anses
French agency for food, environmental and occupational health & safety

Press Kit

A presentation of ANSES's Opinion following its analysis of the study by Séralini et al. (2012)

"*Long term toxicity of a ROUNDUP herbicide and a ROUNDUP-tolerant genetically-modified maize*"

22 October 2012

Maisons-Alfort, 22 October 2012

Press Release

**ANSES highlights the weaknesses of the study by Séralini *et al*.,
but recommends new research on the long-term effects of GMOs**

ANSES was requested by the French Government to examine the paper by Séralini *et al.* published on 19 September 2012. The collective expert assessment carried out by the Agency concluded that the results of this research do not cast doubt on previous regulatory assessments of NK603 maize and Roundup. However, ANSES emphasises the small number of published studies dealing with the potential long-term effects of the consumption of GMOs in association with pesticides and recommends undertaking research into these issues. In addition, the Agency calls for national or European funding to enable large-scale studies and research for consolidating our knowledge of insufficiently documented health risks.

After the publication on 19 September of a study by Séralini *et al*. on the long-term toxicity of the plant protection product Roundup and the genetically-modified, "glyphosate-ready" NK603 maize, ANSES received requests from the Ministers for Health, Ecology, Agriculture and Consumer Affairs to examine the article.

The expert assessment carried out by the Agency concludes that the results of this research do not cast doubt on the previous assessments of genetically-modified NK603 maize and Roundup.

In addition to the criticism already expressed by other bodies concerning the methodology, and based on the in-depth assessment that it has itself undertaken, ANSES considers that the study's central weakness lies in the fact that the conclusions advanced by the authors are not sufficiently supported by the data published. These data do not make it possible to scientifically establish any cause and effect relationship between consumption of the GM maize and/or the pesticide and the pathologies mentioned, nor to support the conclusions drawn by the authors or the mechanisms of action they suggest.

ANSES draws attention, however, to the originality of this study, namely its focus on a subject rarely investigated to date: the long-term effects of GMOs in association with plant protection products.

This concern reflects ANSES's desire to contribute to improving regulatory risk assessment whenever necessary, in order to keep abreast of the constant developments in scientific knowledge and technology.

It was with this in mind that, in 2011, the Agency issued an Opinion recommending more rigorous conditions for carrying out the studies required in the context of applications for authorisation of GMOs, and proposing a very strict methodology for the analysis of data. A draft European Regulation incorporating ANSES's recommendations is currently being finalised and was submitted to the Member States in the spring of 2012.

Regarding plant protection products, ANSES has made a considerable effort to ensure that the European guidelines more effectively take into account the cumulative effects of active substances. These changes are currently being incorporated into the European assessment criteria with the intention of extending them to include the accumulated effects of combinations of active substances and co-formulants.

In addition to the current efforts to reinforce the regulatory framework, a review of the literature and the expert assessment identified only a few studies on the potential long-term effects of the consumption of GMOs together with pesticides. In fact, the Agency was only able to find two other studies which covered the entire lifetime of the subject animals.

With these points in mind, ANSES recommends initiating studies and research on the long-term effects of GMOs in combination with plant protection products. Public funding should be made available for these studies, which should be carried out using precise investigation protocols. ANSES is willing to work together with other partners, including other European health and safety agencies, in order to draw up the general principles for such study protocols.

The issue of public funding for studies and research is of particular relevance in a context where scientific publications can have a wide range of origins: on the one hand, regulatory studies funded by industry and on the other hand, publicly-funded research, with more limited resources and for which the research priorities do not necessarily include an investigation of potential health effects which have only been rarely studied to date. This situation is by no means restricted to GMOs: there are several other areas marked by an equal lack of scientific knowledge and a particularly strong public desire for independent, publicly-funded research.

To address this situation, ANSES calls for public funding on the national and European level to enable large-scale studies and research for consolidating knowledge of insufficiently documented health risks, similar to the National Toxicology Program implemented in the US.

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The approach taken by ANSES

In response to this Request, ANSES set up an emergency collective expert assessment group (ECEAG) of experts from a range of disciplines, bringing together 10 scientists from a number of ANSES's collective expert assessment groups, which had recently been renewed. The ECEAG possesses expertise in a variety of fields including biotechnology, toxicology, plant metabolism, biostatistics, and plant protection substances.

The study examined by the Agency as a result of this Request had been carried out in a context of experimental research and could therefore not be strictly compared with regulatory studies submitted for the authorisation of a product or substance.

In its analysis, ANSES took care to place this publication and the results advanced by the authors in a broader context. The Agency sought to identify, in the scientific literature, other similar studies attempting to identify possible long-term effects of genetically-modified plants, presenting the same type of genetic modifications as the plant in question. These publications were analysed in parallel with the study by Séralini *et al*.

Furthermore, to contribute to its analysis, the Agency interviewed Mr Séralini and some of his co-authors so that they could present their work and provide the Agency with certain additional clarifications. The Agency also heard testimony from the "Générations Futures" association and received a written contribution from Monsanto.

Following his interview, Mr. Séralini sent ANSES raw data on the mortality of the experimental animals and the onset of non-regressive tumours, but without distinguishing the nature of the tumours.

Alongside its literature review, ANSES also undertook a statistical analysis of these data.

How are GM organisms regulated?

GMOs are covered by **two principal European regulations:**

- Directive 2001/18/EC on the **deliberate release into the environment of GMOs** applies to 2 types of activity:

- the experimental dissemination of GMOs into the environment (for example for field trials);
- the marketing of GMOs, for example the cultivation, importing or processing of GMOs into industrial products.

- **Regulation (EC) 1829/2003 specifically regulating GMOs for food and feed** or as potential ingredients in food products. This text regulates marketing authorisations for food and feed of all GMO-based products. It governs how these products are assessed, authorised and labelled.

GMOs

Genetically modified organisms (GMOs) are organisms or microorganisms whose genetic makeup has been transformed in a way that does not occur naturally by mating and/or natural recombination.
This technique, called **genetic engineering**, transfers selected genes from one organism to another, sometimes between different species. It therefore offers the potential of introducing one or more genes conferring new characteristics into the genetic makeup of an organism. The transferred genes can come from any type of organism due to the universal nature of the genetic code. This technique may be applied to microorganisms, plants and animals.

European-level assessment

Before GMOs can be brought to market they undergo an assessment which, for its health aspects, must demonstrate the safety of the GMO compared with a conventional product. European legislation requires that companies submit an application for marketing authorisation including the necessary information for a scientific risk assessment to determine the safety of the GMO and of the derived food or feed. Once the assessment is complete, authorisation of the GMO first depends on the votes of the 27 Member States, after which the European Commission publishes its decision in the EC's Official Journal.
In compliance with Regulation (EC) 1829/2003, the European Food Safety Authority (EFSA) is responsible for assessing marketing authorisation applications for GMOs.
Every marketing authorisation application submitted by a company (exactly as for medical products), must include scientific information enabling the product to be characterised and proving that it satisfies the requirements of European regulations.
Since 2003, EFSA has invited Member States to submit their comments on these applications.

The role of ANSES

At the request of government ministries, ANSES continues to supply its expertise with a view to informing government decisions during the voting by Member States on whether or not to grant marketing authorisation in Europe for GMOs for use in food or feed.

The Agency's Opinions only concern GMOs and their products intended for use in food or feed. Authorisation for cultivation is assessed by the French High Council for Biotechnologies.
On the basis of the opinion issued by the Agency, the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) transmits France's comments on the applications to EFSA, which analyses the comments of all the Member States, before issuing its own opinion.

ANSES, along with other European agencies and in collaboration with EFSA, contributes to the drafting and updating of guidelines for manufacturers. As soon as a new study is published in the scientific literature, the Agency identifies and examines it to determine whether the new information it provides should be taken into account in the continuing adaptation of GMO assessment conditions.
In 55% of the cases examined concerning genetically-modified plants, the Agency considers that the applicant has submitted insufficient data to enable a conclusion to be drawn on the health issues related to consumption of the GMO in question.

ANSES, driving improvement in GMO assessment methods

Starting in 2002, the Agency contributed significantly to reinforcing the requirements that industrial applicants had to satisfy (in terms of data and tests), by identifying the sensitive aspects of health risk assessments related to the consumption of GMOs. ANSES was the first to reveal the existence of accidental contamination of conventional seeds by GMOs, thus paving the way for national and European discussions on this sensitive issue. The Agency was the first in Europe to consider adapting the protocol for 90-day oral sub-chronic toxicity studies to GM plants.
In addition, the Agency issued an opinion on the techniques for statistical analysis of the data from this study which resulted in the establishment of recommendations for the implementation of protocols and analytical methods to apply in order to ensure accurate results.

ANSES and HCB, what scope of action?

In June 2008, under French Act 2008-595 concerning genetically modified organisms, the High Council of Biotechnology was created. The mission of this body is to *"inform the Government on all issues relating to genetically-modified organisms and any other biotechnology, and to issue opinions relating to the assessment of risks for the environment and public health which may be posed by the contained use or deliberate release of genetically-modified organisms, and opinions relating to biological monitoring of the national territory."* These provisions apply without affecting the jurisdiction exercised by the Agency.

How are plant protection products regulated?

The assessment of plant protection formulations and the active substances they contain is strictly regulated and harmonised at European level[1]. The process requires two phases:

⇒ a **first phase**, carried out jointly by EU Member States, involves identifying the hazards of **active substances** and assessing the risks related to a reference product, with a view to ruling on whether or not these substances should be approved in Europe.

⇒ the **second phase**, for approved active substances, consists in assessing the agricultural benefits and the risks related to commercial **preparations**.

Plant protection products

Plant protection products are formulations designed to protect plants and harvested crops. They are a category of pesticide that also includes biocides and parasite control products for human and veterinary use. Plant protection products are intended to protect plants against all harmful organisms, or to prevent these from acting; they can affect the vital processes of plants (insofar as they are not nutritive substances), assist with storage of plant products; destroy undesirable plants; destroy parts of plants, retard or prevent the undesirable growth of plants.
Each formulation is composed of one or more active substances (which give the plant protection product its properties) and substances known as co-formulants. The purpose of these is to give the formulation the appropriate form for application. For example, they may act as foam suppressors, or as diluting or wetting agents.

Assessments are carried out separately in three different geographical zones (North, Centre and South), in order to take account of the specific conditions of each region, such as type of crops or climate. France belongs to the South zone, along with Bulgaria, Greece, Spain, Italy, Cyprus, Malta and Portugal. Within a given zone, manufacturers seeking authorisation for a plant protection formulation may submit their application with any Member State in the zone. The assessment carried out by the Member State is then applicable to all the other countries in the zone.

The assessment procedure

In France, applicants submit a marketing authorisation (MA) dossier to ANSES's Regulated Products Department. To investigate the application, ANSES:

- examines the data supplied and verifies their scientific validity as well as their compliance with regulatory requirements;
- assesses the agricultural risks and benefits related to the use of the formulation.

The investigation is carried out in accordance with the collective expert assessment principles applied by ANSES. When it is complete, the conclusions of the assessment, in some cases together with recommendations for management measures, are laid out in an Opinion.

[1] By Regulation (EC) 1107/2009, replacing Directive 91/414/EEC, in force until June 2011

Conclusions relative to the acceptability of risk refer to the criteria indicated in Regulation (EU) 546/2011[2]. They are expressed as either "acceptable" or "unacceptable", with reference to these criteria.

The Directorate General for Food then uses the ANSES Opinion to decide whether or not to grant an MA or any modification of a current MA. An MA is issued when, under normal conditions of use associated with good agricultural practice, the formulation is deemed effective and free of unacceptable affects on human or animal health or the environment. The decision concerning MA details:

- the crop(s) targeted by this treatment,
- the pest(s), disease(s) or weed(s) targeted,
- the dose, period and frequency of application for the formulation, and any other agricultural practices associated with the treatment,
- restrictions concerning the conditions of use and management measures.

It should be noted that active substances and their associated formulations must be reassessed systematically according to a schedule laid down in Regulation (EC) 1107/2009.

[2] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.