Technical background for a complaint under Article 10 of Regulation (EC) No. 1367/2006 against: (a) the decision of the EU Commission to give market authorisation to herbicide-tolerant genetically engineered oilseed soybeans MON 87708 × MON 89788 (Monsanto), MON 87705 × MON 89788 (Monsanto) and FG72 (Bayer) for food and feed uses, import and processing under Regulation (EC) No 1829/2003; and (b) the continuing failure to set specific MRLs for residues from spraying with isoxaflutole on genetically engineered soybeans

Decision/omission in relation to which an internal review is sought: (a) Commission Implementing Decision (EU) 2016/1215, 2016/1216 and 2016/1217 of 22 July 2016, published on 26 of July 2016 in the Official Journal of the European Union ("the Decisions"); and/or (b) the continuing failure to set specific MRLs for residues from spraying with isoxaflutole on genetically engineered soybeans ("the Omission")

Summary

MON 87708 × MON 89788 (Monsanto), MON 87705 × MON 89788 (Monsanto) and FG72 (Bayer) are genetically modified herbicide-resistant soybeans developed by Monsanto and Bayer, and designed to withstand applications of herbicides, further oil quality has been changed in one of the soybeans:

- MON87708 x MON89788: resistance to glyphosate and dicamba
- FG72: resistance to glyphosate and isoxaflutole
- MON87705 x MON89788: doubled resistance to glyphosate and change in oil quality

The Decisions to grant the authorisation violate EU food law, in particular the GM Regulation and the Pesticide Regulations, as defined below. The Decisiosn and/or the Omission are fundamentally flawed because:

- The Commission failed to ensure a full and lawful assessment of the residues from spraying with complementary herbicides;

- The Commission has failed and continues to fail to set specific MRLs for residues from spraying with isoxaflutole on genetically engineered soybeans;
- The Commission has continued in the Decisions and otherwise to grant market authorisations where the GMO is resistant to a herbicide which has no applicable MRL and/or failed to ensure that conditions and/or monitoring are in place as required by the GM Regulation; and/or
- The Commission failed to ensure a full and lawful assessment of the residues from spraying with complementary herbicides.

The Omission also gives rise to a freestanding breach of the Pesticide Regulations.

There is a substantial body evidence which demonstrates that the requirements of the Pesticide Regulations as well as the GM Regulation are not fulfilled. In summary, substantial harm to human and animal health cannot be excluded as required by EU environmental law. On the contrary, there is clear evidence of unacceptable risks for consumers, animals and the environment. Since the requirements of EU regulations were not fulfilled, food and feed containing these residues can also not be considered as being safe.

Therefore, the authorisation of the three soybeans is a violation of GM Regulation as well as of the Pesticide Regulations. In more detail, the authorisation of the import of these genetically engineered soybeans has to be considered as a breach of Regulation 1829/2003 and Directive 2001/18 (GM Regulation) in combination with Regulation 396/ 2005 and Regulation 1107/2009 (the Pesticide Regulations) and Regulation 178/2002 (Food Safety Regulation). These regulations all request a high level of protection for health and the environment, are based on the precautionary principle and are requiring priority to the protection of health and the environment in comparison with commercial interests. The Omission also amounts to a violation of the Pesticide Regulations.

1. Legal Framework

1.1 Risk assessment based on Regulation 178 /2002

Before GMOs or pesticides can be placed on the market, they have to undergo a risk assessment to safeguard health and the environment.

The European Food Safety Authority, EFSA, is obliged to perform this risk assessment, based on the data provided by industry, taking into account relevant publications and expertise from national authorities.

EFSA was established by Regulation 178/2002, which lays down the general principle and requirements of food law (**“the Food Safety Regulation”**).

Chapter II Section 1 of the Food Safety Regulation sets out the *“General Principles of Food Law”* upon which European measures, such as the GM Regulation, should be based. These include (emphasis added):

- The *"General Objective"* of *"a high level of protection of human life and health and the protection of consumers' interests"*: Article 5 of the Food Safety Regulation (reflected in Recital (3)).

- The principle of *"Risk Analysis"*. According to Article 6 of the Food Safety Regulation:

> *"(1) In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.*
>
> *(2) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner."*

The regulations concerning genetically engineered organisms (GM Regulation) and regarding pesticide authorisation (Pesticide Regulation) were adopted with a view to achieving these General Principles by giving special emphasis on the precautionary principle.

For example, Recitals (2), (3) and (9) of the GM Regulation, Regulation 1829/20013, make it clear that (emphasis added):

> *"(2) A high level of protection of human life and health should be ensured in the pursuit of [Union] policies.*
>
> *(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms...should undergo a safety assessment through a [Union] procedure before being placed on the market within the [Union].*
>
> *(9) The new authorisation procedures for genetically modified food and feed should...make use of the new framework for risk assessment in matters of food safety set up by [the Food Safety Regulation]. Thus, genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority, of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States."*

Further, in Article 1 of the GM Directive 2001/18 it is stated:

> *"In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:*
> *- carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,*
> *- placing on the market genetically modified organisms as or in products within the Community.*

The EU Pesticide Regulation is based on the same principles.

For example, in Regulation 1107 / 2009 it is Recital 8 it is stated:

> *The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.*

Recital 24:

> *The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or animal health, including that of vulnerable groups, or any unacceptable effects on the environment.*

Article 1, 4. reads:

> *The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.*

Article 1 of Regulation 396/ 2005 reads:

> *This Regulation establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, in particular the need to ensure a high level of consumer protection and harmonised Community provisions relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin.*

1.2 GM Regulation

Regulation 1829/2003 for genetically modified food and feed states that in order to protect human and animal health, food and feed that consists of, contains, or is produced from genetically modified organisms should undergo a safety assessment before it is placed on the market in the European Union.

“Genetically modified organism” is defined in Article 2(2) of the Directive as “*an organism, with*

the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination", where an *"organism"* is defined in Article 2(1) as *"any biological entity capable of replication or of transferring genetic material"*.

Food and/or feed that consists of, contains, or is produced from, genetically modified organisms must not:

- *"have adverse effects on human health, animal health or the environment"*: Articles 4(1)(a) and 16(1)(a) GM Regulation; or

- be placed on the market *"unless it is covered by an authorisation granted in accordance with"* the GM Regulation: Articles 4(2) and 16(2) GM Regulation.

In short, an authorisation cannot be granted because it has not been proven that the genetically modified food/feed is safe. EU Regulations require be establish that it is safe: The food or feed can only be authorized if it will not have adverse effects on human health, animal health or the environment.

(a) Particular provisions of GM Regulation

The GM Regulation applies to genetically modified food and feed. Articles 3 to 14 apply to genetically modified food, Articles 15 to 23 to genetically modified feed. The placing on the market of genetically modified food or feed requires an authorisation (Article 4 for food, Article 16 for feed).

Article 5(5) of Regulation 1829/2003 provides that applications for GMOs or food containing or consisting of GMOs must be accompanied by, amongst other things, *"information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision"*.

Article 6(4) provides (emphasis added): *"In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs…"*

The European Commission has the responsibility for authorising the placing on the market of genetically modified food or feed. Accordingly, it has an obligation to attach the necessary conditions to the authorisation in order to ensure that the food or feed has no adverse effects on human health, animal health or the environment (Article 4(1)). It has its own responsibility in this regard and may not rely on the – non-binding – opinion of EFSA; in the past, the Commission has on occasion added supplementary conditions on the placing on the market of genetically modified food products[1].

The GM Regulation, with its specific focus on ensuring that genetically modified food and feed adds an important additional layer of scrutiny which requires EFSA and the Commission to

[1] See for example Commission decision 2010/135/EU, OJ 2010, L 53 p.11, Recital 18 and Article 4(e), where additional monitoring measures were requested.

establish whether it is safe.

The Court of Justice confirmed this interpretation and stated that[2] (emphasis added):

> *"Regulation 1829/2003 applies to the specific field of food and feed. As regards food, its first objective, referred to in article 4(1), is also to avoid adverse effects on human health and the environment. However, Directive 2001/18 [was] drafted primarily from the angle of the concept of 'deliberate release' which is defined in article 2(3).. as an intentional introduction of a GMO into the environment, without specific containment measures designed to limit their 'contact' with the 'general population and the environment'. That approach thus appears to be more general, including with regard to the placing on the market of a GMO as a product. In this respect, … recitals 25, 28 and 32 in the preamble to Directive 2001/18 link the need to introduce an assessment and authorisation procedure to the situation in which the placing on the market includes a deliberate release into the environment. Although Regulation 1829/2003 also includes, in particular in Articles 5(5) and 6(4), aspects of environmental risk assessment of food, it is, as regards food, based overwhelmingly on an appraisal emphasizing protection of human health, which is linked to the specific fact that that food is, by definition, intended for human consumption. Thus, in accordance with recital 3 in the preamble, in order to protect human health, foods containing, consisting or produced from GMOs must undergo a 'safety' assessment. Regulation 1829/2003 thus introduces an additional level of control. That regulation would be rendered nugatory, if the view were to be taken that an assessment carried out and an authorisation issued pursuant to Directive … 2001/18 covered all subsequent potential risks to human health and the environment".*

(b) Particular provisions of Directive 2001/18[3]

Directive 2001/18 requires that the placing on the market of a genetically modified organism (GMO) as or in a product may only take place after written consent by the competent authority has been given (Article 19). The application for such consent (notification, Article 13) must be accompanied by an environmental risk assessment, by other information, and by a monitoring plan (Article 13(2)b, (2)(a), and 2(e)).

The environmental risk assessment

Recital (19) of Directive provides that (emphasis added) *"[a] case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs in the environment."* Moreover, *"[n]o GMOs, as or in products, intended for deliberate release are to be considered for placing on the market without first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by their use."*

Recital (33) of the Directive indicates that the environmental risk assessment submitted as part of the notification procedure has to be *"full"*. Recital 55 stresses the importance of following *"closely"* the development and use of GMOs.

Article 13 (2)(b) provides that the notification must be accompanied by *"the"* environmental risk assessment and the conclusions required in Annex II, section D. Annex II section D provides that information on the points listed in sections D1 or D2 should be included, as appropriate, in

[2] Court of Justice, case C-442/09 *Bablok*, Judgment of 6 September 2011, paragraphs 97 – 102.

[3] These chapters are mostly derived from Ludwig Krämer Dossier, 2012, attached

notifications with a view to assisting in drawing conclusions on the potential impact from the release or the placing on the market of GMOs. This information is to be based on the environmental risk assessment carried out in accordance with the principles laid down by sections B and C of Annex II to the Directive.

Accordingly, the principles with which environmental risk assessments should comply are laid down in Annex II to the Directive. Annex II indicates that the environmental impact assessment is not limited to an examination of the effects of genetically modified products containing GMO on the natural environment, but must also examine the effects on human health from the deliberate release of the GMO. This follows from the general objective of Directive 2001/18 as laid down in Article 1 – *"[i]n accordance with the precautionary principle, the objective of this Directive is…to protect human health and the environment"*[4], in Recital 5 of the Directive, and the reference to *"human health or the environment"* in Annex II itself, where this reference appears five times in the introductory remarks and in each of the four parts A to D of that Annex. Further, section A of Annex II states that (emphasis added):

> *"The objective of an [environmental risk assessment] is, on a case by case basis, to identify and evaluate potential adverse effects of the GMP, either direct, indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The [environmental risk assessment] should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used."*

Article 191(1) TFEU (The Treaty of the Functioning of the European Union) also highlights the obligation of the EU in respect to the *"protection of the environment"*[5].

The introductory remarks to Annex II of the Directive state (emphasis added): *"A general principle of environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment"*.

Section B sets out the general principles governing the performance of an environmental risk assessment, which include (emphasis added) *"identified characteristics of the GMP and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations."*

Section C.2 of Annex II describes the *"Steps in the environmental risk assessment"*. As a first step, this part requires the identification of characteristics that may cause adverse effects, and gives a general indication of what has to be done, noting that *"it is important not to discount any potential adverse effect on the basis that it is unlikely to occur"*. Section C.2 then alerts to *"Potential adverse effects of GMOs will vary from case to case and may include: - disease to humans including allergenic or toxic effects…"* Finally, Section C.2 outlines the steps involved in reaching an overall assessment of the risk posed by a genetically modified plant. These include the evaluation of the potential consequences of the adverse effects (for which the evaluation should assume that such an effect will occur), the evaluation of the likelihood of and the risk posed by the occurrence of each

[4] The importance of the protection of human health is reinforced by the multiple references to it in the Directive – see: Article 13(6), in Recital 5 of the Directive, and the reference to "human health or the environment" in Annex II itself, where this reference appears five times in the introductory remarks and in each of the four parts A to D of that Annex.

[5] Article 191(1) TFEU: " *Union policy on the environment shall contribute to the pursuit of the following objectives:... – protecting human health..."*

potential adverse effect, and the identification of risk management strategies.

The conclusions of the risk assessment shall be part of the notification (alongside the application under the GM Regulation on the facts of this case), in order to allow the competent authority to draw its own conclusions (Annex II, part D). The conclusions on the risk assessment shall include *"Possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMOs [GMHP] and persons working with, coming into contact with or in the vicinity of the GMO [GMHP] release(s)"*[6].

It follows from these provisions that the environmental risk assessment has to include all effects, which the placing of a GMO on the market/deliberate release may have on human health, including any possible cumulative effects. This also includes the potential effects of the use of herbicides or pesticides on the GMO plant or product. Of particular importance is the fact that the assessment of a particular potential adverse effect may not be excluded from the overall assessment on the basis that it is considered it is unlikely to occur. Although the likelihood of a potential adverse effect is one factor of the evaluation, the magnitude of its potential consequences and the risks it would pose to the environment and human health must still be assessed, and both of these elements should be taken into account in the overall risk assessment.

Other information

"Other information" which has to accompany every notification under Article 13 of the Directive, shall include *"considerations for human health and animal health, as well as plant health: (i) toxic or allergenic effects of the GMO and/or their metabolic products"*[7], furthermore *"identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction"*[8]*and, as a catch-all formula "other potential interactions with the environment"*[9]. For genetically modified higher plants (GMHP), Annex IIIB applies, this requires the notifier to supply, with his notification, the following information: *"Information on any toxic, allergenic, or other harmful effects on human health arising from the genetic modification"*[10]; *"Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs"*[11]; and *"Potential interactions with the abiotic environment"*[12].

This wording with regard to the "other information" is thus again very broad and tries to cover all effects that the genetically engineered organism might have on human health or animal health. The choice of the terms *"arising from the genetic modification"* clarifies that information is to be supplied not only on the effects caused directly by the GMO, but also on all other harmful effects on human or animal health and which are, in one way or another, related to the genetically modified plant, such as residues from pesticides.

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6 Directive 2001/18, Annex II, part D1 no.6 and part D2 no.6. Part D1 refers to GMOs other than higher plants, part D2 to genetically modified higher plants (GMHP). For reasons of simplification the two sections D1 no. 6 and D2 no. 6 were assembled in one text.

7 Directive 2001/18, Annex III A, section II, C.2(i)

8 Directive 2001/18, Annex IIIA, section IV B12.

9 Directive 2001/18, Annex IIIA, section IV B.16.

10 Directive 2001/18, Annex IIIB, section D no.7.

11 Directive 2001/18, annex IIIB, section D no.8.

12 Directive 2001/18, annex IIIB, section D no11.

Conclusion on GM Regulation

Under the GM Regulation, the authorisation of GMOs for use as food and feed must not have adverse effects on human health, animal health or the environment. To that end, the competent authority is required to carry out a full and proper safety and risk assessment of the GMO in order to ensure that the GMO does not have any such adverse effects.

It follows from all these provisions, that under the GM Regulation and Directive 2001/18, a notifier's documentation must contain a comprehensive environmental risk assessment of the GMO, which includes all or potential adverse effects on, the environment, human and animal health which could occur from its deliberate release. Unlikely occurrences must also be included in the assessment and evaluated – as well as long-term potential cumulative effects and also all other harmful effects on human or animal health and which are, in one way or another, related to the genetically modified plant, such as residues from spraying with complementary herbicides.

Taken together, the purpose or part of the purpose of the GM Regulation is to protect human and animal health, and as GMO plants are consumed by humans, the risk assessments and the monitoring plan must, therefore, also contain an assessment of such potential effects (risk assessment) and a strategy to verify whether such adverse effects actually occur.

1.3 Pesticide Regulations

The Pesticide Regulation is based on Regulation 1107/2009 for placing on the market of relevant products and Regulation 396/2005 for setting Maximum Residue Levels (MRLs).

Both Regulations require a high level of protection for health and the environment as outlined above (see for example Recitals 8 and 24, and Article 1.4, of Regulation 1107/2009 as well as Recital 5 and Article 1 of Regulation 396/2005).

In consequence, products presenting an unacceptable risk to health and the environment cannot be allowed on the market, safety has to be established to make sure that substances or products produced or placed on the market do not have any harmful effect on human or animal health.

Particular provisions of the Pesticide Regulation

Recital (8) of Regulation **1107/2009** explains explains the purpose of the Regulation as follows:

> *"… to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment."*

Recital (7) notes that plant protection products may (emphasis added) *"involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used."*

Article 4. 2 of Regulation 1107/2009 provides that the residues of the plant protection products, consequent on application consistent with good plant protection practices and having regard to realistic conditions of use, shall meet the following requirements:

> *"(a) they shall not have any harmful effects on human health, including that of vulnerable groups, or a nimal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater…"*

Article 29 sets out the requirements which must be met for authorisation to be gratned for placing a plant protection product on the market. It makes clear that (emphasis added):

> *"1. (…) a plant protection product shall only be authorised where following the uniform principles referred to in paragraph 6 it complies with the following requirements:*
>
> *(a) its active substances, safeners and synergists have been approved;*
>
> *(…)*
>
> *(f) the nature and quantity of its active substances, safeners and synergists and, where appropriate, any toxicologically, ecotoxicologically or environmentally relevant impurities and co-formulants can be determined by appropriate methods;*
>
> *(g) its residues, resulting from authorised uses, and which are of toxicological, ecotoxicological or environmental relevance, can be determined by appropriate methods in general use in all Member States, with appropriate limits of determination on relevant samples;*
>
> *(i) for plants or plant products to be used as feed or food, where appropriate, the maximum residue levels for the agricultural products affected by the use referred to in the authorisation have been set or modified in accordance with Regulation (EC) No 396/2005.*
>
> *2. The applicant shall demonstrate that the requirements provided for in points (a) to (h) of paragraph 1 are met."*

Regulation 396/2005 in Recital (5) explains that (emphasis added):

> *"One of the most common methods of protecting plants and plant products from the effects of harmful organisms is the use of active substances in plant protection products. However, a possible consequence of their use may be the presence of residues in the treated products, in animals feeding on those products and in honey produced by bees exposed to those substances. According to Council Directive 91/414/EEC of 15 July 1991 concerning the*

placing of plant protection products on the market, public health should be given priority over the interests of crop protection, thus it is necessary to ensure that such residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals. MRLs should be set at the lowest achievable level consistent with good agricultural practice for each pesticide with a view to protecting vulnerable groups such as children and the unborn."

Recital (10) states that (emphasis added):

In addition to those basic rules, more specific rules are needed to ensure the effective functioning of the internal market and trade with third countries in relation to fresh, processed and/or composite plant and animal products intended for human consumption or animal feed in which pesticide residues may be present, whilst providing the basis for securing a high level of protection for human and animal health and the interests of consumers. Such rules should include the establishment of specific MRLs for each pesticide in food and feed products and the quality of the data underlying these MRLs.

Recital (13) underscores the complementary nature of food and feed and plant protection production regulation: *"It is appropriate that specific rules concerning the control of pesticide residues be introduced to complement the general Community provisions on the control of food and feed."*

Recital (26) makes the clear the need to set MRLs for imported products, i.e. those produced outside the Community (emphasis added):

"For food and feed produced outside the Community, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Community. It is therefore appropriate that MRLs are set for imported products that take these uses and the resulting residues into account provided that the safety of the products can be demonstrated using the same criteria as for domestic produce."

Article 2 sets out the Regulation's scope.

Section 1 of Chapter II of the Regulation sets out the procedure for applications for MRLs. Section 2 then sets out how such applications should be considered by the authority. Section 3 then addresses, separately, decisions on the setting, modification or deletion of MRLs. Article 14 outlines the steps to be taken by and the decisions which must be made by the EU Commission:

"1. Upon receipt of the opinion of the Authority and taking into account that opinion, a Regulation on the setting, modification or deletion of an MRL or a Decision rejecting the application shall be prepared by the Commission (…)

2. With regard to the acts referred to in paragraph 1, account shall be taken of:

(a) the scientific and technical knowledge available;

(b) the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and their known cumulative and synergistic effects, when the methods to assess such effects are available;

(c) the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals;

(d) the results of any evaluations and decisions to modify the uses of plant protection products; (…)

Summary of the key provisions of the Pesticide Regulations

In the specific context of market authorisation of genetically engineered plants, some of relevant provisions of the Pesticide Regulation are:

Article 29 of Regulation 1107/2009: active substances and synergists have to be approved, the maximum residue levels for the specific agricultural products have to be determined;

Article 4 of Regulation 1107/2009: pesticides must not have any harmful effects on human or animal health, taking into account known cumulative and synergistic effects;

Recital 5 of Regulation 396/2005: residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals;

Recital 10 of Regulation 396/2005: specific MRLs for each pesticide in food and feed products have to be established;

Recital 26 of Regulation 396/2005: MRLs have to be set for food and feed produced outside the Community if produced by different agricultural practices as regards the use of plant protection products;

Article 14 of Regulation 396/2005: the presence of pesticide residues arising from sources other than current plant protection uses and their known cumulative and synergistic effects have to be determined; any potential risks to consumers with a high intake and high vulnerability have to be taken into account.

1.4 Further legal considerations

(a) The interface between GM and Pesticide Regulation

Risk assessment of genetically engineered herbicide resistant plants as currently performed by EFSA is divided in the assessment of the organism, performed by the GMO-panel and assessment of the pesticide, performed by the pesticide panel. However, this division of labour should not result in or be relied upon in justifiying ‘gaps’ in the assessment of the safety of the GMO sprayed with the pesticide.

Consequently, even if a particular pesticide is authorised for use on plants grown in the EU or imported from third counties, further investigation of the residues from spraying with the complementary herbicide may be required (if the active ingredient is the same as the one allowed in the EU). Due to the specific agricultural practices that go along with the cultivation of these herbicide resistant plants, there are for example specific patterns of applications, exposure, occurrence of specific metabolites and emergence of combinatorial effects that require special attention.

For example, agricultural practice as established in the usage of the herbicides on these plants might result in an increase in the amounts of herbicide that are sprayed and subsequently in the amounts of residues in the harvest. Furthermore, herbicide-tolerant plants are meant to survive the application of the complementary herbicide whereas most other plants will die after short time. Thus, the residues might accumulate and interact in the plants in another way than under previous agricultural practices. Finally, if herbicides are meant to be applied in combination to crops, the residues thereof can lead to a specific pattern of combinatorial exposure of the feed and food chain.

As a publication by Kleter et al. (2011) shows, using herbicides to spray genetically engineered herbicide-resistant plants does indeed lead to patterns of residues and exposure that are not, presently, taken into account in regular pesticide registration:

> *"1. GM herbicide-resistant crops can change the way that herbicides can be used on these crops, for example:*
>
> *(a) post-emergent over-the-top applications (i.e. on the crop itself) instead of directed sprays, avoiding herbicide contact with the crop; or*
>
> *(b) pre-emergent and pre-harvest applications made to the conventional crop and not, or in different quantities, to the GM crop.*
>
> *2. The residue profile of the applied pesticide may have been altered on the basis of the nature of the modification.*
>
> *3. The overall pattern of pesticides applied to the particular crop may have been altered, leading to different exposure to pesticide residues overall."*

Also, according to a reasoned legal opinion drawn up by Kraemer (2012) residues from spraying with complementary herbicides have to be taken into account in the risk assessment of genetically engineered plants from a regulatory point of view:

> *41. It is the objective of Directive 2001/18 to avoid any adverse effect of the genetically modified plant on human health. The provisions of the Directive on the environmental risk assessment are very broad and try to catch - in the abstract, it is true – all possible cases, where direct or indirect, immediate, delayed or unforeseen adverse effects might occur. Then, it is only logical that, when genetically modified plants which are tolerant to certain herbicides, are exposed to pesticide or herbicide treatment, the effects of such treatment on the plant – and later on human or animal health – must be examined during the*

environmental risk assessment.

44. The question is thus, whether it can be scientifically excluded that herbicide residues and genetically modified plants have any cumulative or combinatorial effect on humans or animals. As soon as there is any scientific doubt in this regard, be it voiced by only some researchers, there is a need to monitor the consumption of the genetically modified food or feed. This follows from the necessity to exclude any adverse effect.

45. Large scale cultivation of herbicide tolerant genetically modified plants may lead to the increase of the amount of sprayed herbicides and to an increased frequency of spraying. This may lead to a significantly higher level of herbicide residues in the genetically modified plant than in other plants. Moreover, while most plants will be killed by the spraying of herbicides, herbicide tolerant genetically modified plants will survive the spraying. This may lead to metabolites which are specific to such plants.

46. Such risks of complementary herbicides and their residues which are specificf for the usage on genetically modified plans and which might lead to specific metabolites or have combinatorial effects with other plant constituents, cannot be excluded as being completely improbable. Therefore the risk assessment of the genetically modified plant must take this aspect into account and evaluate it.

Such combinatorial effects must also be assessed in determining whether the GMO is safe to be used as food and feed.

It follows that under the GM Regulation, a notifier's documentation must contain a comprehensive safety and environmental risk assessment of the GMO, which includes all or potential adverse effects on the environment as well as on human and animal health. This requirement includes long-term potential and accumulative effects and also all other harmful effects on human or animal health and which are, in one way or another, related to the genetically modified plant, such as residues from spraying with complementary herbicides. Thus it is necessary to take into account the residues from spraying with complementary herbicide in single and in stacked events during risk assessment before any authorisation of genetically engineered organisms is granted.

This is also partially reflected in current practise of risk assessment as performed by EFSA: Both, the guidance documents issued by EFSA and the Commission Implementation Regulation (EU) No 503/2013 require the assessment of herbicide resistant plants with and without the application of the complementary herbicide. Further they require the testing of new constituents other than proteins.

In the context of herbicide resistant genetically engineered plants, these provisions should be interpreted in a way that also residues from spraying with pesticides have to assessed during GMO-risk assessment: Since in the cultivation of herbicide resistant plants, the application of the complementary herbicide is part of regular agricultural practise, it can be expected that the residues from spraying are always present in the harvest and could therefore be seen as new "constituents".

In any case, both, the Pesticide Regulation and the GM Regulation require a high level of protection for health and the environment. Thus in regard to herbicide resistant plants, specific assessment of residues from spraying with complementary herbicides has to be considered as being a prerequisite

before any authorisation for genetically engineered plants can be granted.

In consequence, no authorisation for import and usage in food and feed of genetically engineered plants can be granted if the plants contain residues from spraying with complementary herbicides that pose unacceptable risks or are under suspect to cause harm to health of humans and / or animals.

(b) The legal basis to request an internal review according to EU Regulation (EC) No. 1367/2006

The EU Commission is of the opinion that requests for internal review can not be filed if they human and / or animals health (see case T-33/16, pending at the Court of Justice). Testbiotech is contesting this opinion, see pending case T-33/16 at the Court of Justice and the arguments filed therein by the applicants. Further we draw the attention to the legal opinion drawn up by Kraemer (2016) as attached. Testbiotech's position is that the approach adopted by the Commission is manifestly flawed.

2. Factual Background

In July 2016, the EU Commission, granted market authorisation for genetically engineered soybeans produced by companies Bayer and Monsanto. Prior to this, the European Parliament[13] as well as Testbiotech[14] and other organisations had called on the EU Commission not to authorise these crops.

MON 87708 × MON 89788 (Monsanto), MON 87705 × MON 89788 (Monsanto) and FG72 (Bayer) are genetically modified herbicide-resistant soybeans developed by Monsanto and Bayer, which are designed to withstand applications of herbicides, further one of the soybeans is changed in its oil quality:

- MON87708 x MON89788: resistance to glyphosate and dicamba
- FG72: resistance to glyphosate and isoxaflutole
- MON87705 x MON89788: doubled resistance to glyphosate and change in oil quality

Due to the specific agricultural practices that go along with cultivation of these soybeans, it is evident that these authorisations concern genetically engineered plants that will inevitably hold or contain residues from spraying with the complementary herbicides.

In this context, it is of relevance that isoxaflutole is classified as probably carcinogenic (for more details see: Reuter, 2015). Also dicamba is known to trigger negative health effects (for details, see Reuter 2015).

[13] www.europarl.europa.eu/sides/getDoc.do?pubRef=-%2f%2fEP%2f%2fTEXT%2bMOTION%2bB8-2015-1365%2b0%2bDOC%2bXML%2bV0%2f%2fEN&language=EN

[14] www.testbiotech.org/en/campaign_toxic_soy

Further glyphosate is suspected of being carcinogenic (IARC, 2015). Since concerns about the potential health impacts of glyphosate could not be settled, the EU Commission at the end of June 2016 decided only to extend the approval period of the active substance glyphosate but not to renew authorisation. Further the Commission raised specific concerns regarding the toxicity of POE-tallowamine, which is one of the co-formulants widely used for glyphosate-based products. In consequence, the Commission proposes to Member States to ban POE-tallowamine as a co-formulant in glyphosate-based products[15].

It can certainly be expected that residues from spraying with these complementary herbicides and from co-formulants will be present in the harvest. Therefore, harvested soybeans imported into the EU will contain residues from herbicide formulations allowed for use in countries such as Argentina, Brazil or the US. Commercial large-scale cultivation of these plants in those countries is known to result in a strong selective pressure on weeds to develop resistance to these herbicides (Sammons & Gaines, 2014). This can lead to increasing amounts of herbicide being sprayed on crops and subsequently to increasing amounts of residues in the harvest (see, for example, Bohn et al., 2014; Cuhra 2015; Benbrook 2016).

3. Grounds for the complaint

The decisions to grant the authorisation is a violation of EU food law, especially of the GM and Pesticide Regulation. In more detail the decisions suffer from:

- Failure to assess residues from spraying with complementary herbicides (Ground A);
- Failure to set specific MRLs for residues from spraying with isoxaflutole (Ground B) and/or the flawed granting of market authorisations where the GMO is resistant to a herbicide which has no applicable MRL (Ground C);
- Failure to assess accumulated effects of residues from spraying with complementary herbicides (Ground D).

It summary, substantial harm to human and animal health can not be excluded, on the opposite, there are unacceptable risks for consumers, animals and the environment. Since the requirements of the EU regulations are not being met, food and feed containing these residues cannot be considered to be safe. Therefore, the authorisation of the three soybeans is a breach of GM Regulation and Pesticide Regulation.

[15] FAQs: Glyphosate, Brussels, 29 June 2016, Frequently Asked Questions on Glyphosate, Memo updated at 14:45 on 29/06/2016 following the Commission's decision to extend the authorisation of glyphosate until the European Chemical Agency issues its opinion.

Ground A: Failure to assess residues from spraying with complementary herbicides

Regulation 1107/2009 requires that not only the active substances but also, safeners, synergists and adjuvants (Co-formulants) are assessed in accordance with Article 4 and / or to fulfil the requirements of Annex 2 and 3 of the Regulation. Assessment has to be performed in a way that residues from spraying (which include active substances, safeners, synergists and adjuvants) do not have a harmful effect on human or animal health or pose unacceptable risks for the environment. Furthermore, the protection of vulnerable groups of the population, including pregnant women, infants and children is a specific request made by EU regulation.

However, the extent of the data provided on the herbicide formulations applied to the crop plants prior to import was so insufficient that no reliable risk assessment could be performed. This is particularly evident in EFSA´s opinion on glyphosate and glyphosate-based pesticides.

In its risk assessment of glyphosate, EFSA stated (EFSA 2015a), that not enough data were available on the application of glyphosate to genetically engineered plants resistant to the herbicide

> *"In the framework of the renewal, representative uses were proposed for conventional crops only and residue trials on glyphosate tolerant GM crops were not provided."*

This is the reason why EFSA (2015a) risk assessment on effects on health from glyphosate is limited to conventional crops:

> *"Based on the representative uses, that were limited to conventional crops only, chronic or acute risks for the consumers have not been identified."*

Further, EFSA (2015a) states that more investigations are needed, for example, in regard to the carcinogenicity of the formulations that are applied commercially:

> *"In particular, it was considered that the genotoxic potential of formulations should be addressed; furthermore EFSA noted that other endpoints should be clarified, such as long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of formulations (EFSA, 2015b)."*

In addition, EFSA (2015b) provided an assessment of POE-tallow amine additives, which are used in several formulations with glyphosate, and came to the conclusion that these are more toxic than glyphosate:

> *"Compared to glyphosate, a higher toxicity of the POE-tallow amine was observed on all endpoints investigated."*

However, no data were made available on the actual load of residues from spraying the crop plants with these formulations (EFSA, 2015b):

> *"The genotoxicity, long-term toxicity and carcinogenicity, reproductive/developmental toxicity and endocrine disrupting potential of POE-tallow amine should be further clarified. There is no information regarding the residues in plants and livestock. Therefore, the available data are insufficient to perform a risk assessment in the area of human and animal*

health for the co-formulant POE-tallow amine."

It has to be expected that the genetically engineered soybeans for which authorisation for import is being sought, have been sprayed with formulations that are not allowed in the EU, but are being used in countries such as Argentina, Brazil and the US.

EFSA was unable to deliver a conclusive risk assessment on the actual risks of residues from spraying with glyphosate and the various glyphosate formulations. Therefore, the residues from spraying glyphosate on the genetically engineered soybeans as listed in the complaint, do not meet the requirements of Regulation 1107/2009. This crucial loophole in risk assessment was also cautiously admitted in a letter by the EU Commission sent to EFSA[16]:

> *"A significant amount of food and feed is imported into the EU from third countries. This includes food and feed produced from glyphosate-tolerant crops. Uses of glyphosate-based plant protection products in third countries are evaluated by the competent authorities in those countries against the locally prevailing regulatory framework, but not against the criteria of Regulation (EC) No 1107/2009. (…)*
>
> *EFSA is hence requested under Article 31 of Regulation (EC) No 178/2002 to assess the available information on glyphosate residues in feed, including particular feed imported from outside the EU/ third countries e.g. glyphosate-tolerant GM crops, and conclude on the possible impact of those residues on animal health."*

This letter is especially relevant, since the EU Commission is aware that there are severe health risks stemming from the formulations of glyphosate that contain POE-tallow amine. As it shown in the communication from the EU Commission published at the end of June 2016, the EU Commission is recommending to prohibit these formulations in the EU.[17] It is unacceptable that, at the same time, the EU Commission stays inactive in regard to residues from spraying of POE-tallow amine residues in imported soybeans.

Since it was not shown that the residues from spraying crop plants with glyphosate-based plant protection products in third countries (and to a similar extent also dicamba- and isoxaflutole-based formulations) do not pose harm to health and the environment, the genetically engineered soybeans containing such residues cannot be regarded as safe as requested by GM Regulation 1829/2003 and 2001/18. Thus market authorisation for these crops is a severe violation of both, the Pesticide Regulation and the GM Regulation.

In particular:

(a) The Commission failed to ensure that an adequate safety and environmental risk assessment was carried out;

(b) As a result, the Commission:

   i. erred in granting the authorisations at all;

[16] www.testbiotech.org/node/1636

[17] FAQs: Glyphosate, Brussels, 29 June 2016, Frequently Asked Questions on Glyphosate, Memo updated at 14:45 on 29/06/2016 following the Commission's decision to extend the authorisation of glyphosate until the European Chemical Agency issues its opinion.

ii. erred in law by failing to apply necessary conditions to those authorisations and requiring further investigation;

iii. erred by failing to ensure any or adequate monitoring of the effects of treating the soybeans with the herbicides.

Grounds B & C: Failure to set specific MRLs for residues from spraying with isoxaflutole

Regulation 396/2005 (Recital 10) requests that specific MRLs for each pesticide in food and feed products have to be established. Recital 26 of Regulation 396/2005 establishes that MRLs have to be set for food and feed produced outside the Community if produced by different agricultural practices as regards the use of plant protection products. Article 14 of Regulation 396/2005 requests the presence of pesticide residues arising from sources other than current plant protection uses and their known cumulative and synergistic effects have to be determined; any potential risks to consumers with a high intake and high vulnerability have to be taken into account.

In the case of risk assessment of isoxaflutole, none of these requirements are fulfilled. In 2016, EFSA has presented its peer review of the pesticide risk assessment of the active substance isoxaflutole which clearly shows major data deficiencies in regard to the requirements of Regulation 396/2005:

- Carcinogenicity and developmental toxicity were confirmed for the active substance.
- In soybean seed three different metabolites of isoxaflutole were found, most of them in higher levels than compared to other usages.
- Risk assessment of these residues in food and feed derived from genetically engineered soybeans FG72 could not be concluded and no MRL could be determined due to lack of data.
- Further data gaps concern the method for the determination of residues in food and feed of plant origin.

Since no MRL could be set for the residues from isoxaflutole being applied as complementary herbicide on to genetically engineered soybeans, products containing such residues cannot be allowed on the EU market. In consequence, the genetically engineered plants FG72 also cannot be regarded as safe as requested by GM Regulation 1829/2003 and 2001/18. Thus market authorisation for these crops was a severe violation of several EU regulations. The same conclusion has to be drawn from the EFSA opinions (EFSA 2015 a&b) in regard to the residues from spraying with glyphosate.

Further and/or alternatively, the Commission contines to fail to ensure that adequate data is collected, via the GM authorisation process or otherwise, to permit the setting of the MRLs for isoxaflutole.

Ground D: Failure to assess combinatorial effects from spraying with complementary herbicides.

Article 4 of Regulation 1107/2009 requests that pesticides must not have any harmful effects on human or animal health, taking into account known cumulative and synergistic effects. Regulation 396/2005 requires in its Article 14 that the presence of pesticide residues arising from sources other than current plant protection uses and their known cumulative and synergistic effects have to be determined.

MON87708 x MON89788 and FG72 for the first time in plant production allow that herbicides isoxaflutole and dicamba can be applied to soybeans and in combination with glyphosate. It is known from pesticide assessment that the application of these herbicides leads to the occurrence of residues in the harvested plant material. Therefore, it has to be assumed that the combined spraying of these herbicides will also lead to a combination of these residues in the harvest.

It is also known, that the effects due to the accumulation of residues can have a negative impact on human and animal health: Spraying with isoxaflutole and dicamba results in residues that are assumed to pose risks to human health. Several similar endpoints in regard to negative health effects have been found for glyphosate. For example, the residues from the usage of isoxaflutole and glyphosate are both known (or suspected of being) to be probably carcinogenic. Consequently, it is not unlikely that the negative health effects emerging from combined usage might be more severe than might be expected from the using the single herbicides (see Reuter, 2015). To summarise, the combinatorial health impacts resulting from the consumption of soybeans that have been sprayed with a mixtures of herbicides are likely to be much worse than those resulting from single active ingredients.

However, the effects of these known accumulations on health have not been investigated in the case of MON87708 x MON89788 and FG72. EFSA did not assess the combinatorial effects (synergistic or additive) resulting from the residues of combined usage of these herbicides as it has to be expected due to the agricultural practise that go along with the cultivation of these soybeans. The EFSA GMO panel also failed to request any feeding trials with the whole food and feed.

The EU Commission has confirmed that cumulative effects should be assessed, but, at the same time, said there were no suitable methods available (see attached document, EU Commission, 2016). This latter argument is a long way from being substantiated in this case. EU Regulations 1107/2009 and 396/2005, request the assessment of combinatorial effects. These Regulations were adopted several years ago, but the EFSA and the EU Commission were unable to come up with validated methods to assess the overall combinatorial effects of pesticides. There might be several reasons for this general failure of the risk assessor and the risk manager: Risk assessment of the combined effects of various compounds derived from a broad range of different sources can indeed pose scientific problems.

However, in these cases, there is no reason to assume any difficulties regarding methodology that

can be applied to assess accumulative effects on health. It is a simple scientific procedure to test the combined toxicity of two compounds with known modes of action and similar endpoints as is the case for dicamba and isoxaflutole when applied in combination with glyphosate. For example, the design for feeding trials to test combined carcinogenicity could be developed from existing OECD guidelines.

It also should be taken into account, that GM Regulation also requires the risk assessment of potential accumulated effects. This requirement is not bound to any further criteria, if e.g. such effects are already known, whether they can be expected or not, or if specific methods are available. Although the current approach of EFSA in implementing this requirement might not be seen as being sufficient, the possibility of assessing such effects (for example, combined toxicity of Bt toxins) are not being put into question by EFSA.

It is illogical and unacceptable that EFSA and the Commission are failing to apply these requirements to combined toxicity of residues from spraying with the complementary herbicides. For example feeding trials with the whole food & feed could be established, to assess these effects. The soybeans used in these trials should be sprayed with the single pesticides as well as with the relevant combinations. There is no scientific obstacle to perform such feeding trials. It only would require additional groups for testing and as reference.

In any case, the toxic residues from spraying and their accumulative effects need to be taken into account to fulfil in the EU legal requirements based on the precautionary principle which require a high level of protection for health and the environment. They have to be investigated and assesses no matter if the assessment is performed under the GM Regulation or the Pesticide Regulations.

Failure to test combined toxicity of the residues from spraying with the complementary herbicides infringes EU Pesticide Regulations and GM Regulation. In consequence, the genetically engineered plants FG72 and MON87708 x MON89788 cannot be regarded as safe as requested by GM Regulation and Pesticide Regulations. The grant of market authorisation for these crops is a severe violation of several EU regulations.

Conclusions:

There is a substantial amount of evidence that the requirements of Pesticide Regulation and GM Regulation are not fulfilled. In summary, serious adverse harm to human and animal health cannot be excluded. On the contrary, there are unacceptable risks for consumers, animals and the environment. Since the requirements of EU regulations are not being met, food and feed containing these residues cannot be considered to be safe.

Therefore, the authorisation of the three soybeans is a violation of GM Regulation as well as of Pesticide regulation. In more detail, the authorisation of the import of these genetically engineered soybeans has to be considered as a breach of Regulation 1829/2003 and Directive 2001/18 (GM Regulation) in combination with Regulation 396/ 2005 and Regulation (EC) No 1107/2009 (Pesticide Regulation) and Regulation 178/2002 (Food Safety Regulation). These regulations all request a high level of protection for health and the environment; they are based on the

precautionary principle and require that high priority is given to the protection of health and the environment over and above commercial interests.Therefore, the Decisions of the Commission has to be withdrawn.

Further and/or alternatively, the Omission, as defined above, also amounts to a breach of the Pesticide Regulations.

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