

7. Sept. 2007

I wanted to share information that could be helpful in efforts to counter allegations made by Seralini et al. I've attached excerpts from the 2006 CGB report (French biotech competent authority)

The text includes Seralini's criticism of the regulatory system, and Gerard Pascal's pointed response. Both of them were members of CGB.

[http://www.ogm.gouv.fr/experimentations/evaluation\\_scientifique/cgb/CGB.htm](http://www.ogm.gouv.fr/experimentations/evaluation_scientifique/cgb/CGB.htm)

Best regards,  
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**Gilles-Eric Séralini**

[http://www.criigen.org/index.php?option=com\\_content&task=view&id=57&Itemid=35](http://www.criigen.org/index.php?option=com_content&task=view&id=57&Itemid=35)

## **Personal contributions to the activity report 2006**

### ***CRITICISM AND POSSIBLE IMPROVEMENTS IN SANITARY EVALUATIONS OF DIETARY GMOs***

Like many scientists and citizens, I do not believe either in the effectiveness or the sufficiency of dietary evaluations of GMOs, as practised today, particularly by the CGB (French Biomolecular Engineering Commission). Their scientific logic is, according to me, subject to several questions that I will try and summarise here.

As a preamble, in 2006 the sanitary and environmental evaluations of GMOs are within the area of competence of the CGB even if agencies such as the AFSSA (French Food Safety Agency) or EFSA have similar mandates or partly overlap. Furthermore, the CGB was made aware of these questions by the authorities, NGOs or individuals, and must therefore respond to them.

In addition, it happens that the CGB is held responsible by the authorities only for the environmental risks of a GMO file. The environmental risk files often contain studies on insects: we fail to understand why they do not include studies on birds or mammals, for example. These animals are as susceptible, in the wild, to consuming or carrying these GMOs. Some may consider that this must be reviewed in the sanitary risks file, but one does not prevent the other, and any split-up of files that is too arbitrary, largely favours errors or oversights.

## 1. The case of experimental plant GMOs

In the fields, total isolation is not possible. Even if all precautions for large separation of cultures are taken, phenomena are inevitable over time: involuntary spreading of pollen or seeds, not only during cultivation, but also during transportation, planting, by machines used for processing, crops, or during storage, handling, burying of vegetable remains, without considering the exudate of roots and unforeseen interactions with the soil and its organisms, or the untimely transport by various animals.

These field GMO tests may concern new transformations corresponding to two characteristics mainly marketed worldwide, whether they are combined or separate in the same organism: the tolerance to a herbicide, on the one hand (or even to two herbicides), and the production of one or two insecticides in the plant, on the other. These GMOs can thus contain pesticide residues with effects not investigated in food, new toxins; or even for others to produce proteins conferring the plant with new traits. For these tests, *in vitro* tests, as well as high toxicity tests with recombinant toxins administered *in vivo*, could be progressively required over the years, instead of providing immediate multi-annual authorisations.

The CGB can thus actually propose authorisations for years without studying toxicity tests with a scientific protocol worthy of the name for the experimental GMOs, which, according to me, is insufficient.

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*Two precautions, moreover, are quite difficult to implement:*

(A) Require the reading and the results for the Commission of all that the applicant has manufactured in other countries. It may thus happen that a marketing file of a GMO has been registered in the United States for example, while it is still experimental in France; and yet a marketing file must contain suitable toxicity tests.

It is regrettable that the CGB does not demand access to all the existing data on a GMO before authorising it in an open environment, even experimentally. The monitoring of cultures in other countries where experimental authorisation is already granted, if applicable, must also be provided, as is the case of consumption of pesticides, forming part of the environmental risk, in my opinion.

(B) Require the description of the precise detection method of the experimental GMO in question, owned moreover generally by the person who has created the GMO. This method could be used for monitoring neighbouring crops or nearby silos, on request from concerned farmers or authorities, in order to look for possible contaminations.

Thus, the CGB could actually verify the effectiveness of relative isolation measures that it recommends, and reassure the agricultural environments, if necessary.

These are currently and since the last twenty years completely in the dark regarding contaminations by experimental GMOs; no laboratory (independent of authorities ordering the dispersals) can respond to this in case of a doubt; on the other hand this department exists for marketed GMOs.

The quantity of tests has however been important. The CGB will have to at least avoid being favourable to authorisations of several different GMOs not characterised in the same field, and encourage greenhouse tests.

## 2. The case of GMOs in marketing request.

In 2006, after eleven years of cultures, the statistics of the ISAAA (International Service of the Acquisition of Agri-biotech Applications) once again forecast that almost 100% of marketed GMOs in the environment are plants tolerating or producing one or more pesticides.

For most of them, these GMOs thus contain new pesticide residues and all their metabolites, in a plant organism that would not usually contain them, if not modified. The approval of GMOs must not be used to by-pass more restrictive inspections of pesticides on health.

Here again, the complete toxicity file of the GMO with the associated pesticide residues must be available and be circulated to all the concerned committees.

This is currently not the case. Moreover, the raw data (blood analysis of animals that have consumed the GMOs, for example) must not be accepted by the authorities if they cannot be regarded as public, as no manufacturing industrial secret is involved; the more the scientific assessment of these data will be open, the more complete it will be, particularly with regard to statistical processing methods that need to be significantly improved. This will be proposed additionally.

The toxicity tests for GMOs containing pesticides can be extended beyond 90 days and carried out on several types of laboratory mammals; there is no reason that seems valid to me for their disregarding the same type of tests required for pesticides and medicines. These longer tests are known as chronic toxicity tests and can last two years, which corresponds to the essence of the life expectancy of rat strains generally used in laboratories.

The GMOs must then be present at doses that are normally edible in a balanced diet, while studying hormones and other reproduction parameters, such as the physiology of animals in gestation and development. The prior *in vitro* tests must be examined, in order to ensure, for example, that the various modified Bt insecticide toxins are put into contact with human cells, as will be the case in the digestive system.

Their degradation cannot actually be complete, like for all organic substances, in every alimentary bolus. The reputation of harmlessness or specificity of Bt toxins newly modified in the GMOs, which is often mentioned, is greatly exaggerated, and is not based on any solid scientific documentation in mammals.

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Finally, our disagreement is strong within the committees on the interpretation of results significant for modified blood or organic parameters in animals that have consumed the GMOs, with respect to their closest control animal. Some would like to neglect them on the pretext that they are at times neither durable, nor proportional to the dose of the GMOs in the diet. They are also not comparable between males and females. To me this seems a serious error. Firstly, only two GMO doses generally exist in tested diets: 11 and 33% for example. Two points have always been insufficient to characterise a dose-response effect, so much so that no prior formulation has been claimed for the choice of these doses. Next, the reversibility of an effect (such as the stage for promoting cancerous cells) has never been *a priori* a surety of non-gravity, and finally a hormonal action, such as those that we observe with certain pesticides, for example, is

very often variable according to the sex. This reasoning will also be detailed and clarified, with the support of GMO assessment examples.

The purpose of all these considerations is to provide better human food and meat safety, as well as to do away with a fruitless debate and adopt a more demanding and transparent scientific approach.

## Answer to Seralinin by Gérard Pascal

[http://www.agrobiosciences.org/article.php3?id\\_article=0650](http://www.agrobiosciences.org/article.php3?id_article=0650)

We must thank G.E. Séralini for his contribution which, without any doubt, will help the evaluation methodology for sanitary safety of food and particularly dietary GMOs to progress.

This had actually slipped the several hundred scientists all over the world who have for about 15 years examined the various possible approaches and published several recommendations, that

G.E. Séralini's proposals, which are actually quite simple, could make us progress as much in this evaluation.

These scientists, who have devoted their careers as researchers and experts, in improving the sanitary safety of food and their constituents and the methodologies for their evaluation, emanate from various horizons, have different but complementary abilities, which allow them to adopt an integrated approach to questions. They have exercised their expert activities in action groups for example within the OECD, of the FAO and the WHO, scientific committees of the European Commission and the EFSA as well as the CSHFP (French Higher Public Health Council) and AFSSA in France. For all that relates to the results of their work, I will refer only to the most recent contribution of the GMO panel of the EFSA that has opened for discussion on the Internet

<http://www.efsa.europa.eu/fr/science/Kmo/>

[Kmo\\_consultations/gmo\\_AnimalFeedirtgTrials.html](http://www.efsa.europa.eu/fr/science/Kmo/_consultations/gmo_AnimalFeedirtgTrials.html) at the end of 2006, a consistent report on the use of animal experimentation to evaluate GMOs.

This report, which results from the work of a group of 18 persons for almost 2 years, has been the subject of age-old criticisms of G.E. Séralini who is impervious to any scientific argumentation, as if he suffered from a certain type of deafness.

This is probably why he does not explain himself blindly to this scientific community, which refuses, for several years now, to recognise the relevance of his proposals, except for concluding that they are all incompetent, which is serious, or, which is even more serious, that they all lack impartiality, independence and even integrity.

Will he be finally heard? Frankly I don't think so: he is not in close contact with the specialised collectivity, he does not seem to know all the published literature, all the researches carried out and all the current work. I would like to believe that it is only this ignorance that allows him to affirm that those who belong to this group pursue a science that is not too demanding and not very transparent.

Finally, it would be good for G.E. Séralini to update his knowledge on these tasks and current responsibilities of French authorities and particularly the AFSSA, in the field of evaluation of the safety of GMOs and now pesticides.

Gérard Pascal

OECD: Organisation for Economic Cooperation and Development

FAO: Food and Agriculture Organisation of the United Nations

WHO: World Health Organisation

EFSA: European Food Safety Authority

CSHPF: French Higher Public Health Council

AFSSA: French Food Safety Agency

Biomolecular Engineering Commission