

## EUROPEAN COMMISSION

Cabinet of Commissioner John Dalli  
Head of Cabinet

Brussels, 11 November 2011

Dear Mr Then,

Thank you for your letter to Commissioner Dalli on the risk assessment of genetically engineered maize 'SmartStax'. The Commissioner asked me to reply to you on his behalf.

The above mentioned letter was transmitted to the European Food Safety Authority (EFSA) on 27.07.2011 for the analysis of the scientific elements and the Commission will reply to you as soon as we receive the answer from EFSA. Notwithstanding, I would like to take this opportunity to address several questions that you raised previously.

Application for cultivation of 1507 maize

As already mentioned in your letter of 26 November 2010 EFSA published, in the context of the minutes of the 61<sup>st</sup> plenary meeting of the GMO Panel (held on 20-21 October 2010), an analysis of the elements raised in the Testbiotech opinion. Although the EFSA GMO panel concludes that no scientific studies have been mentioned that would invalidate the previous Panel's scientific opinions on the safety of 1507 maize, the experts consider that recent advances in methodology will allow the EFSA GMO Panel to more accurately quantify the risks to non-target lepidopteran species.

In this context, the panel and EFSA agreed on a self mandate<sup>1</sup> which aims at updating the Environmental Risk Assessment (ERA) on the 1507 GM maize for cultivation. The conclusions will be duly published on the EFSA website. As you can see, further work is ongoing on this GM maize and I am confident that this exercise should allow EFSA to address your remaining concerns about the environmental safety of this GMO maize.

In the same letter, you also make reference to the risk assessment of the use of the herbicides with glufosinate as their active ingredient. I would like to stress that the 1507 application submitted by Pioneer is related to a Bt maize only with a herbicide tolerant gene (pat gene) only used as a marker gene, but not to be used in the field in conjunction with the herbicide to which it encodes tolerance.

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<sup>1</sup> M-2010-0520 (EFSA-Q-2010-01470)

In reaction to your concerns expressed in the letter of 28 March 2011 on the authorisation for MON 89034 x MON 88017 maize, GHB614 cotton and the renewal of application for maize 1507, I want first to underline that the Commission is strongly committed to ensuring that GM food and feed are only authorised when they are not likely to have adverse effects on human and animal health or the environment. To this effect, the EU legislation foresees that the decision on whether to authorise a GMO (and under what conditions) is taken in the light of the outcome of a thorough risk assessment.

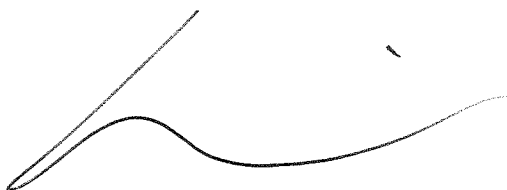
Following this approach, I would like to highlight the fact that a thorough risk assessment of applications for authorisation of maize MON 89034 x MON 88017, cotton GHB614 and the renewal of maize 1507 has been carried out by the EFSA GMO Panel.

Notwithstanding the favourable opinions of EFSA, the Commission has asked EFSA to evaluate your letter of 28 March 2011.

On 19 July 2011 EFSA replied to the Commission by explaining that all deficiencies claimed by Testbiotech are not substantiated by data and by providing a detailed analysis of your comments which can be found attached to this letter.

I would like to conclude by saying that I am confident that the regulatory framework provides for a high level of scientific assessment and transparent authorisation procedure. The Commission will continue to fulfil its responsibilities in the implementation of this legislation.

Yours sincerely,

A handwritten signature in black ink, consisting of a series of fluid, connected strokes that form the name 'Joanna Darmanin'.

Joanna Darmanin

Enclosure: EFSA analysis of Testbiotech comments on the authorisation for MON 89034 x MON 88017 maize, GHB614 cotton and renewal of application for maize 1507.

## ANNEX

### 1.- Maize MON89034 x MON 88017

- Testbiotech: *maize 89034 expresses a highly synthetical Bt toxin is produced. In this case, synergistic effects, selectivity and toxicity have to assessed comprehensively to exclude risks for human health and farm animals.*

EFSA: Maize MON 89034 was previously evaluated by the EFSA GMO Panel and a scientific opinion was issued (EFSA, 2008). In the EFSA 2008 scientific opinion, a comprehensive toxicological assessment is presented in section 4.2.3.1 (Cry1A.105 and Cry2Ab2 proteins used for safety assessment), section 4.2.3.2 (Toxicological assessment of expressed novel proteins and section) and section 4.2.4 (Toxicological assessment of the whole GM food/feed). The risk assessment included an analysis of data from analytical, bioinformatic, *in vitro* and *in vivo* studies. The EFSA GMO Panel concluded that no indications of adverse effects related to the exposure to the Cry1A.105 protein or the Cry2Ab2 protein were found in studies on bioinformatics, *in vitro* and acute oral toxicity in mice. There were no adverse effects in a 90-day feeding study with rats fed diets including grain of maize MON 89034. A feeding study on broiler chickens provided additional evidence of nutritional equivalence of maize MON 89034 to conventional maize.

- Testbiotech: *As Pardo Lopez et al. (2009) and Pigott et al. (2008) show, synthetically derived and modified Bt toxins can show much higher toxicity than native proteins. Even small changes in the structure of the proteins can cause huge changes in its toxicity. EFSA did not evaluate this specific problem in the case of Cry1A.105. Moreover this is not the only protein that is changed in its structure; all the Bt toxins as produced in the plants are technically modified.*

EFSA: The two studies referred in this comment are related to higher toxicity of modified Bt toxins when compared to native proteins. The EFSA GMO Panel has considered in its evaluation of the environmental risk assessment the potential interaction of the GM plant with non-target organisms (single event MON 89034, single event MON 88017 and stacked events MON 89034 x MON 88017). In section 6.1.2.4 of the scientific opinion on MON 89034 x MON 88017 (EFSA 2010b), it is stated that *“The EFSA GMO Panel evaluated whether the Cry1A.105, Cry2Ab2 and Cry3Bb1 proteins might potentially affect non-target organisms by entering the environment through manure and faeces from the gastrointestinal tracts of animals fed maize MON89034 x MON88017”*. *“Considering the scope of the application (that excludes cultivation) and the intended uses of maize MON 89034 x MON 88017, the EFSA GMO Panel concluded that the exposure of potentially sensitive non-target organisms to the Cry1A.105, Cry2Ab2 and Cry3Bb1 proteins is likely to be very low and of no ecological relevance”*. Therefore, the scientific publications referred to might be relevant for the cultivation of maize MON 89034 x MON 88017, but not in the context of the scope of the present application.

With regards to its safety to human and animal health, a comprehensive toxicological assessment has been carried out by the EFSA GMO Panel who had initially assessed the single events MON 89034 (EFSA, 2008) and MON 88017 (EFSA, 2009a) and subsequently, issued a scientific opinion on MON 89034 x MON 88017 (EFSA 2010b). For additional information on the toxicology assessment for the food and feed safety assessment of this scientific opinion please see below.

- Testbiotech: *EFSA discussed potential synergistic effects between the Bt toxins used in the plants and has come to the conclusion that these are not to be expected. EFSA herein refers to studies the Monsanto company performed on target organisms that only showed additive effects but no further interactivity between the proteins. However a recently published study of Sharman et al. (2010) found synergistic effects of CryIAb and CryIAc in target pest insects. Further synergistic effects between CryIAc and other Bt toxins such as Cry2Ab2 and Cry1F are discussed in Lee et al. (1996), Chakrabartj et al(1998), Stewart et al. (2001) and Kashdan et al. (2007). Synergistic effects can become highly problematic for non target organisms: Interactivity between the toxins can cause unexpected higher toxicity and lower selectivity (Then. 2010). These effects also can impact human health.*

EFSA: The scientific publications referred here might be relevant for the cultivation of maize MON 89034 x MON 88017, but not in the context of the scope of the current application which excludes cultivation. The previous answer of the EFSA GMO Panel in relation to environmental risk assessment is also applicable to this comment.

In relation to potential impact on human health, the EFSA GMO Panel issued a scientific opinion on maize MON 89034, maize MON 88017 and maize MON 89034 x MON 88017 (EFSA 2008, 2009a, 2010b). In section 5.1.4.1 of the latter opinion, it is stated that “*the EFSA GMO Panel is not aware of any other new information that would change the conclusions of its previous opinions. Based on the known function and mode of action of the newly expressed proteins CryIA.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS, the EFSA GMO Panel considers the occurrence of interactions among these proteins unlikely*”.

Finally, the EFSA GMO Panel concluded that maize MON 89034, maize MON 88017 and maize MON 89034 x MON 88017 are unlikely to have an adverse effect on human and animal health and the environment, in the context of its intended uses. For additional information on the toxicology assessment for the food and feed safety assessment of this scientific opinion please see below.

- Testbiotech: *In general it is not sufficient to assess risks to human health such as potential synergies of the Bt proteins just by referring to experiments with insects (target organisms). At least in vivo studies on human cells should have been performed, to investigate effects of Bt toxins involved in this case. Especially the properties of the synthetic toxin CplA.105 are not known. But also the other Bt toxins have to be tested in appropriate biological systems to exclude risks for human health: The mode of action of Bt toxins is not fully understood. It is even a matter to controversial debate (Pigott & Ellar, 2007). Risks for human health can not be excluded by assumptions or considerations bur only by empirical testing.*

EFSA: The risk for human health was extensively evaluated by the EFSA GMO Panel. A summary of the evaluation can be found here:

Maize MON 89034 was assessed and an EFSA scientific opinion was issued (EFSA, 2008). The newly expressed proteins Cry1A.105 and Cry2Ab2 were shown to be degraded in simulated gastric fluid and intestinal fluid. In bioinformatics studies, the amino acid sequence of Cry1A.105 and Cry2Ab2 showed no similarity either to proteins that are known to be toxic to humans and other mammals or to allergens. No toxicity of the Cry1A.105 and Cry2Ab2 proteins were observed in acute oral toxicity studies in mice. In a 90-day feeding study in rats with grain material from maize MON89034, no treatment-related adverse effects were observed, and a 42-day feeding study on broiler chickens showed that maize MON 89034 is nutritionally equivalent to its conventional counterpart and commercial non-GM maize varieties included in the study.

In the case of maize MON 88017, Cry3Bb1 and CP4 EPSPS proteins were also rapidly degraded during incubations with simulated gastric fluid containing the digestive enzyme pepsin. Neither proteins showed toxicity in acute oral toxicity studies in mice, nor did they show relevant similarities to known toxic or allergenic proteins in bioinformatics-supported comparisons of their amino acid sequences. The safety of the whole food/feed derived from MON88017 was tested in a 90-day rat feeding study with diets containing 33% grains from maize MON88017. No indications of adverse effects were observed in this study. Also a nutritional, 42-day broiler chicken feeding study was carried out with diets containing between 55 and 60% grains from maize MON 88017, showing that the latter was nutritionally equivalent to conventional maize (EFSA, 2009a).

Finally, related to maize MON 89034 x MON 88017, the EFSA GMO Panel concluded that, based on the known function and mode of action of the newly expressed proteins Cry1A.105, Cry2Ab2, Cry3Bb1 and CP4 EPSPS, the EFSA GMO Panel considers the occurrence of interactions among these proteins unlikely. No new genes in addition to those present in the parental maize varieties were introduced in maize MON 89034 x MON 88017. Neither the structural integrity of the insert in maize MON 89034 x MON 88017 nor the protein expression levels were found to be changed in comparison to the single events MON 89034 and MON 88017. Moreover, the composition of maize MON 89034 x MON 88107 was found to be equivalent to its conventional counterpart and commercial non-GM maize varieties. The EFSA GMO Panel considered all the data available for maize MON 89034 x MON 88017, and the newly expressed proteins Cry1A.105, Cry2Ab2, Cry3Bb1 and CP4 EPSPS, and is of the opinion that interactions between the single maize events that might impact on the food and feed safety of maize MON 89034 x MON 88017 are unlikely. Therefore, in the case of MON 89034 x MON 88017 and based on all the above information, the EFSA GMO Panel did not consider additional animal safety studies with the whole GM food/feed necessary.

- Testbiotech: *Kidney problems were observed in animal feeding studies with MON89034 conducted by Monsanto (as presented in its market application for MON89034). These findings were considered as being not relevant by EFSA.*

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*Already at this point, EFSA should have requested further studies. But EFSA did not even request any feeding studies for health risks at the level of combining MON 89034 x MON88017 in a stacked event. In conclusion there is a high level of uncertainty regarding human health risks. The presence of these risks is supported by a report by Gallagher (2010) dealing with kidney problems that were observed in feeding studies with genetically engineered eggplant which also express a modified CryIAc protein.*

EFSA: A sub-chronic 90-day feeding study of maize MON 89034 was addressed in a previous opinion, section 4.2.4 (EFSA, 2008). As described in the opinion, microscopic findings in organs and tissues were almost equally distributed and no statistically significant differences between males and females of the high dose group and the controls were noted. A numerically higher incidence of kidney alterations in females of the high dose group was attributable to two rats (one died at day 14 of unknown cause, the other survived to the end of the study). The alterations in these two rats included minimal chronic progressive nephropathy, minimal/moderate transitional cell hyperplasia, minimal sub-acute inflammation and moderate hydronephrosis. Both rats had urinary bladder calculi and the study pathologist concluded that the lesions observed most likely were linked to these calculi. It seems unlikely that the urinary bladder calculi and associated kidney alterations could have been induced by the tested maize in 14 days. A low incidence of urinary bladder calculi is known to occur in this rat strain and may be considered a spontaneous finding in sub-chronic studies. According to historical control data supplied in the application, the incidence of urinary bladder calculi in high dose females in this study was also found in female control rats in previous studies conducted with CD rats in the same testing laboratory. Therefore, the EFSA GMO Panel considered the urinary bladder calculi as well as the associated kidney alterations as incidental findings which were not related to administration of maize MON 89034. The same applies to the nephroblastomas, a very rare tumour of the kidney, which were observed in two female animals of the control group.

The report by Gallagher 2010 deals with Bt brinjal event EE1 and not with maize MON 89034 x MON 88017. Gallagher 2010 reports about the adequacy of current toxicology studies to address the safety of Bt brinjal. The author claimed that the toxicity studies were not conducted according to scientific standards. These studies are therefore not relevant for maize MON 89034 x MON 88017.

- *Testbiotech: Also the potential synergies (and related risks) between Cry2Ab2 (as produced in MON88017) and the other Bt toxins in the stacked event were not investigated. It was overlooked that synergistic interactivity between Cry2Ab2 and CryIAb and between Cry2Ab2 and CryIAc has been discussed in Mattila et al. (2005) and Stewart et al. (2001).*

EFSA: The scientific publications referred here might be relevant for the cultivation of maize MON 89034 x MON 88017, but not in the context of the scope of the current application. The previous answer of the EFSA GMO Panel in relation to environmental risk assessment is also applicable to this comment.

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- *Testbiotech: the necessary interplay between risk assessment in herbicides and the risk assessment of herbicide tolerant crops was omitted by EFSA. The maize is made tolerant against the use of Glyphosat preparations by introducing a gene construct for the EPSPS enzyme (see diagram). As a recent overview of the scientific literature shows (PAN AP, 2009) the toxicity of Glyphosat, its metabolites and its additive POEA (polyoxyethylene alkylamine) have to re-evaluated. EFSA should have at least requested detailed analyses of the residues from spraying various Glyphosate formulations on the genetically engineered plants.*

EFSA: Related to the EFSA GMO scientific opinion on maize MON 89034 x MON 88017 (EFSA 2010b), as the scope of this application is for food and feed uses, import and processing and excludes cultivation, the concerns (environmental and for the food and feed assessment) related to the use of glyphosate herbicides apply to imported and processed products that may have been treated with those herbicides in countries of origin. The risk assessment with the purpose of setting maximum residue levels (or import tolerances) in imported commodities falls within the scope of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin. Residue trials would need to be performed according to the agricultural practice relevant to the herbicide tolerant crops and an evaluation of the consumer safety is a prerequisite for the setting of any higher maximum residue level necessitated by that use.

As previously indicated, animal safety studies with the whole food/feed were evaluated by the EFSA GMO Panel for maize MON 89034 and maize MON 88017 and adverse effects were not identified (EFSA 2008, 2009a).

## 2.- Renewal of maize 1507

- *Testbiotech: In maize 1507 a Bt toxin being active against Lepidoptera species is combined with herbicide tolerance against Glufosinate. The Council should request a much more detailed risk assessment in this case. Some examples for the deficiencies of EFSA risk assessment: In maize 1507 the toxicity assessment by EFSA is largely derived by analogy with CryIAb, As Bauer-Panskus and Then (2010) show, this is an insufficient approach: The CryIF protein (as produced in maize 1507) in comparison shows highly different toxicity in the model organism of the greater wax moth (Hanley et al. 2003); a finding that was overlooked by EFSA. Further, EFSA did not deal with the publication by Dona & Arvanitoyannis (2009). These experts come to the conclusion that the animal feeding data as presented by Pioneer indicate severe health effects. No detailed analyses of the residues from spraying and its potential interactions with the CryIF protein was conducted.*

EFSA: On 1<sup>st</sup> December 2010, the EFSA GMO Panel adopted the minutes of its 61<sup>st</sup> plenary meeting where clarifications on issues raised by TestBiotech on maize 1507, entitled "Testbiotech opinion concerning the application for market approval of GM maize 1507", were included. The EFSA GMO Panel stated that "The EFSA GMO

*Panel therefore concludes that no new scientific studies have been mentioned in the Testbiotech report that would invalidate the previous Panel's scientific opinions on the safety of maize 1507. However, with regard to environmental safety considerations, recent advances in methodology will allow the EFSA GMO Panel to more accurately quantify risks to non-target lepidopteran species. Consequently, the EFSA GMO Panel will supplement its previous conclusions and clarify its recommendations to risk managers for methods to reduce exposure and mitigate risks linked to maize 1507 cultivation".* Therefore, the considerations related to the cultivation of maize 1507 are not considered relevant for the scope of the present renewal application.

Hanley *et al.* (2003) refers to the effects of dietary transgenic Bt corn pollen on larvae of *Apis mellifera* and *Galleria mellonella*. Considering that the scope of the renewal maize 1507 is for feed use and excludes cultivation, the Hanley *et al.* (2003) study is not relevant for this application. Please note that the EFSA GMO Panel is updating the environmental risk assessment on maize 1507 for cultivation and the publication of Hanley *et al.* (2003) will be considered.

Dona & Arvanitoyannis (2009) is a critical review of genetically modified foods. No new experimental data are presented in this article with regards to the food safety of maize 1507. An EFSA opinion on the renewal of authorisation for maize 1507 for feed use was issued in 2009 (EFSA, 2009b). The EFSA GMO Panel stated that new information from the literature and from additional studies performed by the applicant does not prompt the EFSA GMO Panel to change its previous opinion on maize 1507. Previous EFSA scientific opinions on maize 1507 with regards to the food and feed safety concluded that maize 1507 is unlikely to have an adverse effect on human and animal health (EFSA 2004, 2005a,b).

Finally, as the scope of this application is for feed use and excludes cultivation, the concerns (environmental and for the food and feed assessment) related to the use of glufosinate herbicides apply to imported and processed products that may have been treated with those herbicides in countries of origin. The risk assessment with the purpose of setting maximum residue levels (or import tolerances) in imported commodities falls within the scope of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin. Residue trials would need to be performed according to the agricultural practice relevant to the herbicide tolerant crops and an evaluation of the consumer safety is a prerequisite for the setting of any higher maximum residue level necessitated by that use.

Animal safety studies with the whole food/feed were evaluated by the EFSA GMO Panel for maize 1507 and adverse effects were not identified (EFSA 2005b).

### 3.- Cotton GHB614

- *On Bt cotton GHB614 Testbiotech did not perform any detailed analysis. But what is evident from the opinions as presented by EFSA is that also in this case the interplay with the herbicide application is missing. The cotton is made tolerant against the use of Glyphosat preparations. As mentioned, a recent overview of the scientific literature shows (PAN AP, 2009) the toxicity of Glyphosat and its additive POEA*

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*(polyoxyethylene alkylarnine) have to re-evaluated. EFSA should have at least requested detailed analyses of the residues from spraying various Glyphosate formulations on the genetically engineered cotton. Further it is a matter of concern that in the case of Bt cotton GHB614 no animal feeding studies for excluding health risks were conducted.*

EFSA: With regards to the EFSA scientific opinion on cotton GHB614 (EFSA 2009c), as the scope of this application is for food and feed uses, import and processing and excludes cultivation, the concerns (environmental and for the food and feed assessment) related to the use of glyphosate herbicides apply to imported and processed products that may have been treated with those herbicides in countries of origin. The risk assessment with the purpose of setting maximum residue levels (or import tolerances) in imported commodities falls within the scope of Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin. Residue trials would need to be performed according to the agricultural practice relevant to the herbicide tolerant crops and an evaluation of the consumer safety is a prerequisite for the setting of any higher maximum residue level necessitated by that use.

In relation to the human and animal health, a safety evaluation of the toxicological assessment of expressed novel protein can be found in section 4.2.3.2 of EFSA opinion on cotton GHB614 (EFSA, 2009c). The EFSA GMO Panel based its conclusions on: i) data from the degradation in simulated digestive fluids, ii) bioinformatics studies, iii) acute toxicity testing in mice, iv) information on maize GA21 (EFSA, 2007b) as the modified EPSPS protein is identical for both crops, and v) the fact that EPSPS enzymes occur in conventional plants, fungi and microorganisms and are thus consumed as part of the normal diet by humans and animals. No adverse effects associated with the intake of these proteins have been identified. Related to the toxicological assessment of the whole GM food/feed, it is stated in section 4.2.4 (EFSA 2009c) that on the basis of the comparative analysis the EFSA GMO Panel concluded that cotton GHB614 is compositionally and agronomically equivalent to the non-GM comparator and other conventional cotton varieties except for the introduced trait. In addition, this analysis as well as the molecular characterisation provided no indications of unintended effects of the genetic modification. Based on all the information available and according to the EFSA GMO Panel guidance document, animal safety studies with the whole food/feed were not required for this application (EFSA, 2006a).

## References

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- EFSA (European Food Safety Authority), 2005b. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation. EFSA Journal, 181, 1-33.
- EFSA (European Food Safety Authority), 2006a. Guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. EFSA Journal, 99: 1-100.
- EFSA(European Food Safety Authority), 2006b. Guidance document for the renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. EFSA Journal 435, 1-14.
- EFSA (European Food Safety Authority), 2007a. Guidance Document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events. EFSA Journal 512, 1-5.
- EFSA (European Food Safety Authority), 2007b. Opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG. EFSA Journal 541, 1-25.
- EFSA (European Food Safety Authority), 2008. Application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of the insect-resistant genetically modified maize MON89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 909, 1-30.
- EFSA (European Food Safety Authority), 2009a. Application (Reference EFSA-GMO-CZ-2005-27) for the placing on the market of the insect-resistant and herbicide-tolerant

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genetically modified maize MON88017, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 1075, 1-28.

EFSA (European Food Safety Authority), 2009b. Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. EFSA Journal 1138, 1-11.

EFSA (European Food Safety Authority), 2009c. Application (Reference EFSA-GMO-NL-2008-51) for the placing on the market of glyphosate tolerant genetically modified cotton GHB614, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 985, 1-24.

EFSA (European Food Safety Authority), 2010a. Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 8(11), 1879.

EFSA (European Food Safety Authority), 2010b. Scientific Opinion on application (EFSA-GMO-NL-2007-39) for the placing on the market of insect resistant and herbicide tolerant genetically modified maize MON89034 x MON88017 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 8(3), 1564.