

COMMISSION EUROPÉENNE  
EUROPEAN COMMISSION  
EUROPÄISCHE KOMMISSION

DE / FROM / VON           NOVAK Nina (SANTE)  
À / TO / AN                +41584629981  
POUR / ATTN / Z. HD.    : 0041584629981  
  
DATE / DATE / DATUM    : 1/14/2016           11:10:21 am  
RÉF / REF / ZEICHEN    : 304772

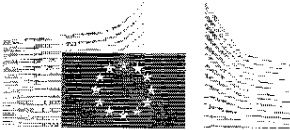
Nombres de pages (page de garde incluse)    **3**  
Number of pages (including this cover sheet)  
Seitenzahl (einschließlich Deckblatt)

OBJET / SUBJECT / BETREFF :

Pour répondre à ce fax, veuillez utiliser uniquement le numéro de votre correspondant. En cas de problème technique, vous pouvez appeler le numéro général (tél. +32 (0)2 299 11 11).

To reply to this fax, please only use the number of your correspondent. Only use the general contact number (tel. +32 (0)2 299 11 11) when a technical problem arises.

Antworten auf dieses Fax bitte ausschließlich an die Nummer des Absenders. Bei technischen Problemen wenden Sie sich bitte an die Zentrale (Tel. +32 (0)2 299 11 11).



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for the Food Chain

Brussels, 13/11/2016  
SANTE/E1/MK/ sante.ddg2.c.1(2015) 6193677

ARES (2016) 185 335

Dear Mr Oberle,

**Subject: Environmental Risk Assessment of herbicide-resistant genetically modified plants**

I would like to thank you for your letter of 6 November 2015 and for the position paper on the impacts of herbicide-resistant genetically modified plants on biodiversity. I have been informed that the same letter was also sent to Mr J. Plewa, Director General of DG Agriculture and Rural Development. Please consider this reply as a reply to that letter as well.

In your letter you state the need for a comprehensive, meaningful and scientifically sound environmental risk assessment of herbicide-resistant GM plants. As you are aware, according to Directive 2001/18/EC, the environmental risk assessment of GM plants forms an integral part of the authorisation process of GM plants in the EU. The requirements for environmental risk assessment of GM plants in the EU legal framework have been designed to take into account the potential immediate or long term, indirect as well as cumulative effects on the environment as a result of several factors, including the changes in management practices.

In your letter you also state the issue of the interplay between the GMO and pesticide legislation and you propose to keep the assessment of the environmental risks due to changes in management practices of herbicide-resistant GM plants within the GMO legislation, in the context of updating the annexes to Directive 2001/18/EC based on the updated EFSA guidelines from 2010. On this issue please note that in the 2008 Environment Council's conclusions the Council *emphasises the need for competent authorities involved with the implementation of Directive 2001/18/EC and of Regulation (EC) 1107/2011 concerning the placing of plant protection products on the market, within the Commission and at national level, to co-ordinate their action as far as possible*. In line with this conclusion, the Commission is considering how the issue of interplay may be addressed in the proposed amendments. Let me reassure you that no matter what the final decision will be, the direct and indirect effects of GM plants will be assessed accordingly, as will the use of any plant protection products (PPP) on such plants.

Bruno Oberle  
Chair of the Joint EPA ENCA Interest Group  
on Risk Assessment and Monitoring of GMOs  
c/o Federal Office for the Environment  
FOEN  
CH-3003 Bern

In your letter you also propose to re-evaluate the herbicide-resistant GM cropping systems with regard to their sustainability in order to prevent further adverse impacts on biodiversity. The impact on biodiversity is taken into consideration during the environmental risk assessment of GM plants. In this context, in the 2010 EFSA guidelines on the environmental risk assessment of GM plants, the applicant is requested to consider other sectorial priorities such as the biodiversity strategy even though GM plants are not explicitly mentioned.

You also mentioned the need for further targeted research on long-term, additive and synergistic effects on herbicide-resistant GM plants. The EFSA guidelines acknowledge that research studies are amongst the appropriate tools to investigate long-term environmental effects during GMO cultivation close to practice. For this reason, EFSA requests that applicants conduct appropriate desk-based studies to assess long-term environmental effects of the GM plant. In addition it is requested that the monitoring plan includes specific parts that are designed to detect possible long-term effects. Monitoring is requested throughout the duration of the authorisation while in some cases (e.g. for perennial species) it could last even longer.

In your position paper you present key messages for agriculture and consequently for the environment. Sustainability of agriculture and the use of plant protection products are considered in various pieces of legislation such as Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides<sup>1</sup>, Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<sup>2</sup>, the Common Agricultural Policy<sup>3</sup> and the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC<sup>4</sup>.

Let me reassure you that the Commission as guardian of the Treaty is working to ensure that all the steps in the authorisation process meet the strict requirements of the EU legislation and that they take into account the scientific developments in order to deliver a science-based decision making.

Yours sincerely,



Ladislav Miko

Cc by e-mail: Ms S. Juclicher, Ms D. André, Ms S. Pelsser, Ms M. Kammenou,  
Ms K. Nienstedt (DG SANTE)  
Ms H. Riemer (DG AGRI)

---

<sup>1</sup> Directive No 2009/128/EC

<sup>2</sup> Regulation (EC) No 1107/2009

<sup>3</sup> Common Agricultural Policy – basic Regulations

<sup>4</sup> Directive 2001/18/EC