Comments on the Approach Proposed for the Food Safety Risk Assessment of GM Animals

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General principles on which EFSA is basing the risk assessment of animals

GM Freeze believes that EFSA's approach to assessing the health and welfare risks associated with GM animals is flawed because it is based on a comparative risk assessment, or "substantial equivalence", with non-GM animals as the starting point. This assumes that the only difference between GM and non-GM animals is the modified trait and that if the GM trait is deemed safe, then the animal is also safe. Scientific evidence suggests that this will seldom be the case.

We also believe this approach is flawed because it fails to recognise that the physical act of genetically modifying a cell will have many impacts other than the intended trait on the receiving cell and organism. These changes could result in alterations to the gene expression, biochemistry, composition and behaviour of the GM animal, which could be harmful to those consuming the products or the animal or its offspring.

The production of GM animals will be expensive, and it is likely to concentrate on a small number of specific traits aimed at producing economic benefits (eg, to produce a specific chemical in milk, such as insulin, or to introduce disease resistance). To ensure these traits are heritable it is highly likely the genetically modified animals will also be cloned in order to try to ensure the GM trait is present in breeding stock. This raises a large number of additional ethical and safety issues that are currently being debated in the EU. Animal welfare is one of the major concerns about the use of cloning in farm animal breeding, as raised during recent consultation processes and in reports. The failure to even acknowledge the role cloning may play in developing GM animals in the future is a major omission in the EFSA document.

We do not believe that it is a sensible approach to compartmentalise issues of science, ethics, environmental impact, socio-economics and animal welfare because final decisions to approve (by politicians) or purchase (by farmers and consumers) should not be based solely on science (and seldom are). No decisions about farming or the food chain are ever based on science alone and never should be.

Scientific uncertainty and the precautionary principle

The consultation document on safety assessment of GM animals also fails to deal with how scientific uncertainty should be addressed when there is a shortage of reliable data, data are ambiguous or there are different interpretations of existing data. This omission is all the more concerning because the document fails to mention the precautionary principle and how it should be applied in the context of assessing the safety of food and feed from GM animals.

Limits placed on consultation by EFSA

Genetic modification of domesticated animals could also fundamentally change our relationship with them and makes it far more likely that sentient animals will be increasingly seen as commodities to be traded in a global food system.

We would therefore like to put on record that the limits placed on this consultation process by EFSA to issues "related to policy or risk management" weakens the process to the point that it greatly reduces its credibility in the eyes of EU citizens.

Flaws in the comparative risk assessment or substantial equivalence approach

GM Freeze rejects the use of comparative risk assessment as a concept for assessing the risks of GM animals because it fails to recognise that many risks are specific to the GM animal. At best it is a tool to assist in the process of food and feed safety assessment.

GM Freeze sees a number of flaws in using this approach as a main means of assessing the risks

of food and feed from GM animals because it:

- Fails to recognise that GM modifications will be outside the control of the animal genome regulatory mechanisms.
- Fails to systematically investigate unintended and unpredicted effects due to transformation-induced mutations.
- Fails to systematically investigate changes to the animal's biochemical pathways due to interaction and interferences induced by the GM events.

Post Market Monitoring (PPM)
GM Freeze would like to put on record that post market monitoring should not be used as a substitute for robust premarket risk assessment. Reliance on comparative risk assessment increases the chances that unintended consequences of GM events in animals would be missed by the risk assessment. We strongly doubt that a chronic health problem arising in farmed animals or humans as a result of products from GM animals entering the market would be detected by PPM given the rapid introduction of other novel products into the food chain, the global nature of food distribution and the unreliability of traceability. Accurate and effective labelling and traceability of GM animals and their products would be an essential requisite for an effective PPM strategy.

We have previously commented on the likelihood that GM animals will also be subject to cloning. We firmly believe that all cloned animals and their offspring should also be labelled and traceable otherwise it may prove impossible to assess if any unexpected health or welfare effects are due to the GM event or cloning itself.

A better approach to food and feed safety for GM animals
GM Freeze believes that each GM animal should be assessed as would any novel product, namely by looking at the broadest possible range of data and the use of long-term and intergenerational safety testing that seeks to test whether any observed differences have long- or short-term health implications for those consuming the products from GM animals. This approach would need to assess animals reared in different environments as this may impact on gene functions and the safety of any derived products.

Animal welfare in GM animals
Assessment of the impact of genetic modification on animal welfare cannot be achieved without extensive and long-term trials including intergenerational trials. Before any such trials proceed, it is essential that the European public is fully consulted about the acceptability of cloning and cloned products in the EU. A negative response should lead to a ban on cloning and cloned products, which will mean the use of cloning in GM animals would be abandoned as well.