia, including Bangladesh, Bhutan, India, and Sri Lanka are members of Codex Alimentarius Commission. These four countries have integrated the science-based framework outlined in the Codex *Principles for the Risk Analysis of Foods derived from Modern Biotechnology* and Codex Alimentarius *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* into their national guidance document for regulation of foods derived from rDNA plants. The EWG recognised the opportunity to strengthen and harmonise the process for safety assessment of foods derived from rDNA plants by regulatory authorities in the region. The EWG agreed that a regional approach to assess safety of foods derived from rDNA plants, based on Codex guidelines, may be adopted. The EWG also agreed that the regional harmonised approach could be operationalised through adoption of common information elements recommended for safety assessment of foods derived from rDNA plants and a common application format. Use of common formats would enable developers to prepare and submit a single dossier for consideration by the regulatory authorities, encourage parallel review of application dossiers by regulatory agencies, and facilitate synchronous approvals.

9.2.6 Process followed for drafting of consensus document and other documents

The process for drafting the Consensus Statement and other documents was modelled after the process followed by the OECD WP-SNFF for developing the consensus documents on compositional considerations for new plant varieties. It was an iterative process that involved drafting of the text followed by review and feedback until the text of each document was agreed upon by all involved parties. A written account detailing the viewpoints of all experts, areas of concern, any differences, and resolution of the differences, at each step of the process during the development of the consensus documents was maintained. This was done with an objective to serve as a future reference resource. Clarification on the objective was provided to experts from all countries at the outset indicating that harmonisation was an attempt to bring everyone on the same page regarding food safety assessment for foods derived from rDNA plants, and not to change or modify national legislation. Safety assessment aspect was addressed in the EWG meetings. It was clarified that decision-making was out of scope of the discussions. Some findings that emerged during this process are summarised below:

- Recognition by the EWG of commonalities in the national guidelines of all 4 participating countries
- Recognition by some experts that their guidelines may be in need of an update

- Experts were aware of minor differences in information requirements and agreed to use of language in the consensus documents around case-specific safety assessment

9.2.7 Next steps: Engagement with in-country stakeholders to facilitate operationalisation of the consensus approach to harmonisation

AFSI is now working to compile all drafted documents into a report with the potential title "Towards a Harmonised Approach to Food Safety Assessment of GM Plants in South Asia: Consensus Report of the Expert Working Group on Harmonisation" which will serve as the basis for proceeding to the next step. AFSI is in the process of working with experts from all participating countries to provide support for operationalisation of the consensus documents. This involves developing separate plans driven by country-specific need. Each plan will accordingly involve engagement with in-country stakeholders to present the consensus report and/or conduct capacity-building events followed by introduction of the harmonised approach at regional platforms. This may be a key step towards potential use of a common set of recommended information elements, application form, and template for preparing a risk assessment summary report. This will potentially benefit both applicants and regulators, thereby increasing confidence in the regional approach. Use of the harmonised approach will provide encouragement to the countries to engage in collaborative safety assessments/joint reviews and to work toward mutual recognition of Codex compliant safety assessments done by other regulatory authorities.

9.3 Economic Community of West African States (ECOWAS) collaborative effort in biosafety regulation

9.3.1 Type of collaborative work

This initiative is a form of "enabling regional harmonisation through collaboration" as described in Section 4.8. The Economic Community of West African States (ECOWAS), the West African Economic and Monetary Union (WAEMU) and the Permanent Interstate Committee for Drought Control in the Sahel (CILSS) came together to proffer a harmonised approach to the management of modern biotechnology through the adoption of a West Africa region biosafety regulation. This collaboration was premised on a number of provisions in the revised ECOWAS Treaty establishing the Council of Ministers and defining its composition and functions. Key provisions were that of Articles 3, and 2 (a) and (b) on "the harmonisation and coordination of national policies and the promotion of programmes, projects and activities, particularly in the sectors of agriculture, natural resources, environmental protection, industry, health, science, technology". An additional consideration was the recognition that nearly all ECOWAS Member States were Parties to the Convention on Biological Diversity and its Protocols (the Cartagena Protocol on Biosafety and the Nagoya Protocol on Access and Benefit-sharing of genetic resources), noting that Article 14 of the Cartagena Protocol provides for the conclusion, by State Parties, of bilateral, multilateral, or regional agreements on matters relating to Living Modified Organisms.

Taking cognizance of the above and other considerations, ECOWAS Member States welcomed the collaborative effort among the ECOWAS Commission, the UEMOA Commission and the CILSS Executive Secretariat, which culminated in the formulation of the harmonised policy instrument – "Regulation C/REG.4/09/20 Relating to the Prevention of Risk in Biotechnology in ECOWAS" and the subsequent adoption in September 2020. The scope of the Regulation covers, among others, institutional arrangements in the administrative handling, review and decision-making processes and address matters including environmental safety, food safety, socio-economic considerations and liability and redress. This example describes the aspects of the Regulation that relates to the safety assessment of food and feeds derived from rDNA plants.

9.3.2 Principles of the collaborative work

The objective of the Regulation is to provide a regional regulatory mechanism that establishes the legal and institutional framework required to prevent, reduce, or eliminate the potential risks to human and animal health associated with the use of modern biotechnology and products thereof. The principles guiding the regulation and its implementation are highlighted below:

Harmonisation

In line with the provisions of the Convention on Biological Diversity and its Protocols, to which most members are signatories, and noting the purposes of achieving its objective of harmonisation, Member States agreed on the coordination of policies and actions relating to biosafety.

Recognition of International Standards

Noting that harmonisation requires recognition of relevant international standards, Member States agreed that for purposes of regulating the use of foods and feeds derived from rDNA plants within the ECOWAS region, and of encouraging international and regional trade therein, under adequate health conditions; the health protection measures adopted, shall be based on international standards, directives and other recommendations, with specific reference to provisions in the Cartagena Protocol on Biosafety, and other relevant international standards and directives.

Mutual Recognition

A Member State may, based on the principle of mutual recognition, accept as equivalent, assessment procedures for food and feeds derived from rDNA plants from another Member State.

The above-referenced principle shall pertain to:

(i) technical regulations, standards, and specifications

(ii) compliance and validity of assessment procedures and certificates of compliance of other Member States

The ECOWAS Commission shall develop, in collaboration with Member States, harmonized guidelines for standards and specifications in conformity with assessment procedures related to the use of food and feeds derived from rDNA plants within ECOWAS.

The above three referenced provisions for mutual recognition, notwithstanding, Member States may conclude bilateral agreements with each other.

Equivalence and the Principle of National Processing

Each Member State shall accept into its territory, any food or feeds derived from rDNA plants, that comply with technical regulations or assessment procedures adopted by another Member State, and is deemed equivalent to its own, where the exporting country, in collaboration with the importing country, proves to the latter that the said food or feed derived from a rDNA plant was legally developed or marketed in its territory, in compliance with the provisions of this Regulation.

Free movement of Products and Equivalence

Food and feeds derived from rDNA plants may move freely within the ECOWAS region, provided that they comply with the standards of protection and risk acceptance agreed by the Member States in accordance with the provisions of the relevant provisions of this Regulation.

Subject to Article 49 of the Revised ECOWAS Treaty, each Member State shall accept into its territory such food and feeds derived from rDNA plants as shall conform to the technical and health standards adopted by ECOWAS.

9.3.3 Implementation of the collaborative work

Implementation procedures as provided for in the Regulation C/REG.4/09/20 is explained in this section.

Any person intending to undertake production, development, import, and marketing of food and feeds derived from rDNA plants is required to submit a notification, request, or application to the competent national authority of the Member State concerned. The submission shall contain information prescribed by the relevant implementing Regulation, to ensure it is acceptable to all Member States. The concerned Member State then undertakes all necessary regulatory processes such as acknowledgement of submission receipt, screening for administrative completeness, review of risk assessment (food and feed safety), and assessment of socio-economic considerations. A draft decision of the competent national authority concerned shall then be referred to the Regional Biosafety Authority for an opinion. Based on national findings and the opinion from the Regional Biosafety Authority, the competent national authority issues a decision. The decision may only be issued if the intended use of food and feeds derived from rDNA plants is beneficial to at least one Member State and in terms of human and animal health, the food and feeds derived from rDNA plants have been evaluated to be as safe as their conventional counterparts.

The opinions of the Regional and National Biosafety Authorities are based on considerations including:

(i) information provided by the notifier

(ii) the findings of the risk assessment (food and feed safety)

In the event of an unfavourable opinion from the Regional Biosafety Authority, the competent national authority may request a reappraisal, whereby additional information is provided to the Regional Biosafety Authority, which shall respond to the objections made. In the event of a second negative opinion, the notifier may appeal. The appeal procedure shall be as laid down in the Implementing Regulation.

The collaborative effort is underscored by the concept of “Simplified Procedure” that may be adopted by Member States. Subject to adequate measures being implemented to issue a decision, competent national authorities may adopt simplified procedures.

Prior to the adoption of the simplified procedure, the competent national authority of the Member State concerned shall submit the list of the food and feeds derived from rDNA plants concerned to the Biosafety Clearing House as well as the Regional Biosafety Authority.

Based on the above, and the principle of mutual recognition, other Member States can take advantage and apply same simplified procedures to the concerned food and feeds derived from rDNA plants.

9.3.4 Process followed for the harmonisation initiative

The harmonisation initiative was achieved through series of stakeholder consultations with representations from the competent national authorities (where applicable), representatives of civil society organisations and other relevant experts from all concerned Members States as well as the regional bodies (ECOWAS, UEMOA and CILLS). The African Union Development Agency- New Partnership for Africa's Development (AUDA-NEPAD), through its flagship biosafety programme, provided support to ensure that the procedures adopted were in line with international best practices.

9.3.5 Current status and next steps

This initiative is still at its infancy and implementation is yet to commence. There remain few actions to be taken before actual implementation is rolled out. These actions include the following:

(i) Review and finalisation of implementing regulations as provided for in the Regulation C/REG.4/09/20

(ii) Establishment of the regional biosafety organs

   a. Regional Biosafety Authority

   b. Regional Biosafety Committee

   c. Regional Scientific and Technical Biosafety Committee

(iii) Allocation of adequate resources for the administrative and technical functioning of the institutional arrangements

We hope to share challenges and lessons learnt in the near future as implementation evolves.

9.4 African Union member states and the approval of GMOs for direct use for food, feed, or for processing (FFPs)

9.4.1 Type of collaborative work

This approach is based on “referencing another agency’s assessment/application to inform an agency’s own assessment/application of the same or similar product” as described in Section 4.6.

9.4.2 Principles

The basic principle employed by this approach is reliance on / recognition of conclusions from food/feed safety assessment reviews done by other agencies based on the principles of the Cartagena protocol (science-based, case-by-case, history of safe use, substantial equivalence) – to uphold safety for humans, animals and the environment, to prevent unnecessary trade disruptions, and to support an innovative and competitive agriculture sector.

9.4.3 Considerations

Organisms containing rDNA undergo thorough safety assessments before entering the marketplace. The global grain system depends on bulk handling to consistently deliver affordable commodities and the international movement of grains is based on the concept of fungibility as comingling may occur in each link of the supply chain, thus making it quite expensive to keep various foods and feeds derived from rDNA plants and conventional produce totally separated. Thus, a shipment of maize grains, for instance, may contain various genetically modified (GM) maize events authorised in that country.

Access to safety assessment dossiers of various GM events in a shipment by an independent trader/importer/exporter is impractical. This impairs the possibility of subjecting such an application for import to the usual documentation requirement for GM event registration. The latter is done by the developer, who has access to safety assessment dossiers for all GM events developed by the company for the regulator to review for subsequent decision-making.

In the case of highly processed food or feed, the novel genetic material is unlikely to be detectable in the resulting product, therefore, it is not possible to determine the GM event to be assessed, and more so, the

safety assessment dossier cannot be accessed to be provided for safety assessment review by the regulators.

History of safe use - numerous GM events have the same inserted gene and express the same specific protein. This implies individual genes (and proteins they produce) are often reviewed for safety hundreds of times.

9.4.4 Implementation of the collaborative work

This approach is being employed by some AU member states, such as Ghana, Nigeria and Togo. It is applicable to imported GM whole grains/cereals for direct use for food, feed or for processing, and food/feed products derived from GM grains/cereals; where the associated GM events have been authorised in the country of origin but not yet authorised in the destination country.

There are available platforms that enable regulators to have access to authorised GM events in various countries, including the OECD BioTrack Product Database, Biosafety Clearing House (BCH), Food and Agriculture Organization (FAO) GM Foods platform.

Scenario I*: The applicant being a separate entity from the GM event developer*

An applicant submits a request to the regulator (competent national authority) for authorization to import food and/or feeds derived from rDNA plants. Given the country of origin, the regulator obtains information on the approved biotechnology products in that country and associated regulatory decision documents from the platforms mentioned above. Other countries that have also approved these events are also identified on the platform and the relevant regulatory decision documents are also accessed. These decision documents are reviewed to determine that there are no biosafety concerns with the event(s) or otherwise, and that the biotechnology product(s) is/are as safe as conventional counterpart(s). Thereafter, these are regulated under other existing national laws, regulations, and guidelines governing the evaluation and marketing authorisation of conventional food and feed. The approval permit by the biosafety competent national authority being a pre-requisite documentation for these authorities.

Scenario II*: The applicant being the GM event developer*

A developer or the legal representative submits a request to the regulator (competent national authority) for authorisation for a genetically modified organism (GMO) intended for direct use for food, feed, or for processing. Here, the applicant (developer) is required to submit evidence of authorisation in various countries where the events have been approved, along with other documentation requirement in the relevant guidelines for event registration. Based on the submitted evidence, the regulator obtains information on the approved biotechnology products in the country(ies) and associated regulatory decision documents from the platforms mentioned above. These decision documents are reviewed to determine that there are no biosafety concerns with the event(s) or otherwise, and that the biotechnology product(s) is/are as safe as conventional counterpart(s).

With this approval, any person intending to import the event(s) will be required to notify the competent national authority without the detailed review of related decision documents. Thereafter, these are regulated under other existing national laws, regulations, and guidelines governing the evaluation and marketing authorisation of conventional food and feed. The approval permit by the biosafety competent national authority being a pre-requisite documentation for these authorities.

For both scenarios, the time standard provisions are based on the stipulated timeframes in the Cartagena Protocol on Biosafety (CPB), being 270 days to make a decision on a GMO import for food, feed, or processing [Article 11(6)]. The timelines generally start at the receipt of an application. The time needed for decision-making usually shortens as biosafety officers become familiar with the procedures and risks

associated with specific GMOs and as they gain confidence in the effectiveness of the biosafety process. Timelines for decisions made so far, based on these principles, have been less than 270 days.

9.4.5 Examples of decisions made based on this approach as of December 2022

Some examples of decisions made based this approach include:

- Approval for direct use for food, feed or for processing in Ghana –
  - Events: Maize event T25 (ACS-ZM003-2), Soybean event A2704-12 (ACS-GM005-3), Soybean event A5547-127 (ACS-GM006-4)
- Approval for direct use for food, feed or for processing in Nigeria –
  - Events: Soybean event SYHTOH2, Maize events 3272 and MZIR093
- Approval for processing into feed in Nigeria –
  - Maize events MON863, DAS-40278-9, MON863 X MON810 X NK603, MON89034 X NK603
- Approval of highly processed foods in Ghana and Togo –
  - Ghana: Instant maize meal porridge
  - Togo: Corn-soy blend plus (CSB Plus), Bulgur-soy-fort (SFB), vegetable oil (produced from genetically modified rapeseed, corn, cotton seeds or soybeans)

9.4.6 Benefits of this approach

Some benefits of this approach include:

- It ensures a streamlined importation process for GMOs for direct use for food, feed or for processing.
- It addresses the challenge of inability of independent traders to access the dossier required for review of risk assessment by the Regulators.
- It encourages cooperative links between the regulatory frameworks for GMOs and for conventional products, in order to avoid any safety or legal gap.

9.5 Memorandum of Understanding between Brazil and Argentina for Cooperation in Biosafety of Modern Biotechnology Products (Oct. 2022)

A Memorandum of Understanding (MoU) was signed in October 2022 between the Ministry of Science, Technology and Innovations of the Federative Republic of Brazil and the Ministry of Economy of the Argentine Republic for Cooperation in Biosafety of Modern Biotechnology Products. It proposes to synchronise Argentina and Brazil regulatory agencies on the assessment of products derived from modern biotechnology, both for guaranteeing biosafety in the agroecosystem and for animal and human food safety. Argentina and Brazil have an important flow of bilateral trade of products derived from modern biotechnology. Both countries also have a developed scientific and technological system that has allowed them to obtain their own products derived from the application of modern biotechnology. Therefore, the agreement tries to synchronise authorisations in both countries. Going forward in the assessment and joint authorisation of products derived from modern biotechnology, regulatory cooperation will reduce developer costs and promote the commercialization of national developments from both countries.

It is an example of Parallel/Concurrent assessment and/or Joint safety assessments as be mentioned in the document. It offers opportunities for aligning assessment processes and criteria, increasing

furthermore the acceptance and legitimacy of producers and consumers. It brings mutual capacity building and learning. Allowing furthermore innovative products to be brought to market faster which benefits users and consumers, especially local developments.

9.6 Multilateral forums in South America

There are two multilateral forums in South America that have been in operation for many years:

1. the “Agricultural Biotechnology Commission” within The Southern Common Market (MERCOSUR) framework; and
2. the “Working Group on Public Policies in Biotechnology” within the framework of the South Agricultural Council;

where countries exchange information regarding normative and product authorisations, and work to enhance cooperation in other multilateral forums.

The type of collaboration could be like enabling regional harmonisation through collaboration and capacity building.

Annex A. Further readings and websites

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

BioTrack Product Database

https://biotrackproductdatabase.oecd.org/

Consensus documents: work on the safety of novel foods and feeds

www.oecd.org/chemicalsafety/biotrack/consensus-documents-safety-of-novel-foods-and-feeds.htm

INTERNATIONAL INITIATIVES / ORGANISATIONS

Food and Agriculture Organisation (FAO) - GM Foods Platform

https://www.fao.org/food/food-safety-quality/gm-foods-platform/en/

Codex Alimentarius – International Food Standards (FAO, WHO)

General Principles of the Codex Alimentarius (website, accessed February 2023)
https://www.fao.org/fao-who-codexalimentarius/codex-texts/procedural-manual/sections/section1/section1-3/en/

Codex Alimentarius, Principles for the Risk Analysis of Foods derived from Modern Biotechnology, CAC/GL 44-2003 (2003, Amendments 2008, 2011)
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B44-2003%252FCXG_044e.pdf

Codex Alimentarius, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, CAC/GL 45-2003 (2003)
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B45-2003%252FCXG_045e.pdf

Codex Alimentarius, Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology (TFFBT)
https://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=TFFBT