



Food and Agriculture
Organization of the
United Nations

Bilateral collaboration on GM Food Safety assessment in Canada (Health Canada) and Australia (FSANZ)

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Project overview

Goal: to improve the efficiency, as well as the synchronisation, of GM food safety assessments.

- The joint project is between Health Canada's Food Directorate and Food Standards Australia New Zealand
- Work on the project began in 2013
- Both Health Canada and FSANZ believe this process can better leverage the safety assessment capacities of each organisation
- FSANZ and Health Canada liaised closely with CropLife and its member companies – the end user of the proposed system

Foundation for Collaboration

- Previous collaboration between both agencies at international level (Codex, OECD) on GM foods
- An existing agreement (2001) for information sharing on GM foods
- The two agencies have similar approaches to GM food safety assessment
- Strong support for this approach from industry and willingness to cooperate
- Potential time and cost savings to government and industry

Benefits

- Sharing expertise and learning from each other
- May ultimately lead to improved synchronisation of GM food approvals to facilitate trade

Regulator pre-conditions for this collaboration

- Should not require changes to existing legislative framework under which each agency operates
- Should be flexible to accommodate the different operating procedures of both agencies
- Each agency will continue to make its own independent regulatory and risk management decisions according to its own timeframes

Requirements for the applicant

- The applicant must be seeking a GM food approval from both Health Canada and FSANZ
- The applicant must agree to full information exchange between Health Canada and FSANZ on all aspects of the application
- The applicant must satisfy the data requirements of both Health Canada and FSANZ
 - a full dossier must be submitted to both agencies
- The food must be one that both agencies regulate

Project development: Five stages

Stage 1: Compare the regulatory approaches taken by the two organizations (2013)

- Triggers for assessment
- Timelines for assessment
- Data requirements
- The decision-making process
- Consultations and communication

Stage 2: Benchmarking exercise to compare the safety assessment processes and build trust (2013-2014)

- Compared two previously completed safety assessments (data requirements, general approach, conclusions)

Finding: only minor differences identified in approach and data requirements – not enough to preclude joint work

Project development (cont'd)

Stage 3: Formulating an approach for the joint work (2014)

A number of options for collaboration were considered

1. Joint safety assessment review
2. Safety assessment sharing ✓
3. Mutual recognition of one safety assessment prepared by one agency
4. Mutual recognition of a decision

Project development (cont'd)

Stage 4: Trust-building (2015-2017)

- A concurrent safety assessment of a (simple) new application submitted at the same time (but separately) to each agency
- A HC evaluation of a FSANZ safety assessment document for a concurrent application submitted separately to each agency
- A concurrent safety assessment of a nutritionally complex, new application submitted at the same time (but separately) to each agency

Project development (cont'd)

Stage 5: Administrative, legal, and communication considerations (2018 - present)

- Development of the details for implementing the process for shared safety assessment
- Development of communication/guidance documentation about the process – for prospective applicants, agency websites and media
- Liaison with senior executives of both agencies and relevant Government ministers

Conclusions

- This has been a strong and fruitful collaboration
 - Sharing of technical expertise
 - Validation of our approaches to safety assessment
 - Understanding of peer regulatory systems
- Next step: industry is invited to identify a suitable products to undergo the safety assessment sharing process.

