ANNEX

The proposal put forward by EFSA in its new guidelines is not sufficiently rigorous. Indeed, methodology for the risk assessment of GMOs is an area of debate and controversy amongst scientists. However, in its guidelines, EFSA mostly adopts the methodology favoured by scientists who work closely with the agro-biotech industry. If the current draft guidelines are adopted by Ministers, priority is given to quick and easy market approval by ignoring the need for a high level of protection for consumers and the environment.

1. Improvements to the new EFSA guidelines

“Problem formulation" is the essential prerequisite for a systematic risk assessment. In this initial phase of risk assessment, critical elements such as the determination of the nature and severity of the damage analysed (e.g. death or reduced mobility of an organism), or acceptable thresholds for damages should be determined in a consultative approach. Since "problem formulation" is also a normative and not exclusively scientific procedure, a broad range of stakeholders should be involved. In its chapter on "problem formulation" EFSA only recognises approaches that have been established by or with scientists working with the agro-biotechnology industry. Approaches by research groups developed outside of industry networks are not considered by the guidance. According to the guidance, the applicant companies have full freedom to determine these essential elements of risk assessment in a way to receive quick and easy approval for their products. The guidance needs to be amended to ensure more transparent and credible problem formulation.

Choose appropriate starting point:
As laid down in the guidance document,1 EFSA introduces a "comparative safety assessment" (also called concept of substantial equivalence or concept of familiarity) as a decisive step in the environmental risk assessment. The comparative risk or safety assessment starts with a comparison between the genetically engineered plant and its conventional counterpart. It ignores that many risks are specific to the genetically engineered plant: the methods for introducing DNA are not based on the mechanisms of common gene regulation and heredity. The newly introduced gene constructs have a specific potential to escape and /or disturb the process of normal gene regulation that is unique for this specific technology. Applying a risk assessment that is based on a concept of “comparison” as a starting point can be described as the same as comparing apples with oranges.

The comparison between conventional breed plants and those produced by genetic engineering can only be a tool, but it is not a scientific concept or an adequate starting point.

The EU should reject the idea that substantial equivalence can serve as safety assessment in itself or that the concept of familiarity can be applied to environmental risk assessment.

Instead, GM plants should be subjected to a risk assessment 'per se' that starts with a broad range of data concerning the regulation of the inserted additional genes and its interactivities with the plants genome, its metabolism and its reaction to confined stress reactions.

Acknowledge and define scientific uncertainty
It is a first step in the right direction that the guidance requires applicants to express uncertainty with respect to the risks of the cultivation of GM crops. However, the EFSA document does not describe any concept for how to assess and qualify these uncertainties

[1] see Figure 1, p.11 and Chapter 2.1, p.12-13 of the Guidance

and their consequences in the overall risk assessment. Such guidance would be crucial, as there are many unknowns, i.e. unexpected pathways and components in the plants or unexpected toxicity to organisms. It is important that these uncertainties are addressed properly to enable the Commission to apply the precautionary principle as required by EU law.

Define reasons for rejection
The guidance lacks clarification under what conditions a GM crop will be rejected on environmental safety grounds. For instance, if the persistence of a GM crop is not taken into consideration, it would make it extremely difficult to recall this GM crop if something goes wrong. The guidance should define as reason for rejection if genetically engineered plants are showing pattern of persistence and / or invasiveness and cannot be recalled. In addition, unsustainable methods of cultivation intrinsically linked to a particular type of genetically engineered plant have to be defined as a reason for rejection of the market application.

Sound assessment of combinatorial and synergistic effects
According to the guidance document, combinatorial and synergistic effects, e.g. of different toxins produced by a GM plant or of different herbicides, do not have to be investigated. Empirical testing of these effects before any release is considered should be mandatory. Synergistic effects cannot be predicted from the properties of the single substances, that is why combinatorial effects have to be tested in empirical testing. Further, a closer interplay with the assessment of pesticides, its residues and additives have to be established. If the plant produces pesticides (e.g. insecticides), reliable and comparable methods have to be defined and made available in order to determine its content in the different parts of the plants and in the environment.

Full assessment of stacked events
Each so-called stacked event - GM crops combining different genetically engineered traits, e.g. tolerance to several herbicides and/or producing several pesticides – should be treated as a new application and should undergo a comprehensive risk assessment including empirical tests for combinatorial effects. So far EFSA is basing its risk assessment mainly on consideration based on the assessment of the single genetically plants that were used to create stacked plants. This ignores the fact that synergistic effects (for example between insecticidal toxins produced by the plants and the residues stemming from the application of herbicides) cannot be predicted. Further, the risk assessment of the single genetically engineered plants will always leave uncertainties and cannot be regarded as a sufficiently safe basis for all subsequent combinations of these plants.

Comprehensive assessment
Concerning risks for non-target organisms at all levels in the food web, such as soil organisms, insects, aquatic organisms and red list organisms and wildlife species, have to be included. It is not sufficient to reduce the risk assessment just to some low levels of the food web (so called tiered approach) and then conclude that other levels do not need further investigations. Furthermore, long-term effects and accumulative effects have to be fully integrated into the risk assessment.

2. Allowing independent testing
Transparency and availability of data
A clause should be included into the guidance ensuring that EFSA makes raw data submitted by the applicants transparent and publicly available, in a form that allows further statistical analysis. It also has to be mandatory that applicants give full access to material needed for additional, independent research before the EFSA has finalised its opinion.