Responding to Adventitious Presence – An NZFSA Case Study

NZFSA deals with a range of situations where an unintended low-level presence of an unapproved substance is found in food. These situations are commonly referred to as adventitious presence. Adventitious presence of unapproved substances in food is a general food incident issue, which applies equally to chemical, biological and physical contamination and to the unexpected presence of genetically modified food (GM). When dealing with adventitious presence, NZFSA applies a risk management framework, which is consistent with New Zealand's WTO obligations under the Sanitary and Phytosanitary (SPS) Agreement. In situations where adventitious presence is found, NZFSA assesses the potential for harm and determines whether a recall or public statement is necessary to protect public health.

Recent examples of adventitious presence include Liberty Link Rice (LLRICE 601) and the lead in cornflour incident. In both cases, NZFSA applied a risk management process (explained below) to identify potential hazards and the possible exposure of New Zealand consumers to those hazards.

Overview of the risk management process

NZFSA applies a risk management framework to its response and standard setting activities to ensure they are proportional relative to the issue under consideration.

The framework is a four step process as follows:

1. Preliminary risk management activities
2. Assessment of management options
3. Implementation of the risk management decision
4. Monitoring and review

Step 1: Preliminary risk management activities

- identification of the food safety issue
- establishment of a risk profile
- ranking of the food safety issue for risk management
- commissioning of a risk assessment, where necessary
- consideration of the results of risk assessment

A risk assessment is in turn made up of four components

1. Hazard identification
2. Hazard characterization

3. Exposure assessment
4. Risk characterization

NZFSA considers risk to be the function of severity and likelihood of adverse health effects. Data is gathered from a range of sources in order to complete the above activities and enable high quality, consistent decision making.

Step 2 Assessment of management options

- Discuss risk management options among representatives of the organisation with appropriate expertise
- Assign a team leader
- Monitor the scale of the issue
- Discharge actions

Step 3 Implementation of the risk management decision

- Monitoring of status
- Internal and external communication

Step 4 Monitoring and review

- Formal close-off of the issue
- Review of the process for improvement and the risk management measures

Case Study – Liberty Link Rice 601 (LLRICE 601)

On 18 August 2006, the US Department of Agriculture (USDA) announced that trace amounts of an unapproved genetically-modified (GM) rice variety (LLRICE 601) developed by Bayer CropScience were detected in samples of commercial non-GM long grain rice in the US. At the same time, the USDA and the US Food and Drug Administration (USFDA) stated that they had reviewed the available scientific data and concluded that there were no human health, food safety, or environmental concerns associated with LLRICE 601.

NZFSA applies a risk management framework to all its response and standard setting activities to ensure that any risk management decisions are proportionate to the risk posed. NZFSA considers risk to be the function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard or hazards in food. In all food incident response cases, information regarding the hazard and the likely exposure of consumers to that hazard is essential in determining NZFSA's risk management response. Such information is gathered from a range of sources to enable high quality, consistent decision making.

When the LLRICE 601 incident came to the attention of NZFSA, officials immediately sought to obtain information regarding:

a. any potential hazards that might affect the safety of consumption of LLRICE 601 (specifically, details in relation to the novel transgene/s and protein/s present in the GM rice); and
b. the quantity of long grain rice imported into New Zealand from the US, which allowed NZFSA to estimate possible exposure.

Assessment of potential hazards associated with consumption of LLRICE 601

With regard to any potential hazards associated with LLRICE 601, NZFSA was able to quickly obtain information regarding the novel traits in LLRICE 601 and assess the findings of trusted overseas agencies. This included, but was not limited to the following:

- The developer of LRICE 601, Bayer CropScience has developed many herbicide tolerant GM crops (commonly referred to as Liberty Link) which all express the same novel protein. This protein has been scientifically reviewed and used safely in food in nearly a dozen countries, including New Zealand and Australia.
- The Organisation for Economic Co-operation and Development (OECD) has concluded that the novel protein in Liberty Link crops is non toxic to human and animals.
- While LLRICE 601 has not been through a full safety evaluation, two other GM Liberty Link Rice lines (LLRICE 62 and LLRICE 06) that carry the same transgene as LLRICE 601, have been through safety evaluations in the US and Canada. Both of these lines have been found to be safe for use in food and safe for the environment, and have been given unregulated status in the US. LLRICE601 was not intended for commercialisation and therefore an application for unregulated status (status given when an application has been assessed and approved) in the US was not sought.
- Food Standards Australia New Zealand (FSANZ) is the agency responsible for assessing the safety of GM foods prior to them being sold in Australia or New Zealand. Although FSANZ has not assessed this specific Liberty Link rice, it has assessed and approved the use of other crops, such as soy, that contain the same novel protein.

NZFSA officials concluded that because no new hazards were likely to be present in the rice, LLRICE 601 posed no greater food safety risk than conventional rice. This conclusion was consistent with regulators in the US, Canada and the EU.

Assessment of potential exposure

In parallel with the assessment of potential hazards, NZFSA determined the potential level of exposure of New Zealand consumers to LLRICE 601 by obtaining importation statistics for US-sourced long grain rice. While exact figures for long grain rice imports were not immediately available, NZFSA was able to determine total US rice imports, which equated to

less than 3 percent of all rice, imported into New Zealand. This figure included imports of short, medium and long grain rice, of which only long grain rice potentially contained trace amounts of LLRICE 601.

Further investigation led to NZFSA determining that US long grain rice imports equated to 0.23 - 0.41 percent of the total rice imported into New Zealand since January 2005. Therefore the potential for exposure, even if a novel hazard had been identified, was considered to be very low.

Risk management decision

Because no novel hazard was identified and exposure to LLRICE 601 was likely to be very low, if at all, NZFSA determined the risk to be negligible. NZFSA then considered its risk management options, including testing for LLRICE 601 for compliance purposes, but having taken into account other considerations, such as the very low probability of finding any non-compliant rice and competing food safety testing priorities, NZFSA came to the conclusion that such testing was not justified.

Findings of New Zealand's trading partners

NZFSA agrees with food regulators in the EU, Canada and the US that LLRICE 601 is unlikely to pose a food safety risk. Below are press statements regarding the safety of LLRICE 601 that have been issued by regulators in these countries:

"based on the available data and information, the US Food and Drug Administration (USFDA) has concluded that the presence of this bioengineered rice variety in the food and feed supply poses no food or feed safety concerns".

The Canadian Food Inspection Agency (CFIA) issued the following media release:

"…. assessments determined that it is unlikely that low levels of LLRICE601 pose a risk to human health, livestock or the environment".

The UK Food Standards Agency (FSA) has stated that "our independent scientific experts have looked at the data on this material and have concluded that there is no food safety risk". The UK FSA has also informed consumers that if they have US long grain rice at home, they can continue to eat it safely.

The European Food Safety Authority's expert panel on genetically modified organisms (GMOS) has evaluated the available scientific data on LLRICE601 and while it was unable to complete a full risk assessment, as would need to be carried out for the authorisation of new GM foods, it released the following statement:

“…. the Panel considers that the consumption of imported long grain rice containing trace levels of LLRICE601 is not likely to pose an imminent safety concern to humans or animals”.