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Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC[1]

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2008-316)

Adopted on 2 July 2008

PANEL MEMBERS*

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SUMMARY

Hungary submitted to the European Commission additional information regarding the cultivation of genetically modified maize MON810 to support a safeguard measure initially notified, under Article 23 of Directive 2001/18/EC, by the Hungarian authorities on 20 January 2005 to provisionally prohibit the use and sale of the authorised genetically modified maize MON810 on its territory. The European Commission received from Hungary a written submission made of four supporting documents.

As a consequence, the European Commission requested in a letter, dated 18 April 2008, the EFSA's Scientific Panel on Genetically Modified Organisms (GMO Panel) to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to the environment.

In the light of the information package provided by Hungary in support of its safeguard clause and, having considered all relevant publications, the GMO Panel concludes that, in terms of risk to human and animal health and the environment, no new scientific evidence was

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presented that would invalidate the previous risk assessments of genetically modified maize MON810. The GMO Panel also concludes that no new scientific data or information was provided in support of adverse effects of maize MON810 on the environment and on human and animal health in Hungary.

Therefore, no specific scientific evidences, in terms of risk to human and animal health and the environment, were provided that would justify a prohibition of use and sale of maize MON810 in Hungary.

Key words: GMOs, maize (*Zea mays*), MON810, Hungary, safeguard clause, human health, animal health, environment, Directive 2001/18/EC.

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BACKGROUND

Maize MON810 (notification reference C/F/95/12-02) was authorised in the European Union (EU) for all uses with the exception of food by the Commission Decision 98/294/EC on 22 April 1998 (EC, 1998). A final consent was granted by France on 3 August 1998. Food use of maize derivatives was notified according to Article 5 of Regulation (EC) No 258/97 on 6 February 1998 (EC, 2004a).

The Hungarian authorities informed the European Commission on 20 January 2005 of their decision to provisionally prohibit the use and sale of the genetically modified (GM) maize MON810 and gave reasons therefore. On 8 June 2005, the EFSA's Scientific Panel on Genetically Modified Organisms (GMO Panel) considered that the information submitted by Hungary did not constitute new scientific evidence which would invalidate the environmental risk assessment of *Zea mays* L. line MON810 and therefore would justify a prohibition of the use and sale of this product in Hungary (EFSA, 2005b). A Commission proposal asking Hungary to repeal its measures concerning MON810 has been presented to the Regulatory Committee. As no opinion was delivered by the Committee on 18 September 2006, the Commission submitted to the Council a proposal relating to the measures to be taken. On 22 February 2007, the Environment Council indicated its opposition by qualified majority to the proposal requesting Hungary to repeal its national safeguard clause. Hungary informed the European Commission that it was conducting additional studies that were recently forwarded by the European Commission to EFSA on 18 April 2008.

As a consequence, the European Commission requested in its letter, dated 18 April 2008, the GMO Panel to assess these additional studies regarding cultivation of maize MON810 in Hungary.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 18 April 2008, EFSA was requested by the European Commission, under Article 29(1) and in accordance with Article 22(2) and 22(5)(c) of Regulation (EC) No 178/2002, "*to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to the environment*".

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ASSESSMENT

1. Evaluation of documents delivered by Hungary

The GMO Panel has examined the submission of additional information consisting of four report documents on maize MON810 from Hungary. The GMO Panel looked for evidence for GMO-specific risks taking into consideration the EFSA guidance document for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006a) as well as any related risk assessments carried out in the past.

EFSA is requested by the European Commission to assess whether the set of four report documents submitted by Hungary comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to the environment.

Risk assessment and approval of GMOs according to Directive 2001/18/EC are done on a case-by-case basis. The Directive provides the possibility for Member States to raise objections against marketing of specific GMOs. If necessary, the risk assessment may include features specific to certain geographical regions or subregions. Moreover, the Directive provides safeguards in the case where new or additional information would affect the risk assessment of an authorised GMO. Provisions foreseen by Hungary seek to provisionally extend the validity of an existing ministerial decision prohibiting the cultivation of maize MON810 in Hungary.

Based on the four Hungarian reports, two main concerns were identified and therefore considered by the GMO Panel:

1. Effects of maize MON810 on soil biology;

2. Effects of maize MON810 on target and non-target organisms.

In addition the GMO Panel considered the relevance of the concerns in the light of the most recent scientific data and relevant peer-reviewed papers.

2. Assessment by the GMO Panel

The GMO Panel evaluated the four reports (described below). To present and clarify the provided set of data, an informal meeting between Hungarian scientists, representatives from the Hungarian competent authorities, several experts of the GMO Panel and the EFSA staff was held on 11 June 2008. Representatives of the European Commission attended this meeting as observers.

In its risk assessment and in addition to the information package supporting the Hungarian national measure on maize MON810, the GMO Panel reviewed all relevant and most recent publications, as well as those considered specific for Hungarian receiving environment.

Hungary provided four reports:

- Report #1: On the results of the tender entitled "Assessment of the soil biological effects of genetically modified organisms" (No. NTA-1030/2006) Part 1. Confidential (51 pages);

- Report #2: On the results of the tender entitled "Assessment of the soil biological effects of genetically modified organisms" (No. NTA-1030/2006) Part 2. Confidential (5 pages);

- Report #3: Research Report entitled "Data on ecological risk assessment in Hungary of MON810 maize varieties producing Cry1Ab toxin that can be applied against European corn borer (*Ostrinia nubilalis*) larvae" (No. NTE-725/2005). Confidential (64 pages);

- Report #4: Closing Report entitled "Supplementary ecological impact assessments concerning the MON810 maize varieties I. Biological studies involving MON810 pollen and DIPEL, as well as protected and rare butterflies living on stinging nettle" (No. NTE-1436/2005). Confidential (80 pages).

Hungary requested that the four submitted reports are considered as confidential information.

2.1. Effects of maize MON810 on soil biology

<u>Decomposition of MON810 and Cry1Ab protein persistence in soil</u>

Hungary reported a decomposition study of Bt-maize and data on degradation of Cry1Ab protein in soil. In addition Hungary raised concerns on the persistence of Cry1Ab protein in soil due to the cultivation of maize MON810.

The GMO Panel has addressed the issue of decomposition of MON810 extensively in its previous opinion (EFSA, 2005b). The GMO Panel evaluated the data presented by Hungary and agreed with the conclusions drawn by the authors: "*In the current stage of our studies and based on the available techniques we have no data at all concerning whether the differences found in some cases in the decomposition of organic material are a consequence of differences in the chemical composition of the two maize strains or of the presence of Bt-toxin*" (Hungarian report #3). In addition the Panel reviewed other studies on the decomposition and persistence of Bt-maize. Recently, Hönemann et al. (2008) examined the decomposition of transgenic Bt-maize plants (including MON810) and found no evidence for any effect related to the genetic modification. Icoz and Stotzky (2008) reported in a review paper various results regarding the persistence of Cry proteins in soils. Half-lives of Cry1Ab protein ranged from 1.6 days (Sims and Holden, 1996) up to 34 days (Wang et al., 2006). The long-term persistence of Cry1 proteins in soils seems to be variable to some extent. Cry1Ab proteins in low concentrations were detected up to 56 days (Donegan et al., 1995) or up to 234 days (Tapp and Stotzky, 1998) or up to 180 to 350 days in residues of Bt-maize (Saxena et al., 2002). Schrader et al. (2008) observed a strong decline of immunoreactive Cry1Ab in plant residues of maize MON810 in microcosm experiments to 14.1% in leaf material and 12.8% in root material of the initial approximately 5 µg/g concentration after five weeks.

Baumgarte and Tebbe (2005) and Andersen et al. (2007) reported that the Cry1Ab protein concentrations found in soil were higher in a given season for the plots with maize MON810 varieties in comparison to non-Bt-maize fields, but they did not seem to increase from year to year. Hopkins and Gregorich (2003, 2005) and Dubelman et al. (2005) also reported that Cry1Ab proteins from transgenic plants do not persist and degrade within three months after harvest in soil.

The GMO Panel concludes that the concerns on Cry1Ab protein persistence in soil raised by Hungary are not substantiated by the available scientific data.

Microbial communities

According to the Hungarian report #1, the impact of maize MON810 on rhizosphere and rhizoplane microbial communities has been studied in a pot experiment, in which DK-440 BTY maize (MON810 event) expressing the Cry1Ab protein and the non-trangenic isogenic line were planted. Forest soil was used as growth substrate and the duration of the experiment was eight weeks. The authors concluded that no changes were observed in the case of bacteria and actinomycetes. However, a smaller quantity of fungi, including saprophytic and arbuscular mycorrhizal fungi, was observed in the rhizosphere of DK-440 BTY than in the rhizosphere of its isogenic counterpart.

The GMO Panel is of the opinion that the generated data are of limited relevance in the context of risk assessment. The data do not provide relevant baseline information (i.e. variation between cultivars, transient effects, effects by agricultural practices), nor a more detailed analysis about which microorganisms and functions are affected. It is important that baseline fluctuations along with seasonal variations are taken into consideration when microbial population studies are undertaken; otherwise the magnitude of observed differences cannot be placed in the context of other sources of variation (Gyamfi et al., 2002; Heuer et al., 2002; Rasche et al., 2006a,b; Icoz et al., 2008).

Because the variation in microbial communities observed in the Hungarian study is similar to that observed in other studies performed with plants expressing Cry proteins from *Bacillus thuringiensis* (reviewed by Icoz and Stotzky, 2008) and other GM crops (Gyamfi et al., 2002; Heuer et al., 2002; Rasche et al., 2006a,b), the study provides no new information about the effects of Bt-plants on soil microorganisms.

The method selected in report #1 to characterise microbial communities was the phospholipid fatty acid (PFLA) compositional analysis. This method can only discriminate few microbial groups and is known to have a low resolution power. A combination of different techniques is required for understanding the effect of GM crops on soil microbiology (e.g. Lynch et al., 2004; Icoz et al., 2008).

With regard to soil microbial communities, a potential hazard can only be defined by a reduction in diversity or population shifts that exceed the baseline variation and/or by a significant reduction of beneficial microorganisms such as mycorrhizal fungi over various sampling times in the field. Icoz et al. (2008) recently studied soil microbial communities under Bt-maize cultivation (including three Cry1Ab expressing varieties, one Cry3Bb1 expressing variety, and their near-isogenic non-Bt-varieties). They reported no consistent, statistically significant differences in numbers of different microbial groups, community structures and enzyme activities over four consecutive years.

Effects of GM crops on soil biology can only be adequately assessed using data obtained from appropriate experimental designs (e.g. Lynch et al., 2004; Icoz et al., 2008). The GMO Panel concludes that no new data were presented to show that maize MON810 would pose a risk to soil biology and more specifically soil microbial communities in Hungary.

Nematodes

In report #1 submitted by Hungary, the potential impact on nematodes of a Cry1Ab producing maize variety is compared to that of its isogenic counterpart. The comparison is based on an analysis of the nematode community structure, comprising data on the density of nematodes, the number of nematode taxons, the ratio of fungivores to bacteriovores, the maturity index (MI), the enrichment index (EI), the structure index (SI), the channel index (CI) and on the different genera of nematodes[2]. Based on the obtained results, the Hungarian researchers concluded that the presence of maize producing Cry1Ab proteins does not affect the structure of the nematode communities, which is in line with other studies on nematodes (Saxena and Stotzky, 2001; Griffiths et al. 2005, 2006, 2007b). In report #2, there is a reassessment of the data on the indices, and the authors suggested trends in the indices EI and CI. They concluded that "*the relationships between the food chains based on bacteria and those based on fungi underwent a process of rearrangement*" in the Cry1Ab expressing maize, compared to its isogenic counterpart.

The presented evidence is based on one experiment with one Cry1Ab protein producing maize without any comparisons to baseline data. In addition no data on normal variation in control and comparator material at different plant development stages in a range of soil types was supplied. Therefore, the data presented by Hungary are not sufficient to show that any differences between the nematode communities in soil growing isogenic and Bt-maize are due to the presence of the Bt-maize. Also, the analysis of the data in report #2 was not sufficient to merit the conclusions drawn. In addition the observations are not verified by the cited papers (Saxena and Stotzky, 2001; Griffiths et al., 2005, 2006, 2007b), which concluded that any effects on the nematode community by Bt-plants and their products are of minor importance, when compared to effects of agricultural practices and of differences between localities and maize varieties.

Rearrangements of nematode populations occur frequently and are not necessarily an indication of environmental harm. Rearrangements are associated with several sources of variation in the agricultural environment (e.g. different cultivars, Griffiths et al., 2007b). The GMO Panel considers that there is no evidence presented supporting the conclusion of rearrangements of nematode populations due to maize MON810 and concludes that no new data were presented to show that maize MON810 would pose a risk to nematode populations in Hungary.

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[2] The nematode indexes represent a well established framework for describing and analysing nematode communities (Bongers, 1990; Ferris et al., 2001). The maturity index (MI) is an index describing nematodes on a colonizers (c) to persisters (p) scale and is calculated as the weighted mean of the individual c-p values (the values are defined at nematode family level). The enrichment index (EI), the structure index (SI) and the channel index (CI) are indexes based on the categorisation of nematodes into functional guilds (Ferris et al., 2001). This categorisation includes the colonizers to persisters scale and the nematodes feeding habits, and therefore the inferred function in the food web. The EI reflects the responsiveness of nematodes to increase in available resources; SI reflects the nematodes community structure (with weight on persisters) and recovery from stress and CI the "decomposition channels" through the soil food web.

2.2. Effects of maize MON810 on target and non-target organisms

Bt-pesticide spray (DIPEL®) studies

Reports #3 and #4 submitted by Hungary provide a number of data concerning the effects of Bt-pesticides, such as DIPEL®, on target and non-target organisms. The entomopathogenic bacterium *B. thuringiensis* and its toxins are extensively used worldwide for pest control purposes in agriculture, forestry and public health programmes since the 1930. A main reason for the importance of Bt as a pesticide is the assumed environmental safety concluded from the high specificity of its δ-endotoxins (Cry proteins) towards a limited number of target organisms, mostly distinct groups of pests (e.g. Hilbeck and Schmidt, 2006). DIPEL® contains a mixture of different Cry proteins (Cry1Aa, Cry1Ab, Cry1Ac, Cry2A, and Cry2B) and spores of the *B. thuringiensis* itself. Due to the different composition and mode of action of Cry toxins formulated in bacterial insecticides and in Bt-maize, it is not possible to conclude on the environmental risks of maize MON810 and the Cry1Ab protein from data generated with DIPEL®.

Target organisms

The Hungarian report #3 considers resistance development in target organisms as a matter of concern. The EFSA GMO Panel has previously identified this issue as a potential risk with Bt-maize cultivation, and has therefore recommended case-specific monitoring and management measures (EFSA, 2005c,d).

The EU research project ProBenBt has provided key elements for managing resistance development in targeted lepidopteran pest species in the EU (Schuphan, 2006). No major resistance alleles in populations of the European corn borer (*Ostrinia nubilalis*) and Mediterranean corn borer (*Sesamia nonagrioides*) to Bt-maize have been detected yet. This indicates that recessive resistance alleles are rare in European populations of both pest species. Population genetic studies confirm that only small genetic differences occur among European populations of both pest species. Therefore, gene flow is likely to be high enough to delay resistance development to Bt-toxins in maize. Applying the high-dose/refuge resistance management strategy is likely to maintain the sensitivity to Bt-toxins in the European corn borer and Mediterranean corn borer.

In relation to monitoring and insect resistance management plan, the GMO Panel gives its opinion on the scientific quality of the post-market environmental activities proposed by applicants. The definitive and final endorsement of post-market environmental monitoring activities is under the responsibility of risk managers.

Non-target organisms: Collembola

The Hungarian reports #1 and #3 refer to the publication of Bakonyi et al. (2006) and the GMO Panel comments on this paper. The paper described preference tests with Collembola on one maize MON810 variety and its near-isogenic counterpart. Finely ground maize plant material was placed in portions of 100 mg in Petri dishes using two different measurements of collembolan response: (1) the preference to stay on one of the two maize types, and (2) the consumption of the plant material as indicated by faecal pellet production.

In the experiment where Collembola were fed yeast prior to the test, one of the three species, *Heteromurus nitidus*, showed a significantly higher preference to stay on the non-Bt-maize variety: of 20 individuals, on average, 2 were found to stay on the Bt-maize, while an average of 4.4 were found to stay on the non-Bt-maize, and the rest of the individuals remained outside the two areas with plant material. *Folsomia candida* defecated 30% less around Bt-maize, but did not show preference to stay on any plant material. Preference was not linked to consumption, so the tendency to stay on the plant material was not linked to palatability. For well fed *F. candida*, the consumption was 30% less on Bt-diet, but when they were starved, they indiscriminately consumed both diets. The two other studied species (*H. nitidus* and *Sinella coeca*) did not show any difference in consumption between the two diets.

An interpretation of the study in toxicological terms relies on the value of an avoidance of toxic substances for predicting the toxic potential in a realistic field situation. Hitherto the Cry1Ab protein has not been shown to be toxic to Collembola. In addition to the presence of the assumed toxicant (cf. Cry1Ab protein), there were differences in C/N ratio in the plant material. Such differences are common because GM maize is a F_1 hybrid and comparators are of similar hybrid origin or single lines and therefore not fully isogenic. Different varieties have been shown previously to elicit various responses related to their background genetic composition and not to the GM event or its products (Griffith et al., 2007b). The different consumption of Bt-maize may be due to nutritional differences, as suggested by the C/N ratio. The study shows that *F. candida*, which responded with a lower consumption of the Bt-toxin, did not discriminate between the two diets under starved condition.

The GMO Panel concludes that no new data are presented which demonstrate that maize MON810 would pose a risk to Collembola.

Non-target organisms: Protected and rare butterfly species

Reports #3 and #4 submitted by Hungary summarise data on butterfly species potentially occurring in maize field margins in Hungary, shed maize pollen and on estimated pollen densities on host plant leaves. Data from these Hungarian studies demonstrated a potential hazard for certain non-target caterpillars consuming high amounts of maize MON810 pollen on host plants.

In the Hungarian study, larvae of the protected European peacock (*Inachis io*) were exposed to varying concentrations of maize MON810 pollen in four studies in outdoor pot experiments carried out in 2002, 2003 and 2005. Other less detailed experiments were carried out for two additional butterfly species, Red admiral (*Vanessa atalanta*) and Comma butterfly (*Polygonia c-album*). In all these studies an unspecified number of butterfly larvae were exposed on an unspecified number of stinging nettle (*Urtica dioica*) leaves dusted with maize pollen.

Results present mortality rates of butterfly larvae exposed to Bt-maize pollen, but do not contain statistical analysis, nor do they discriminate between mortality due to Bt-maize or mortality due to other causes (viral diseases and parasites).

The data presented in the Hungarian reports #3 and #4 suggest that the protected butterfly *I. io* was found to be susceptible to MON810 pollen in high concentrations. Outside Bt-maize fields, such pollen concentrations could occur within 1 or 2 m of their edge. Felke et al. (2002) and Felke and Langenbruch (2005) studied exposure of *I. io* to pollen of maize Bt176 (containing higher Cry1Ab concentrations than pollen of maize MON810) in laboratory and field experiments. They showed that maize pollen containing Cry1Ab is a hazard to exposed butterfly larvae. This information is in line with the observations of Sears et al. (2001) who reported similar lethal and sublethal effects when Monarch butterfly larvae (*Danaus plexippus*) consumed high concentrations of MON810 pollen. However, Sears et al. (2001) estimated that the proportion of population exposed to toxic levels was very small and concluded that impacts on *D. plexipus* populations were minimal particularly when considered against the wide range of existing environmental and agronomic stressors currently influencing populations. These exposure studies are relevant to a range of European environments.

In summary, the data presented by Hungary

- were collected under conditions of high pollen exposure where pollen was synthetically adhered to host plant leaves. This is unlikely to occur in the field where environmental factors (e.g. rain, wind) decrease the exposure of lepidopteran larvae to pollen (e.g. Pleasants et al., 2001; Gathmann et al., 2006a);

- do not examine exposure of butterfly populations. There is no indication of the proportion of butterfly populations that will be exposed to toxic levels of Bt-maize pollen in Hungary. Other factors influencing butterfly populations in agricultural landscapes should be considered (Gathmann et al., 2006b), such as butterfly phenology, crop rotation, other pesticide usage, refuge areas and cultivation.

The GMO Panel concludes that there are no new data presented which demonstrate that maize MON810 would constitute a risk for non-target butterfly populations.

2.3. Environmental damage

In the safeguard application, Hungary refers to the National Nature Conservation Plan, produced on the basis of Act LIII of 1996 on Environmental Protection, which specifies the following: "*TEV-5. Protection of natural habitats, particularly those of endangered plant and animal species, shall be ensured*" (Anonymous, 1996, 1998). Hungary stated that "*populations of protected species must not be thinned or destroyed by any means; indeed, the unchanged quality of their habitats must be preserved*". Hungary also stated that "*the level of tolerance of deviation from the natural state is zero*" in Hungary.

The GMO Panel scientific opinions are based on assessments carried out in line with the EFSA guidance document (EFSA, 2006a). The definition of environmental damage used in the guidance document is in accordance with the definition provided by the EU Directive 2004/35/EC (EC, 2004b). In particular, the EU Directive 2004/35/EC puts emphases on three environmental compartments: biodiversity, water and land. 'Damage' [to the environment] is defined as a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly. According to Annex I of Directive 2004/35/EC the significance of any damage that has adverse effects on reaching or maintaining the favourable conservation status of habitats or species has to be assessed by reference to the conservation status at the time of the damage, the services provided by the amenities they produce and their capacity for natural regeneration. Significant adverse changes to the baseline condition should be determined by means of measurable data such as:

- the number of individuals, their density or the area covered;

- the role of the particular individuals or of the damaged area in relation to the species or to the habitat conservation, the rarity of the species or habitat (assessed at local, regional and higher level including at Community level);

- the species' capacity for propagation (according to the dynamics specific to that species or to that population), its viability or the habitat's capacity for natural regeneration (according to the dynamics specific to its characteristic species or to their populations);

- the species' or habitat's capacity, after damage has occurred, to recover within a short time, without any intervention other than increased protection measures, to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

In accordance with Annex 1 of Directive 2004/35/EC, the GMO Panel does not classify as significant damage:

- negative variations that are smaller than natural fluctuations regarded as normal for the species or habitat in question;

- negative variations due to natural causes or resulting from intervention relating to the normal management of sites, as defined in habitat records or target documents or as carried on previously by owners or operators;

- damage to species or habitats for which it is established that they will recover, within a short time and without intervention, either to the baseline condition or to a condition which leads, solely by virtue of the dynamics of the species or habitat, to a condition deemed equivalent or superior to the baseline condition.

CONCLUSIONS AND RECOMMENDATIONS

The GMO Panel has investigated the claims and documents provided by Hungary. In these documents which were presented and clarified by the Hungarian authorities at the bilateral meeting of 11 June 2008, the GMO Panel did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on maize MON810 which currently has marketing consent in the EU. In addition the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU. The GMO Panel considered all the available data on the potential eco-toxicity of maize MON810 together with available data on possible environmental impacts. The GMO Panel reaffirms its previous conclusions on the safety of maize MON810 and reiterates its previous recommendation that a full risk assessment should be based on reliable data on toxicity, environmental exposure and statistical analysis of the impact on populations of non-target species.

Having considered the scientific information submitted by Hungary as well as a broad range of relevant scientific literature, the GMO Panel is of the opinion that

- there is no new data that would invalidate the previous risk assessments carried out on maize MON810 (SCP, 1998, 1999; EFSA, 2005a,b, 2006b,c);

- there is no specific scientific evidence, in terms of risk to human and animal health and the environment, that would justify a prohibition of the placing on the market of maize MON810 authorised under Directive 90/220/EEC (repealed by Directive 2001/18/EC) and the prohibition of cultivation of maize MON810 in Hungary.

In conclusion, the GMO Panel finds that the scientific evidence currently available does not sustain the arguments provided by Hungary and that maize MON810 in Hungary is unlikely to have an adverse effect on human and animal health and the environment in the context of the uses laid down in the corresponding consent.

DOCUMENTATION PROVIDED TO EFSA

Note, dated 18 April 2008, with four supporting documents from M.P. Carl, Director-General Environment EC, to Catherine Geslain-Lanéelle, Executive Director EFSA (ref ENV/B3/YK/gm D(2008) 3735) – New information submitted by Hungary in the context of its safeguard measure on MON810 invoked under Article 23 of Directive 2001/18/EC.

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