Comments on the EFSA draft guidance for the environmental risk assessment of genetically modified animals

COGEM opinion CGM/120831-01

On the 21 of June the European Food Safety Authority (EFSA) launched a public consultation on its draft guidance for the environmental risk assessment (ERA) of genetically modified (GM) animals. According to EFSA the document that focuses on GM fish, insects, mammals and birds, outlines the specific data requirements and methodology for the ERA of GM animals should applications be submitted for market authorisation in the European Union (EU) in the future. Stakeholders and interested parties can submit their comments on the guidance not later than August 31.

The size of the document, the relative short period available for reviewing, and the fact that the public consultation period overlaps completely with the summer holidays, hamper a thorough and detailed assessment of the draft guidance. Therefore, in its comments the Netherlands Commission on Genetic Modification (COGEM) is forced to restrict itself to main issues without going into details.
GM animals are a highly controversial subject in Europe, especially due to moral objections. Although the document focuses on the ERA of GM animals and ethical and socio-economic issues are not part of the scope of the document, COGEM points out that the unfortunate timing of the public consultation does not help to gain public support. The overlap with the summer holidays limits the possibility of stakeholders and interested parties to submit comments and thus fuels public distrust.

COGEM welcomes the timely initiative of the European Commission and EFSA for the development of a guidance document on the ERA of GM animals. Due to developments abroad, through permit applications for market admittance, the EU will be faced with GM animals and animal products in the future. A guidance document on how to conduct the ERA of GM animals can therefore be of great use for risk assessors and applicants.

EFSA states that that the document provides detailed guidance to applicants how to conduct the ERA of GM animals to be released in the environment and assists applicants in the preparation and presentation of the ERA part of their applications. The drafting of a guidance document on the ERA of GM animals is indeed a formidable task. Experience and expertise with the deliberate release in the environment of GM animals is very limited, and GM animals are a very large and heterogeneous group of organisms. To address the latter, the guidance document is subdivided in three sections dealing with the ERA of GM insects, GM fish and GM mammals and birds, next to general chapters on strategies for the ERA of GM animals and cross-cutting considerations. However, there is still a considerable variation and diversity within these groups of animals. Moreover, there is a great variety in the different possible receiving environments. These challenges in drawing up a guidance document for the ERA of GM animals are reflected in the present document.

The EFSA draft guidance is an impressive and lengthy document, which seems to cover nearly every conceivable aspect of the ERA of GM animals. As such, it is of considerable value for both applicants and risk assessors. The document provides a very useful enumeration of points-to-consider for the ERA of GM animals.
However, the document fails in its intention to provide detailed guidance for applicants. It lacks in identifying clear criteria or methods for the ERA, much of the text is ambiguous, and all the aspects and elements that presumably have to be considered in the ERA of GM animals are dealt with in the same manner, irrespectively of their relative importance for the ERA.

For instance in paragraph 4.2.3 (Interactions of the GM insects with NTOs) it is stated that changes to other ecosystem functions such as decomposition of organic matter or water regulation have to be considered. The possibility that such changes occur are far-fetched and the ERA should focus on changes in competitiveness, displacement of insects by the GM insect, and changes in aggressive behaviour.
Strikingly, in the paragraphs 4.2.1 (Persistence and invasiveness, including vertical gene transfer) and 4.2.6 (Impact on human health) little attention is given to possible changes in behaviour of the GM insect, especially those which are important in the interaction with humans, like raised aggression or adaptation to live indoor houses or outdoors.

Some of the elements of the ERA mentioned seem too far-fetched or not related to the genetic modification. On page 82 of paragraph 4.2.3 (Interactions of the GM insects with NTOs) it is stated that a successful GM based suppression program can lead to complacency about environmental hygiene for mosquito control, making the impact of any failure in a GM insect campaign more serious than it may have been. Although this is probably true, it is a problem associated with every successful prevention, eradication or suppression program and not associated with genetic modification.

In all three chapters on the ERA of GM fish, insects, and mammals and birds considerable attention is given tot horizontal gene transfer. As indicated in the different paragraphs of the guidance document horizontal gene transfer is a rare event. Horizontal gene transfer possibly only occurs between organisms, which are in close contact like symbionts and their host, or parasites, and on an evolutionary time scale. The element of the need for ‘intimate contact’ between organisms is lacking in the paragraphs on horizontal gene transfer.

On page 8 it is mentioned that the guidance document covers (1) captive, (2) semi-captive and (3) non-captive GM animals. The differences between these three groups of animals are of considerable importance for the ERA. However, this distinction appears to play no role in the deliberations on the ERA in the guidance document. At least the consequences for the ERA of the various degrees of captivity should be discussed in the chapter on cross-cutting considerations.

Finally, there appear to be differences in the set-up of the chapter on GM mammals and the chapters on GM fish and insects. Such textual differences can lead to confusion. Editing and shortening of the text and removal of ambiguities would further improve the usefulness of the document.