

Stance on Safety Assessments of Genetically Modified Feed and Feed Additives

(Food Safety Commission Decision of May 6, 2004)

1. Background

Pursuant to the Act on the Assurance of Safety and Improvement of Quality of feed, the Ministry of Agriculture, Forestry and Fisheries has carried out confirmation of the safety of feed and feed additives manufactured using recombinant DNA technology (genetically modified feed and genetically modified feed additives), with a view to preventing the production of harmful livestock products and preventing obstructions in the production of livestock products due any harm caused to said livestock. As of July 1, 2003, the Food Safety Commission became responsible for conducting assessments of the effect on human health of livestock products made from livestock that have consumed genetically modified feed or feed additives.

2. Fundamental Stance

Generally speaking, in respect of the effect of foodstuff associated with feed on human health, it is reasonable to assess the safety of feed and livestock products, taking into consideration the possibility that harmful substances contained in said feed can be transferred to meat, milk, eggs, and other livestock products through providing said feed to livestock animals, and that the components of said feed could transform into harmful substances and accumulate in livestock through in vivo metabolism.

Furthermore, in respect of the effect of foodstuff associated with feed additives, it is reasonable to assess the safety of said feed additives and livestock products, taking into consideration the transfer of harmful substances contained in said feed additives to meat, milk, eggs, and other livestock products.

Accordingly, safety assessments of genetically modified feed and feed additives are handled case-by-case, based on the following approach:

Basically, in safety assessments of genetically modified feed and feed additives, it is appropriate to assess the above-mentioned additional risks that have the possibility of developing, using existing non-recombinant feed or feed additives as a reference, in the same manner as genetically modified food or food additives manufactured using genetically modified microorganisms.

3. Safety Assessment Process

When conducting safety assessments of genetically modified feed and feed additives,

- i. the possibility that new harmful substances derived from recombinants are generated in said genetically modified feed or feed additives and transferred to meat, milk, eggs, and other livestock products,
 - ii. the possibility that components in said genetically modified feed or feed additives which are derived from genetic modification are transformed into harmful substances and accumulate in livestock products, and,
 - iii. the possibility that components in said genetically modified feed or feed additives which are the result of genetic modification interact with the metabolic system of livestock animals and produce new harmful substances,
- are to be considered, and if such possibilities are putative an assessment shall be made as to whether it is possible that the consumption of livestock products derived from said feed or feed additives could have an effect on human health.

(1) If the possibilities mentioned in i, ii and iii above do not exist, a safety assessment is not necessary. However, whether or not an assessment is necessary will basically be determined on a case-by-case basis upon consideration of (a) and (b) below:

(a) Generally speaking, there are no reports of the inserted gene or protein produced from said gene being transferred into meat, milk, eggs, or other livestock products, and since the possibilities mentioned in ii, iii as well as i above are unlikely for items that have been transduced with traits such as pest resistance, herbicide tolerance, virus resistance, antibiotic tolerance etc., it is generally thought that livestock products derived from livestock animals that have consumed the feed or feed additives in question will not result in new safety issues.

(b) Also, it is thought that, for genetically modified foods for which safety assessment as foodstuff has been completed, since the safety of protein that said gene produces has been already assessed, as long as there is no rational reason to question that components contained in said feed transform into harmful substances and accumulate in livestock, there are no safety concerns regarding livestock products derived from livestock animals that have consumed the genetically modified feed. Furthermore, due consideration should be given to the possibility that livestock animals may consume parts of said genetically modified

feed that are not considered edible, and the relevant materials will be requested as necessary.

- (2) If there is a possibility of either i, ii or iii above, a safety assessment of said genetically modified feed or feed additives will be necessary. In such a case, the safety assessment of genetically modified feed will basically be conducted in accordance with "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)" and that of genetically modified feed additives will be conducted in accordance with "Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms". In addition, depending on the particular case, it is assumed that there will be cases where it is difficult to conduct the safety assessment in accordance with these assessment standards. In such cases, the safety assessment will be conducted comprehensively after requesting the necessary materials.
- (3) Since recombinant DNA technology is advancing on a daily basis, these principles for safety assessment will need to be reconsidered as required, in accordance with the advancement of said technology.

4. Other

Regarding genetically modified feed which has the potential to be used as food, such as grain, consideration will be taken, as a general rule, that safety assessment as food will be conducted simultaneously.