

Split Approvals Policy Overview

Issues and Policy Objectives

GMOs and GM products that have not been assessed as safe for human consumption and/or that have not received appropriate approvals for use as human food by Food Standards Australia New Zealand (FSANZ) may pose risks to human health and safety. One possible source of exposure to this risk is if GM crops that are approved for animal feed but not human food, become incorporated into human foods inadvertently.

The Gene Technology Regulator has developed a policy to manage this risk as follows:

For general (commercial) DIR applications:

The Regulator will impose a licence condition requiring that neither the GMOs nor their products can be used in animal feed unless the same GMOs/products, have been approved for human food use by FSANZ.

For all other dealings:

The Regulator will impose containment conditions that can be applied with confidence to the GMOs, parts thereof containing modified genetic material, and products derived from the GMOs (eg. by issuing DNIR licences or limited and controlled DIR licences), to manage the risk of them becoming incorporated into human foods.

Background:

A genetically modified plant that is approved for use as animal feed but not human food is said to have received a split approval. The issue of split approvals arose following an incident in the USA where traces of genetically modified (GM) StarLink™ corn, approved for animal feed only, were found in taco shells, corn chips and other human food corn products. The split approval occurred because the US Environmental Protection Agency had approved StarLink™ for use in animal feed, although it had not been approved as human food by the US Food and Drug Administration. No conclusive evidence was ever found to indicate that StarLink™ corn impacted human health and safety adversely.

In the absence of policy preventing split approvals of GM feed and food from occurring, there is potential for split approvals to occur in Australia. This is because under the current regulatory system the environmental release of a GMO is regulated under the *Gene Technology Act 2000* by the Regulator and separately from the regulation of GM foods, which is regulated by FSANZ.