EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Natural Capital
ENV.B.1 - Agriculture, Forests and Soil

Brussels, 01/06/2016
ENV/CP

NOTE TO [redacted]
DG SANTE. E.3

Subject: **REPLY FROM DG ENV.B.1 TO 3 INTERSERVICE CONSULTATIONS LAUNCHED BY DG SANTE**
ISC/2016/01312 de la DG SANTE
Draft Commission Implementing Decision authorising the placing on the market for cultivation of genetically modified maize Bt11 (SYN-BTØ11-1) seeds, in accordance with Directive 2001/18/EC of the European Parliament and of the Council
ISC/2016/01316 de la DG SANTE
Draft Commission Implementing Decision renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-00810-6) seeds for cultivation pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
Consultation ISC/2016/01321 de la DG SANTE
Draft Commission Implementing Decision authorising the placing on the market for cultivation of genetically modified maize 1507 (DAS-Ø15Ø7-1) seeds, in accordance with Directive 2001/18/EC of the European Parliament and of the Council

Notes signed by: MIKO Ladislav
Deadline for replies: 1/06/2016
Service: DG SANTE. E.3

☐ Favourable opinion
☒ Favourable opinion subject to account being taken of the following comments
☐ Unfavourable opinion

Contact: [redacted] *(Tel.:* [redacted]*)*

Comments

Thank you for consulting DG Environment on the 3 draft proposals indicated in subject.

Before the authorisation in the market of these maize varieties, we would ask that our comments as presented below are taken into account.

DG SANTE is proposing to authorise or renew the marketing of seeds for cultivation in the EU of the 3 following maize varieties:

- The genetically modified maize MON810 (for renewal) which confers protection against certain lepidopteran insect pests, including the European Com Borer (ECB) (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp).
- The genetically modified maize Bt11 which confers resistance to the European Corn borer (Ostrinia nubilalis) and the Mediterranean com borer (Sesamia nonagrioides) and tolerance to the herbicide glufosinate ammonium.
- The genetically modified maize 1507 which confers resistance to the European Corn borer (Ostrinia nubilalis) and certain other lepidopteran pests and tolerance to the herbicide glufosinate ammonium.

These proposals are based on scientific opinions provided by EFSA quite some time ago, which include environmental risk assessments:

- On maize MON 810, EFSA published an opinion on 30 June 2009 which concluded that MON 810 is unlikely to have any adverse effect on the environment. Three additional opinions were published in 2012 (two) and 2015.
- On maize Bt11, EFSA published an opinion on 19 May 2005 which concluded that there is no evidence to indicate that the placing of maize Bt11on the market is likely to cause adverse effect on the environment. Since then, 5 additional opinions addressing or being relevant for maize Bt11 have been published.
- On maize 1507, EFSA published an opinion on 3 March 2005 which concluded that there is no evidence to indicate that the placing on the market of maize 1507 is likely to cause adverse effects on the environment. Since then, 6 additional opinions addressing or being relevant for maize 1507 have been published.

We are concerned that the risk assessments which are used as the basis for the decision are comparatively old and do not take account of more recent substantial evidence.

Moreover, these assessment have, in our view some additional gaps.

Teosinte is maize's ancestor and the gene flow between maize and teosinte is known. However the EFSA assessment do **not take into account the occurrence of teosinte in the EU** and are all based on the following assumption: "*for Zea maize any vertical gene transfer is limited to other maize plants as populations of sexually compatible wild relatives of maize are not known in Europe*". However, the presence of teosinte in Spain is attested in the regions Aragón and Cataluña and is also suspected to be present in Navarra. In the region of Aragón, information from 2014[1] estimated that teosinte could be present in about 200-300 ha. According to other sources, the total affected surface in Spain would be around 750 ha, most of it located in Aragón. The difficulties of identification of teosinte could have led to an under-estimation of the problem. There is no information on the possible presence of teosinte in natural areas. The development of teosinte as a weed in the fields has been so problematic that the regional authorities have promoted measures to fight against it in the areas affected[2]. In November 2014, a parliamentary question (question E-008766-14) alerted the Commission of the introduction of teosinte into Aragon and Catalonia (Spain).

Therefore the scientific opinions of EFSA on the 3 GM maize varieties should be up-dated in order to take into account the presence of teosinte as a weed in the EU and the

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1 http://www.aragon.es/estaticos/GobiernoAragon/Departamentos/AgriculturaGanaderiaMedioAmbiente/TEMAS_AGRICULTURA_GANADERIA/Areas/03_Sanidad_Vegetal/PUBLICACIONES_CSCV/I_F_TEOSINTE.pdf; https://www.ruralcat.net/c/document_library/get_file?uuid=f1205dc5-5cbf-4a00-adb7-127d84c6b0da&groupId=10136; - http://www.ruralcat.net/c/document_library/get_file?uuid=00058f39-ecb2-4d88-973c-3bff29035955&groupId=10136

2 https://www.ruralcat.net/web/guest/noticia/-/journal_content/2002/10136/9842282/

possibility of modified gene flow from the 3 GM maize varieties under consideration should also be assessed as part of an environmental risk assessment.

In our view it is necessary at least to analyse the risks linked to the possible following events:

- possible transfer of genes which confer resistance to certain pests into teosinte which could lead to possible effects on non-targeted organisms: given the serious decline of biodiversity in agricultural areas and in particular, but not only, the alarming loss of pollinators, DG ENV is concerned that this possible transfer would lead to the uncontrolled presence of a weed with insecticidal properties that would affect many species which were not initially targeted by the introduction of the GMO, in particular native species, including threatened species. We consider that the recommendations of EFSA to limit exposure "*by means of imposition of isolation distances to Bt maize pollen of non-targeted Lepidoptera of conservation concern in protected habitats as defined under Directive 2004/35/EC of the European Parliament and of the Council*" have to be reviewed in the light of this new element.
- possible transfer of genes which confer tolerance to the herbicide glufosinate ammonium into teosinte: since teosinte seems to be already a problematic weed which farmers have difficulties to eliminate, the consequences of the introduction of such a resistance must be assessed carefully. DG SANTE has indicated that glufosinate ammonium is not allowed to be used on maize cultivation, but the risks linked to the possible propagation of teosinte outside maize fields should be assessed.
- possible transfer of genes from teosinte into other maize cultivation (subsequently to a transfer from GM maize): there could be a cascade effect with a transfer from the GMO maize to the teosinte to other conventional or organic maize. This cascade possibility it should be assessed as the potential economic consequences would be non-negligible.

The environmental risk-assessment should be reviewed also in the light of a possible spread of teosinte in other EU countries where the conditions seem to be suited for its development, notably Portugal, France and Italy.

On other aspects of the draft Decision, we also note that the requirements of monitoring after release seems seem very limited. The proposals do not include provisions for ensuring minimum distances with traditional varieties for cultivation. In addition, there is no threshold for adventitious and not avoided presence of these OGM varieties in conventional seeds.

Conclusion:

DG Environment considers that the Commission should proceed with the proposed approval (or renewal in the case of MON 810) of the three GM maize varieties for cultivation in the EU but only further to an updated and complete environmental risk assessment performed by EFSA. The Post Market Environmental Monitoring Plans for the 3 GM maize varieties should be reviewed in the light of the up-dated scientific opinions from EFSA.

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