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EPA and ENCA Network
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Subject: EPA-ENCA position paper entitled "Impacts of Genetically Modified Herbicide-Resistant Plants on Biodiversity"

Ref.: Your letter dated 6/11/2015 – EFSA incoming No 129321 - 24/11/2015

Dear Mr Oberle,

I would like to thank you for your letter dated 6 November 2015, received on 24 November 2015, and the supplied position paper entitled "*Impacts of Genetically Modified Herbicide-Resistant Plants on Biodiversity*" that has been prepared by an expert Working Group mandated by EPA and ENCA network. The European Food Safety Authority (EFSA) appreciates your work in this area, and has carefully read the position paper. We note that many of the scientific aspects and concerns raised and publications cited in your position paper are addressed in our environmental risk assessments (ERAs) of genetically modified herbicide tolerant (GMHT) plants for cultivation, as well as plant protection products (PPPs). ERAs of GMHT plants assess whether, and under which conditions, altered cropping and management practices associated with the cultivation of GMHT plants can: (1) reduce farmland biodiversity; (2) induce changes in weed community diversity; (3) select for resistant weeds; and (4) affect soil microbial communities. PPP ERAs consider the fate and behaviour of the pesticide active substances and the risks to terrestrial vertebrates, aquatic organisms, non-target arthropods including bees, soil macro- and micro- organisms and terrestrial non-target plants.

In line, we have prepared a response, which is structured in three parts. In the first two parts, clarifications are given on the ERA of GMHT plants and plant protection products (PPPs) performed by EFSA in the European Union (EU), respectively. In the third part, the interplay between the EU GMO and PPP legislation is briefly touched upon.

ERA of GMOs

Within the EU, the use of GMOs is regulated by Directive 2001/18/EC for their release into the environment, and Regulations (EC) No 1829/2003 and 503/2013 for derived food and feed products. According to GMO legislation, GMOs and derived food and feed products are subject to a risk analysis before they can be put on the EU market. In this process, the role of the EFSA is to independently assess and provide scientific advice to

risk managers on any possible risks that the use of GMOs may pose to humans, animals and the environment. EFSA's advice is given by its GMO Panel, assisted by working groups and the GMO Unit. The main focus of the EFSA GMO Panel lies in the evaluation of the scientific risk assessment of GMO market registration applications and the development of risk assessment guidelines.

In November 2010, the EFSA GMO Panel issued guidelines on the ERA of genetically modified (GM) plants[1], which include the evaluation of potential adverse effects of altered cropping and management practices associated with the cultivation of GMHT plants on farmland biodiversity. The guidelines recommend the use of a scenario-analysis: (1) to assess under which situations the specific cropping and management practices adopted under GMHT cropping systems may lead to greater, similar or lower adverse environmental effects than the current practices applied in conventional cropping systems they are likely to replace; and (2) to identify for which situations mitigation and monitoring may be required or not.

The scenario-analysis as proposed by the EFSA GMO Panel was applied to the ERA of soybean 40-3-2[2]. The analysis compared the environmental impact of various possible cropping and management practices, which may accompany the introduction of GM glyphosate tolerant soybean in EU receiving environments, on weed community diversity with that of the current practices applied in conventional cropping soybean systems. Based on this analysis, the EFSA GMO Panel concluded that "*The EFSA GMO Panel is of the opinion that potential adverse environmental effects of the cultivation of soybean 40-3-2 are associated with the use of the complementary glyphosate-based herbicide regimes. These potential adverse environmental effects could, under certain conditions, comprise: (1) a reduction in farmland biodiversity; (2) changes in weed community diversity due to weed shifts; (3) the selection of glyphosate resistant weeds; and (4) changes in soil microbial communities. The potential harmful effects could occur at the level of arable weeds, farmland biodiversity, and food webs and the ecological functions they provide. The magnitude of these potential adverse environmental effects will depend on a series of factors, including the specific herbicide and cultivation management applied at the farm level, the crop rotation and the characteristics of the receiving environments*".

The EFSA GMO Panel anticipated that "*the repeated use of glyphosate at recommended application rates on soybean 40-3-2 grown either in rotation with other glyphosate tolerant crops, or continuously may lead to a greater risk of reducing weed community diversity than the current practices applied in soybean cropping systems. This may therefore result in reductions in weed community diversity and/or weed density to a level that might adversely affect food chains and webs, but not necessarily biological control functions, at the field and landscape level. Such reductions in weed community diversity and consequential reductions in farmland biodiversity may be considered problematic by risk managers depending upon protection goals pertaining to their region. Under such situations, the EFSA GMO Panel recommends that risk mitigation measures are put in place to manage potential herbicide effects, in order to ensure that glyphosate is used on soybean 40-3-2 in ways that result in similar or reduced adverse effects on farmland biodiversity compared with conventional soybean cultivation. Possible risk mitigation measures include reduced tillage, crop rotation, less intense in-crop weed management, protecting adjacent habitats from herbicide drift, and (re)introduction and better management of field margins and other 'out of crop' measures*".

The EFSA GMO Panel also recommended that "*risk mitigation measures are put in place to reduce the selection pressure and hence to delay the evolution of resistance. This can*

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1 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1879.pdf
2 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2753.pdf

be achieved by crop rotation (i.e., rotating glyphosate tolerant crops with non-glyphosate tolerant crops, alternating autumn- and spring-sown crops), using variable rates and timing of herbicide application, applying a variety of herbicidal active substances with different modes of action, and using non-herbicide weed control tools such as pre- and post-emergence cultivation and cover crops. To be most effective, these methods should be used in combination. A clear advantage of increasing cropping system diversity is that it would increase or conserve farmland biodiversity as well as reducing the risk of weed shifts and the evolution of glyphosate resistant weed biotypes".

With regard to post-market environmental monitoring, the EFSA GMO Panel recommended *"case-specific monitoring to address: (1) changes in weed community diversity; and (2) evolution of resistance to glyphosate in weeds due to changes in herbicide and cultivation regimes".*

The EFSA GMO Panel drew similar conclusions on other GMHT plants for cultivation for which a market registration application was submitted to EFSA (see Table 1 for an overview).

Table 1: Overview of market registration applications covering the cultivation of GMHT plants submitted to EFSA under Regulation (EC) No 1829/2003

Application reference	**Plant species**	**Transformation event**	**EFSA GMO Panel scientific opinion issued**	**Current application status**
UK-2005-17	Maize	1507×NK603	-	Withdrawn
NL-2005-22 & RX-NK603	Maize	NK603	2009[3]	Withdrawn
NL-2005-24	Soybean	40-3-2	2012[4]	Withdrawn
NL-2005-26	Maize	MON810×NK603	-	Withdrawn
UK-2006-30	Maize	59122×1507×NK603	-	Withdrawn
NL-2007-46 & RX-T25	Maize	T25	-	Revised scope excluding cultivation
CZ-2008-54	Maize	MON88017	2011[5]	Withdrawn
UK-2008-60	Maize	GA21	2011[6]	Withdrawn
DE-2008-63	Sugar beet	H7-1	-	Withdrawn
BE-2009-71	Maize	MON89034×MON88017	-	Withdrawn
NL-2009-72	Maize	MON89034×NK603	-	Withdrawn

3 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1137.pdf
4 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2753.pdf
5 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2428.pdf
6 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2480.pdf

Application reference	Plant species	Transformation event	EFSA GMO Panel scientific opinion issued	Current application status
UK-2010-84	Maize	Bt11×MIR604×GA21	-	Withdrawn
ES-2012-104	Cotton	GHB614	-	Withdrawn

I took note of your concerns about the potential adverse environmental effects associated with the cultivation of GMHT oilseed rape (including those associated with vertical gene flow and altered persistence, weediness and invasiveness), but wish to clarify that no market registration applications for the cultivation of GMHT oilseed rape has been submitted to EFSA at present. Should such an application be submitted to EFSA in the future, a consideration for the ERA of GMHT oilseed rape would be the evaluation of the potential for it to cause adverse effects on the environment from increased persistence, weediness and invasiveness in relation to the comparator(s), or through the acquisition of transgenes by sexually cross-compatible plants, as required by the appropriate GMO legislation and EFSA GMO Panel risk assessment guidelines.

ERA of PPPs

Within the EU, the approval of PPPs is regulated by the Regulation (EC) No 1107/2009 (repealing Directive 91/414/EEC) and the Regulations (EU) No 283/2013 and 284/2013, which establish the data requirements. The use of PPPs, including their environmental impact once on the market, is regulated by the Sustainable Use Directive 2009/128/EC. Regulation (EC) No 1107/2009 establishes that a PPP can be approved only if its use is safe i.e. if its use does not cause unacceptable effects to humans, animals and environment. This Regulation explicitly introduces the general protection goal for protecting biodiversity and ecosystems. Under Regulation (EC) No 1107/2009, EFSA is responsible to perform the peer review of the risk assessments of each active substance, including ERA, and to provide the Conclusion on the risk assessments to the risk managers. The peer review is based on the risk assessment performed by the responsible Member State and the dossier submitted by the applicant. This dossier should include information with respect to one or more representative uses on a widely grown crop in each zone of at least one PPP containing that active substance, demonstrating that the approval criteria of Regulation (EC) No 1107/2009 are met. The ERA includes the investigation of the fate and behaviour of the pesticide active substance in the environmental compartment soil, water body, groundwater, air, and the evaluation of the effects and of the risk to non-target organisms i.e. birds and other terrestrial vertebrates; aquatic organisms; bees and non-target arthropods; earthworms, other soil macro-organisms and micro-organisms; other non-target organisms (flora and fauna) and organisms involved in biological methods for sewage treatment. For ERA a tiered approach is followed and direct acute and long-term effects are taken into account. Tiers are characterised by an increasing complexity starting with simple conservative assessments (worst-case assumptions) towards more realistic evaluations (i.e. more realistic assumptions).

In the last 20 years, several scientific methodologies were developed and reflected in guidance documents to address first and higher tier risk assessments

(SANCO/4145/2000 for birds and mammals, SANCO/10329/2002 and SANCO/3268/2001 for terrestrial and aquatic organisms, respectively, and ESCORT2 for non-target arthropods). However, the science behind the ERA is constantly evolving e.g. more structured data, metadata and availability of tools. In this context, EFSA's role is also to revise and develop updated ERA approaches by taking into account the new scientific knowledge and the legal framework. EFSA developed several opinions and guidance documents for the ERA, including an overarching opinion to define ERA specific protection goals based on the ecosystem service concept. This opinion aimed at defining the principles for further developing ERA approaches in order to meet the general protection goal on biodiversity and ecosystems as laid down in the Regulation (EC) No 1107/2009[7]. Scientific opinions and guidance documents were already published covering the following non-target organisms: birds and mammals[8], bees[9,10], aquatic organisms[11], non-target terrestrial plants[12], non-target arthropods[13], sediment organisms[14]. Others are still on-going or to be initiated i.e. opinion for in-soil organisms, amphibian and reptiles, population modelling for aquatic organisms.

As regards the herbicidal active substance glyphosate, EFSA has recently issued a Conclusion[15] in the context of the EU renewal of the approval of this substance. The representative uses evaluated were on emerged annual, perennial and biennial weeds in all crops [crops including but not restricted to root and tuber vegetables, bulb vegetables, stem vegetables, field vegetables (fruiting vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, and sugar- and fodder beet; orchard crops and vine, before planting fruit crops, ornamentals, trees, nursery plants etc.] and foliar spraying for desiccation in cereals and oilseeds (pre-harvest), as proposed by the applicants. The outcome of the ERA for these uses indicated a high long-term risk to wild herbivorous mammals and to insectivorous birds (a data gap was identified to address risk) and the need to apply mitigation measures to manage the risk identified for terrestrial non-target plants. In addition, it was acknowledged that the indirect effects on non-target organisms via trophic interaction of extensively used herbicides such as glyphosate should be considered as an important risk management issue.

As regards the herbicidal active substance glufosinate, EFSA has issued a Conclusion[16] in 2005. The representative uses evaluated were in apple (non-selective herbicide use in conventional crops), potatoes (use as crop desiccant) and transgenic maize (use as selective herbicide). The outcome of the ERA for these uses indicated the need of further data to conclude on the risk assessment for wild mammals and the need to apply mitigation measures to manage the risk identified for terrestrial non-target plants and non-target arthropods. The Standing Committee on the Food Chain and Animal Health issued a review report[17] in support of the approval of glufosinate, in which only the use on apple orchards was considered safe. However, it was a specific provision of the approval that further studies on mammals and non-target arthropods in apple orchards needed to be submitted by the applicant. Following the evaluation of those new studies, EFSA issued a Conclusion[18] in 2012 on the data submitted to further address the risk

7 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1821.pdf
8 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1438.pdf
9 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2668.pdf
10 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3295.pdf
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13 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3996.pdf
14 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4176.pdf
15 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4302.pdf
16 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/27r.pdf
17 Review report for the active substance glufosinate finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 March 2013 in view of the inclusion of glufosinate in Annex I of Directive 91/414/EEC. SANCO/10453/2006
18 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/2609.pdf

identified for wild mammals and non-target arthropods. Overall, based on these data, a high acute and long-term risk to mammals was not excluded for the representative use in orchards and the risk was still considered as high to non-target arthropods.

Interplay between GMO and PPP legislation

Directives 2001/18/EC and 91/414/EEC, which was repealed by Regulation (EC) No 1107/2009 on 14 June 2011, are both relevant for the ERA of GMHT plants and their associated weed control management practices.

In the current legislation governing the registration of PPPs in the EU, the ERA of PPPs includes an assessment of impacts on certain non-target organisms (such as fish, *Daphnia*, algae, birds, mammals, earthworms, bees and beneficial arthropods and non-target plants) and studies of residual activities in soil and water (environmental fate). However, the ERA under Directive 91/414/EEC did not include studies of impacts on biodiversity within crops and changes in agro-ecosystems, which are required under Directive 2001/18/EC in relation to GM plants. Although an assessment of indirect effects of herbicidal active substances on biodiversity was not required for the ERA of PPPs under Directive 91/414/EEC, the new Regulation (EC) No 1107/2009, concerning the placing of PPPs on the market, explicitly mentions biodiversity as a protection goal, while Directive 2009/128/EC further supports biodiversity by promoting the sustainable use of PPPs. Therefore, such an assessment could be envisaged under the PPP legislation.

The European Commission is currently in the process of revising Annexes II and III of Directive 2001/18/EC and aims to clarify the interplay between GMO and PPP legislation to avoid duplication in assessment. Since this revision process is on-going, it remains to be seen whether the evaluation of potential adverse environmental effects of altered cropping and management practices associated with the cultivation of GMHT plants will be performed in the frame of PPP legislation in the future, instead of GMO legislation.

I hope that the information given above clarifies EFSA's role and position on the ERA of GMHT plants for cultivation and their associated cropping and management practices, as well as the ERA of PPPs in the EU, and confirms that most of your scientific concerns have already been accounted for in EFSA's work.
Please do not hesitate to contact me if you wish further clarifications. I remain available for any further enquiry you may have on this matter.

Yours sincerely,

Bernhard Url

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