

# Health Canada-FSANZ Shared Assessment Process (SAP) for GM foods

**Shai Joseph, PhD**

**Food Standards Australia New Zealand**

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# Outline

01	About FSANZ and GM food approvals
02	HC - FSANZ shared assessment process
03	Where to next



# About FSANZ



## Statutory agency

We are a statutory agency within the Australian Government Health portfolio



## The Code

Our main function is to develop and administer the Australia New Zealand Food Standards Code (the Code)



## Legislative instrument

The Code is a legislative instrument given effect by state and territory or New Zealand laws



## Safe standards

We set standards for safe food but are not responsible for enforcement

# Food Standards Code and GM Foods

GM foods are regulated under Standard 1.5.2 —  
*Genetically modified food*



prohibits GM foods unless expressly  
approved by FSANZ



GM foods require pre-market safety  
assessment before approval



approved GM foods are listed in the Code  
(Schedule 26)



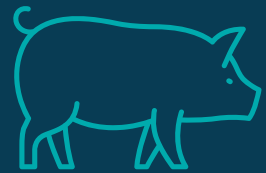
# GM Food approvals in ANZ



>100 GM food approvals listed in Schedule 26



Vast majority of these are GM plants



We have yet to assess a GM animal





# Health Canada-FSANZ Shared Assessment Process (SAP)

# Why collaborate?



Developers submit applications for GM foods to jurisdictions worldwide:

- duplication of work
- potential trade disruptions

Most jurisdictions are working from international guidelines (Codex, OECD) for the safety assessment of GM foods.

Scope to utilise the safety assessment capacities and expertise of each organisation

# Foundations



**Existing MoU**  
between agencies

**Previous international  
collaboration** on GM foods

**Similar approach** to  
GM safety assessment



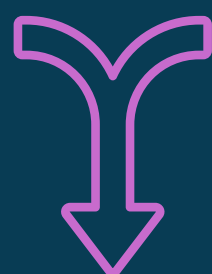


# Potential benefits



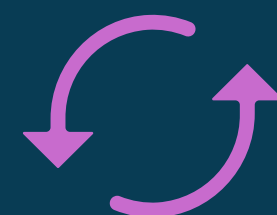
## **Time and cost savings**

for both government  
and product developers



## **Reduced duplication**

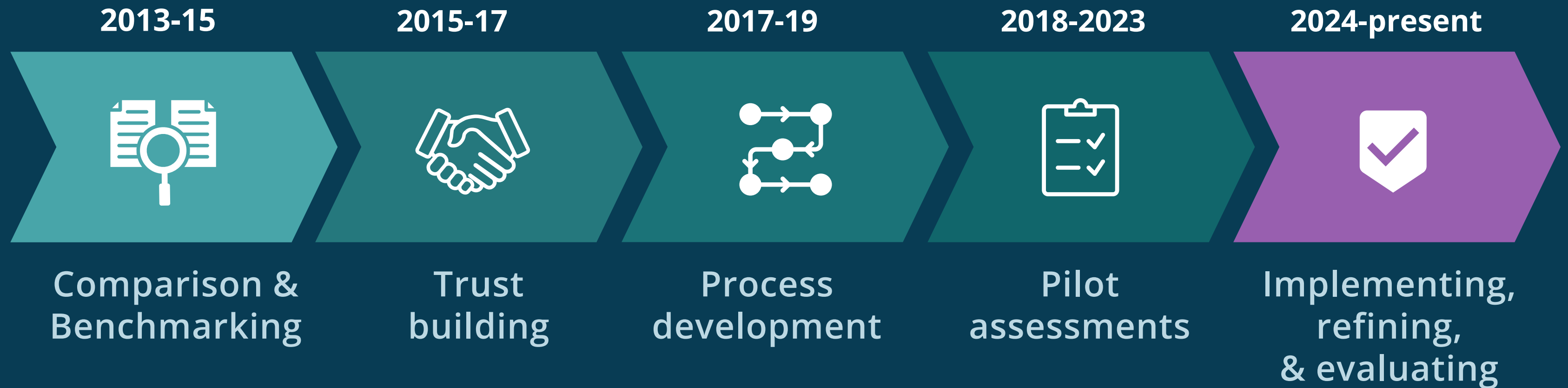
by sharing safety  
assessments



## **Improved synchronisation**

without compromising  
our respective regulatory  
processes

# Developing the SAP



During the early stages of the project, FSANZ and Health Canada liaised closely with CropLife and its member companies – end users of the proposed system





# Comparison and benchmarking



- Comparison of the regulatory approaches of each agency: data requirements, timelines, decision-making, consultation
- Comparison of two previously completed safety assessments
- **Conclusion:** only minor differences identified in approach and data requirements

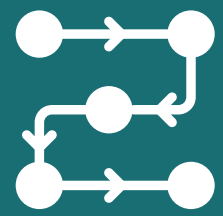


# Trust building

- 01** A concurrent safety assessment of a (simple) new application
- 02** HC evaluation of a FSANZ safety assessment document for a concurrent application
- 03** A concurrent safety assessment of a nutritionally complex new application







# Scope and requirements



## GM Foods

requiring pre-market assessment by both agencies



## Identical information

needs to be provided to both agencies by applicants



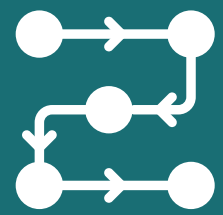
## Similar timeframes for approval

Applicants should be seeking approval from ANZ and Canada in the same or similar time period



## Agreement to information exchange

for the purposes of the shared assessment



# The Shared Assessment Process



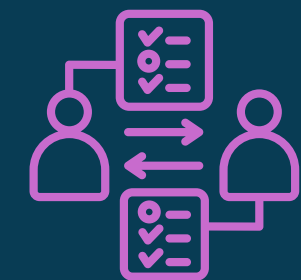
Applicant informs both agencies of their intent to use the SAP for an upcoming application



FSANZ/HC decide on primary assessor



Applicant submits separately to each agency



Primary assessor completes assessment and shares with secondary assessor for review



FSANZ-HC liaison to discuss assessment



Post-assessment processes



Final regulatory decisions and approvals remain independent





# Pilot assessments

## **Pilot 1:** Herbicide-tolerant GM canola

Health Canada undertook the food safety assessment as the primary assessor

Approval processes were both completed in April 2021.

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## **Pilot 2:** Insect-resistant and herbicide-tolerant GM maize

FSANZ undertook the food safety assessment as the primary assessor

FSANZ and Health Canada approval processes were completed in February and July 2024, respectively.





# Lessons and challenges



Operational and structural differences between FSANZ and Health Canada



Differences in each agency's reports and public-facing documents



Applicants require clear guidance to understand the requirements for submitting an application under the SAP

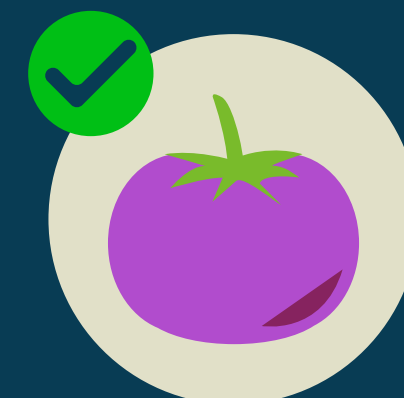




# Outcomes



Four more assessments completed



Publication of guidance for applicants on our websites





# Benefits realised



Time, resource and cost savings

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A closer working relationship with Health Canada

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Expanded pool of expertise







## Publication of OECD consensus document: *Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants*

Outlines the many types of collaborative work that are possible:

- Inter-agency Peer Review
- Parallel/Concurrent Assessment
- Safety Assessment Sharing
- Joint Safety Assessments
- Recognition/Acceptance
- Referencing Assessments
- Capacity Building
- Regional Harmonisation

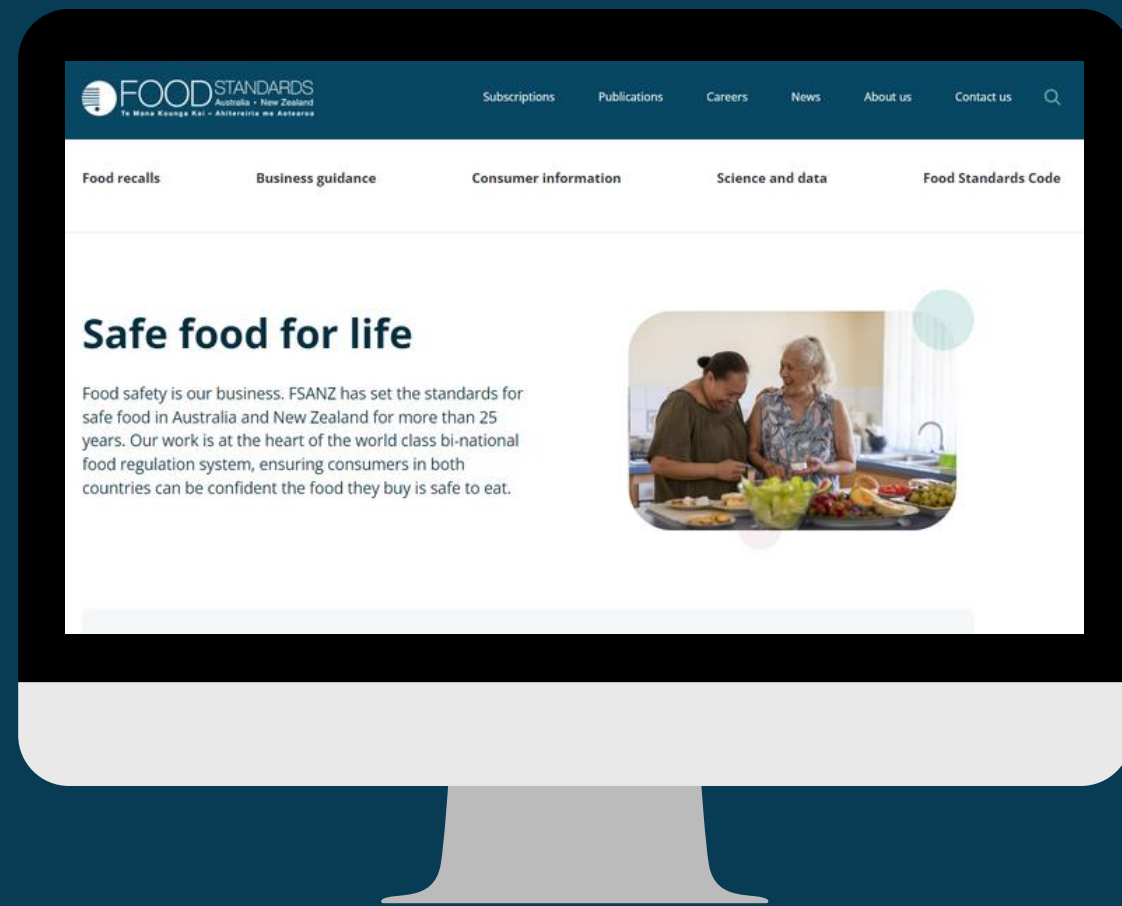




# Where to next?

- Seek detailed feedback from applicants on their experiences with the SAP
- Continue to use the SAP and look for further opportunities to refine the process
- Potential to use the SAP to assess a **GM animal** - open to discussions with potential applicants

# Further information



Search 'shared assessment process' on our website or scan the QR code