FAO GM Foods Platform

Interview with a Focal Point: Australia - Janet Gorst

"*We are just two of us in the safety assessment team for GM foods*"

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In order to facilitate Focal Points to learn from each other's experiences, FAO interviews Focal Points from various countries to share their national requirement, process and experience on GM food safety assessment. This article features an interview session with Janet Gorst, the Focal Point for Australia, who is a safety assessor.

Interviewer: Please tell us about you and your background.

Apart from being a great risk assessor, Janet is also a great swimmer!

Janet Gorst (Janet): I am a Senior Scientist at Food Standards Australia New Zealand (FSANZ) and have been working on GM food safety assessment for the last 7.5 years. I have a Ph.D. in plant cell biology. Post-doctoral work experience included several years as a university lecturer, where I developed a keen interest and knowledge in the area of biotechnology and GMOs, and a position at a biotech-forestry company in Indonesia carrying out micro propagation and genetic selection. Prior to joining FSANZ I worked as an Evaluator for 2.5 years in the Australian Government Office of the Gene Technology Regulator.

Interviewer: How and why were you nominated by your Government to be the Focal Point to the FAO GM Foods Platform?

Janet: The Codex Contact Point first contacted FSANZ since it is the regulatory agency responsible for safety assessment of GM food. Since I work as a senior scientist in the GM safety assessment team, I was nominated to be the Focal Point.

Interviewer: How many people are in your GM food safety assessment team? What types of expertise do you have in the team?

Janet: Currently, we are just two of us in the safety assessment team for GM foods; ideally we would like three people and are anticipating recruiting a third person soon. The work we do extends beyond just carrying out safety assessments and we are responsible for all aspects of GM including dealing with GM enquiries, preparing material for the Government, updating GM information available to the public, liaising with other agencies and contributing to the corporate life of FSANZ. I am located in the Canberra office, and the GM team leader (Dr Lisa Kelly) works remotely from Tasmania. We have a background in molecular biology/biotechnology. Usually for a particular application, only one person works on the safety assessment. When there is a need for advice in other specialist areas such as nutrition, or toxicology, we seek help from our experts inside FSANZ. Thus, you can say that there is an informal network inside FSANZ for scientific advice in assessing the dossier. On occasion, where an application may fall outside what we would call 'routine', FSANZ will send the safety assessment out for peer review to independent experts, such as academics and researchers, who have relevant expertise. At times FSANZ also liaises with other GM regulators.

Interviewer: Does FSANZ have guidelines for GM food safety assessment? If yes, are these in line with the Codex guideline for the conduct of food safety assessment of foods derived from recombinant DNA plants?

Janet: Yes, The safety assessment process and data requirements used by FSANZ are described in detail in the FSANZ Application Handbook available at http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx (March 2016). The FSANZ protocol for conducting safety assessments of GM foods is based on the internationally agreed principles and guidelines contained within the various relevant Codex documents. The data requirements in the latest version of the Application Handbook, have been substantially updated to reflect recent scientific developments, improve clarity and transparency, remove superfluous requirements and to introduce a more streamlined form of safety assessment approach for those products which are known through prior knowledge, evidence and experience to be lower risk.

Interviewer: What is the process of the safety assessment once you receive an application?

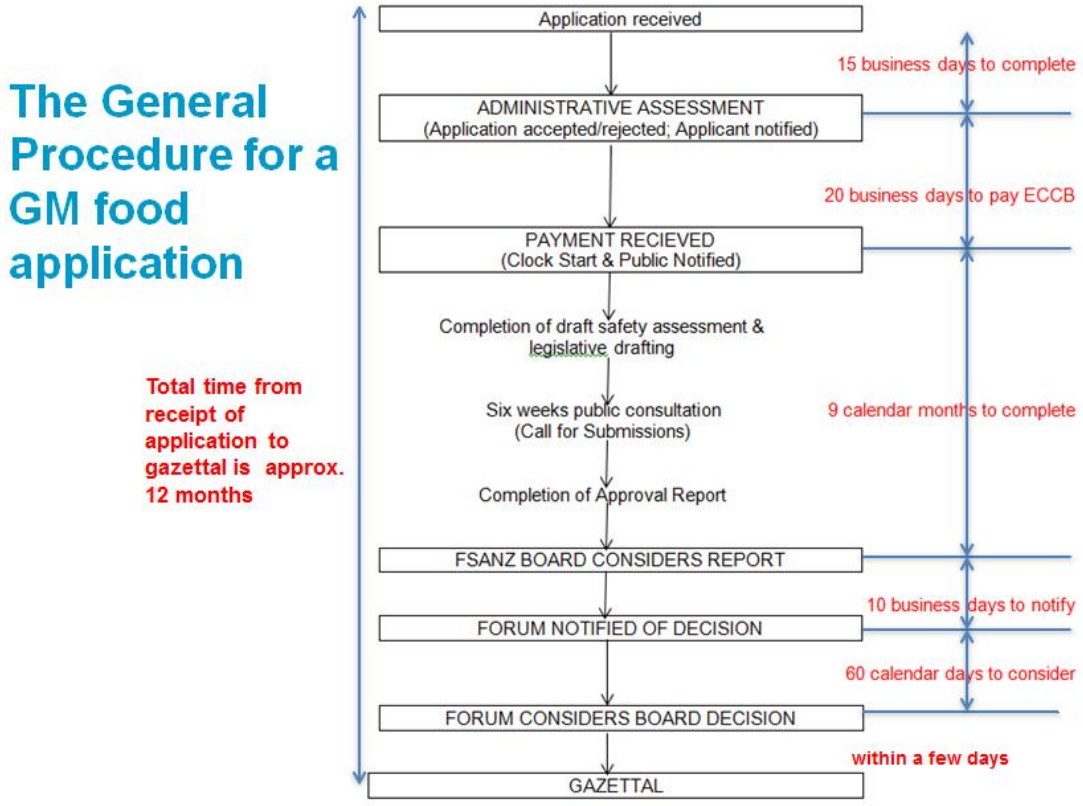
Janet: There are two relevant GM food standards in the Australia New Zealand Food Standards Code. A standard that provides definitions and labelling requirements and another standard called "Schedule 26" which lists GM food approvals. In submitting a GM food application to FSANZ, applicants request a variation to Schedule 26 to include food derived from a particular GM line.

The first step after receiving an application is to check if the applicant has addressed all of the administrative and data requirements in the Application Handbook. This process has to be done within 15 business days after receipt of the application. If/once the application has been accepted, the applicant has 20 business days to pay a fee to FSANZ. All GM food applications in which the applicant will gain a financial benefit are categorized as having an Exclusive Capturable Commercial Benefit (ECCB) and the applicant is required to pay the full cost of processing their application. We do not start our work until the applicant has paid. Once the payment is received, a member of the

FSANZ GM team prepares the safety assessment over a period of several months and seeks expert advice if required.

After this, there is a Call for Submission which involves a public consultation period, usually of 6 weeks. The Call for Submissions documents include the safety assessment and an administrative report containing the proposed legal drafting for the variation to Schedule 26, should the food be approved. Following the Call for Submissions, an Approval Report is prepared, taking into account any issues raised during the consultation. This Report is then taken to the FSANZ Board for a decision on the proposed variation to Schedule 26. The Board is appointed by the Australian Minister for Health and comprises 11 people, qualified in specialist areas relevant to food, from outside FSANZ plus the head of FSANZ. The Board approval is notified to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) for their response. If the Forum does not request a review of the Board's approval, the approval will be gazetted almost immediately and hence become legal. If the Forum asks for additional review a further few months is added to the timeframe while FSANZ addresses the Forum's concerns.

The process from the point of payment to FSANZ Board approval takes around 9 months on an average. The Forum then has approximately 2 months to respond to the FSANZ Board notification. If the Forum accepts the FSANZ Board approval the entire process for one application from receipt to gazettal takes approximately 1 year. A flow diagram of the FSANZ process is given in the Figure below.



Interviewer: What are some of the challenges that you face as the Focal Point and person in charge for the safety assessment of GM Foods in your country?

Janet: With new techniques continuously evolving for molecular characterization and protein characterization, it can be quite a challenge to keep up with the new methodologies as one has to understand the way the technology works while assessing the safety of the GM food. A lot of background reading and discussion with relevant scientists are essential. However, applicants keep us informed through presentations before submitting their applications, about any new technology that they use in the GM Food production and testing process.

Interviewer: Do you have any tips for countries with little experience with conducting GM Food safety assessment or for countries that are still in the process of developing a regulatory framework for the same?

Janet: Because GM foods have been in the market for a while now without any food safety problems, it would be a good option, particularly in products containing 'routine' traits such as herbicide-tolerance and Cry protein insect-protection, to consider more streamlined regulation. The Codex Guidelines have their place but the safety assessment process, particularly the data requirements, can be simplified a little in many cases. There is also the problem all regulators with a developed regulatory system are facing now with the new breeding techniques, since their regulatory systems may well have been developed many years before the new techniques were even thought of; we are having to decide whether definitions for transgenics are still applicable to the products of new breeding techniques. Therefore for those countries still developing a regulatory framework, it is very pertinent that they ensure the new breeding techniques can be taken into account in their framework – whether that means including or excluding certain products/techniques.

To my mind, good regulation should embrace a framework in which the risk assessment approaches are commensurate with the level of risk. We should not be stifling innovation with regulatory systems that have costly and excessive data requirements if the science is telling us such requirements are not necessary.

FAO would like to express its appreciation to Janet Gorst, Lisa Kelly and other relevant FSANZ officers for providing valuable information on the process of GM food safety assessment in Australia. There are various ways and approaches that can be taken to set up GM food safety assessment process at national level, but for countries with limited experience, the real-life examples can be the best teacher. Visit http://tiny.cc/FAO-GM-Aus to further read about the country profile of Australia on GM food safety assessment and review their submitted records.