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Testbiotech comment on EFSA´s draft Guidance for environmental risk assessment of genetically engineered animals

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EFSA´s Guidance suffers from a major imbalance between factual risks and the risk assessment as proposed - there is no general framework for risk analysis of genetically engineered animals

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Testbiotech comment on: *EFSA (2012) draft Guidance on the environmental risk assessment of genetically modified animals EFSA Panel on Genetically Modified Organisms (GMO), Available online: www.efsa.europa.eu/efsajournal European Food Safety Authority (EFSA)*

1. Terms of reference as provided by the European Commission and scope of the draft Guidance

Any guidance on risk assessment of genetically engineered animals must be incorporated in an overall framework of *risk analysis*, integrating aspects of ethics, interests of consumers, the future of agriculture and specific issues of animal welfare.

Animals are emotionally sensitive living beings and as such protected by animal welfare regulations. Therefore, introducing genetically engineered animals to the markets cannot be done in the same way as, for example, genetically engineered microorganisms.

Opinion polls show that genetic engineering and cloning of animals for food production is a very delicate area that deserves special attention. Many people object to the idea generally of genetically engineering vertebrates to meet economic interests in food production or for fanciful purposes.

Genetic engineering interferes with the integrity of the animals on several levels; the integrity of the genome, of the cell, of the individual animal and the overall population. Especially in regard to vertebrates, the ethical debate must not only be about issues of animal welfare, but also take into consideration the integrity of the intrinsic value of animals. To which extent these ethical questions are considered in existing animal welfare legislation has to be discussed in detail before any genetically engineered animals might be allowed to enter the market.

It is beyond the mandate of EFSA to deal with these questions. The overall *risk analysis* has to be performed by the *risk manager* (the political decision making bodies, especially the EU Commission) thereby integrating ethical and socio-economic issues. However, before the draft Guidance is discussed in further detail, one should first have a look at the overall framework of *risk analysis* and determine how to integrate the various aspects, and what implications this will have for actual *risk assessment*.

By taking a look at current *risk analysis* practice for genetically engineered plants, it is evident that so far risk assessment and important aspects of risk management such as ethics and socio-economic questions are not well harmonised. In general, socio-economic questions and ethics are – if at all – only considered at a late stage in the process of risk analysis. The whole process is mostly driven by the level of *risk assessment* and does not give sufficient weight to other crucial issues. That is why Testbiotech has already proposed developing an integrated approach of *risk analysis* for genetically engineered plants in order to bring together the various elements at a much earlier stage in the process (http://www.testbiotech.de/sites/default/files/Testbiotech_Consultation_Commission.pdf).

Since animals are – at least from an emotional and ethical point of view – a much more sensitive issue than plants and microorganisms, the overall process of risk analysis cannot be driven by risk assessment. Ethics, socio-economic aspects and participatory decision making involving the perspective of the consumers are issues that will gain much more weight in this context. These aspects should be accepted as the main driving elements during any authorisation process. This will also affect the requirements of *risk assessment* as, for example, in deciding at which stage animal welfare issues come into play and which criteria have to be applied.

The Commission asked EFSA to prepare a Guidance as far back as 2007. The Commission, however, has never managed to identify the essential elements of an overall *risk analysis* process for genetically engineered animals. In addition, crucial issues relating to the cloning animals for food production still need to be resolved.

Based on this observation, EFSA should not adopt any guidance for the *environmental risk assessment* of genetically engineered animals before the risk manager has done his job, which is to develop an overall framework integrating all aspects of a proper *risk analysis*.

To start by adopting guidance on *risk assessment* as an isolated element would send the wrong signal to markets and the general public. Such an initiative would not mirror the concerns of civil society groups, consumers, farmers and food producers. In this scenario, EFSA might even be held responsible for failures that are within the remit of the Commission.

All in all this draft Guidance touches on highly emotional issues affecting basic interests of consumers, farmers, food producers and general society. At stake are not only basic questions concerning our relationship with mammals and other vertebrates. Civil society should be positioned to be the driving factor in the introduction of new technologies that will so widely affect consumers and food production. EU citizens should not repeatedly be at the mercy of particular economic interests.

Besides the debate on ethical and the socio-economical issues, there is another major issue that has to be reiterated when it comes to the scope of this draft Guidance. Many of the aspects discussed here are not related to food production issues, such as the release of genetically engineered insects. As such, these issues are outside of the EFSA mandate and should not be dealt with by the Food

Safety Authority, but by another EU body, as for instance, the European Environment Agency (EEA).

2. Strategies for the ERA of GM animals

There is major discrepancy between what is described under risks that have to be taken into account during risk assessment (chapter 4) and the specific means and tools as discussed under the *strategy* of ERA and *cross cutting issues*. If these discrepancies are not addressed properly, the final Guidance will claim some degree of certainty and safety that is not based on factual scientific evidence.

Many of the risks described are multi factorial, nonlinear and emergent therefore they cannot be assessed and predicted by applying the existing strategies for risk assessment. Especially the comparative approach is likely to fail in the light of the risks described in chapter four.

Even more than plants, animals have to be considered as heterogenous organisms, they can be described as an ecological system of their own. Animals live in symbiosis with various microorganisms, in addition they can become infected by broad range of viruses, bacteria, parasites and fungi . A further level of complexity is their immune system that is influenced by a broad range of external and internal factors. Animals can move and are exposed to many different environmental conditions that are not limited to sites used for agricultural production. The genetic variation within most animals is higher than within high yield crops used in industrial agriculture. Thus unintended effects can emerge from molecular effects, from specific climatic conditions, special food uptake, infections, changes in the endosymbionds fauna and changes of behaviour. All these factors and their interdependencies can render unintended effects that will hardly be detected by following a comparative approach that was established to investigate only a limited number of criteria under a limited range of conditions.

The approach of comparative risk assessment is very much influenced by the DNA centered paradigm of the last century that tries to predict effects in the cell or in organisms and even on the level of ecosystems on the basis of genomic structures. Many of the risks and effects that can be expected in this context are far beyond what can be investigated on the level of the DNA or its products. In the light of recent knowledge about cell biology, including epigenetic, epistatis and pleiotrophic effects (none of them are mentioned in this draft Guidance) and in awareness of many genome x environment interactions, the reductionist model of comparative assessment is no longer adequate.

Comparison should be regarded as just a tool, but no longer as a concept. Much more specific strategies and methods such as screening for metabolic and genetic activity have to be applied at an early stage of risk assessment to develop reliable hypotheses for the following steps of risk assessment.

A crucial point in the strategy of environmental risk assessment that should be taken into account as a starting point is the question of whether a genetically engineered animal can be controlled in its movements and/ or if it is likely to be persistent or even if it can become invasive. These risks are considered in chapter four, but not enough weight is given to it in the risk assessment strategy. There should be a clear decision making tree within the strategy of environmental risk assessment that integrates this issue. If it is known that a genetically engineered animal cannot be controlled in

regard to its persistence and/ or its movements and thus cannot be swiftly be withdrawn if necessary from the environment , prevention has to be applied, the application has to be rejected and no detailed risk assessment performed.

3. Long-term effects and analysis of uncertainty

The draft Guidance does not give adequate advice on how to address limits of knowledge. While the draft Guidance proposes that uncertainties have to be expressed, the factual limits of knowledge are not integrated within the ERA. Categories of knowledge/ non-knowledge (Boeschen et al., 2006) go beyond the ones of uncertainties. While uncertainty mostly reflects gaps within the strategies and methods being applied for the risk assessment, limits of knowledge can also be used to judge the suitability of the strategies, approaches and methods.

Thus, the categories of knowledge /non-knowledge should be addressed on the molecular level as well in regard to the animal and its internal ecology, further on the interactions between the animal with the environment, with biotic and abiotic factors, target and non target organisms, the quality of food etc. This could help to identify the gaps between the risks as described in chapter four and the strategies and methods for risk assessment that are actually available, and give some indication of whether precautionary or preventive measures need to be applied.

Another reason why the limits of knowledge should be properly indicated is the necessity of obtaining a better understanding of methods, approaches and strategies that need to be developed in future.

In general, identified categories of knowledge and non-knowledge, uncertainties and possible long term effects have to be put in context with the precautionary principle, which is the underlying basis of Directive 2001/18. This most relevant principle is not mentioned in the dossier at all. The high degree of complexity, the factual gaps between potential risks and the available strategies and methods, all go to show that precaution must have priority.

Instead of referring to the precautionary principle, EFSA places some emphasis on standard operating procedures (SOPs) that might come into effect if something goes wrong. For example, in line 4360 it is proposed in the context of health risks posed by genetically engineered insects:

> *"when the risk of emerging pathogen(s) is identified, or when in the case of malfunctioning of the GM release technology, implementation of specific standard operative procedures (SOP) to prevent the possible hazard caused by these agents might be required."*

However, any SPOs applied at a stage when the risks of emerging pathogens are already identified might no longer be effective. Thus, the precautionary principle has to be addressed consistently on all levels of risk assessment and the limits of knowledge have to be identified.

References:

Boeschen S., ,Kastenhofer, K., Marschall, L., Rust,I., Soentgen, J., Wehling, P., 2006, Scientific Cultures of Non-Knowledge in the Controversy over Genetically Modified Organisms (GMO) The Cases of Molecular Biology and Ecology, GAIA 15/4: 294 – 301