Executive Summary

A joint FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from genetically Modified Animals, including Fish was held at the Headquarters of the Food and Agriculture Organization of the United Nations (FAO) in Rome from 17 to 21 November 2003.

The objective of this Consultation was to provide scientific advice to FAO/WHO and their Member States on the safety assessment of foods derived from genetically modified animals, including fish (hereafter "GM animals"). The Consultation focused on discussing what strategies are appropriate and applicable to the food safety assessment of GM animals. Additionally, it addressed specific issues originating from the production of GM animals as well as environmental and ethical issues. The Consultation did not address all environmental issues but focused on the connection between environmental entry of GM animals and food safety. The Consultation also addressed ethical consideration that relate directly to the scientific assessment of foods derived from GM animals.

Potential benefits of GM animals might be realized in the near-to-medium term, such as improved animal production and product quality and novel animal products. Other applications that might be realized over the longer term include use of GM animals as bioindicators, for biological control, and for xenotransplantation.

Effort should be invested in making GM animals safer from the outset, e.g., by wise selection of breeding goals, improved techniques such as design of vectors, and avoidance of unnecessary DNA sequences such as marker genes that raise safety concerns.

The food safety assessment of GM animals and derived products can largely be performed along the lines that have already been established for the evaluation of GM plants and derived products on a case-by-case basis. This means that the initial step of the food safety assessment will be a comparative safety assessment of the GM animal with its conventional counterpart, including a food intake assessment, followed where appropriate, by a full risk characterisation.

Rigorous pre-market safety assessment of foods derived from GM animals should provide sufficient safety assurances. The use of post-market surveillance as an instrument to gain information on the potential long-term or unexpected adverse and beneficial effects of food either GM animal-derived or traditional should be further explored. Post-market surveillance could be useful in certain instances where clear-cut questions require, for instance, a better estimate of intake and nutritional consequence of foods derived from GM animals, or better estimate of environmental fate of GM animals and their transgenes.

Accessible databases on the natural variation in key compositional constituents in animal products are necessary tools in the assessment of unintended effects of the genetic modification. There is a need for a worldwide accessible database, linked to ongoing efforts in this area, with information on detection and identification methods and reference materials for food products derived from GM animals on the market and in development.

There is a need for capacity building, particularly in developing countries, for food safety assessment and management of GM animals, including environmental and ethical aspects related to food safety.

The Consultation recommends participatory deliberation by all stakeholders and the general public, starting at an early stage, including communication about potential benefits, risks, and uncertainties posed by genetic modification of animals.

There is a need to develop a framework for the ethical consideration of animal biotechnology. This framework should make the assessment more transparent, methodical and amenable to quality assurance