Technical background for a complaint under Article 10 of Regulation (EC) No. 1367/2006 against the decision of the EU Commission to give market authorisation to herbicide-tolerant genetically engineered oilseed rape MON88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto

Decision in relation to which an internal review is sought: Commission Implementing Decision (EU) 2015/687 of 24 April 2015, published on 30 of April 2015 in the Official Journal of the European Union ("the Decision")

Summary

MON88302 is a genetically modified herbicide-resistant oilseed rape developed by Monsanto, which is designed to withstand even higher dosages and even more frequent applications of herbicides. Monsanto filed an application for the import and usage of MON88302 in food and feed in the EU. Authorisation was granted in April 2015 by way of the Decision for the import of viable whole kernels, thereby risking the uncontrolled spread of the plants in the environment. Accordingly, the Decision violates EU GMO regulation and other relevant EU legislation for several reasons.

The risk assessment prepared by EFSA has considerable shortcomings. For example:

- The European Food Safety Authority (**"EFSA"**) failed to consider evidence which shows that and/or to require Monsanto to investigate whether biological components such as miRNA can be passed to humans and animals at the stage of consumption.

- Although the evidence available disclosed clear indications that the genetic modifications resulted in unintended effects in the plants, EFSA failed to consider this evidence properly and/or failed to require Monsanto to carry out further investigations were required. Potential health effects were not assessed sufficiently and/or investigated in accordance with the necessary standards.

- Despite the fact that the plants are genetically engineered to tolerate a higher dosage of glyphosate than other genetically engineered plants, EFSA failed to require Monstanto to obtain and submit data on the residues from spraying.

- EFSA failed to require Monsanto to produce reliable and sufficient data for the assessment of unintended releases and for gene flow into the environment. Further: (a) EFSA, and consequently the Commission, failed to impose case specific monitoring obligations on Monsanto in respect of potential spillage, accidental releases, misuse, and potential gene

flow into the environment. The Commission did not impose any obligation to take immediate action in case of unintended release. These missing requirements for specific monitoring and for effective control mechanisms are manifest violations of the relevant EU EU legislation: this failure could result in a permanent, uncontrolled and unauthorised release of MON88302 into fields and the environment.

- EFSA failed to take account of and/or consider properly the data or information available in important publications which were relevant to the assessment of long-term effects and the risks for gene flow to native plant populations.

Overall, the way in which the risk assessment was carried out by EFSA falls short of the legal requirements governing genetically modified foods and feeds within the EU pursuant to both Regulation 1829/2003 (**"the GM Regulation"**) and 178/2002 and Directive 2001/18 require (**"the Directive"**).

As to the safety and assessment of MON88302 as food and feed, EFSA, and the other EU institutions, are obliged to ensure that a high level of protection for both humans and the environment is maintained, with due regard to the precautionary principle. In order to ensure that such a high level of protection is provided, EFSA is required to investigate and assess all of potential implications of authorizing the use of the genetically modified food and feed in the manner sought – and where there is doubt the precautionary principle applies. Instead of fulfilling the legal requirements imposed by the EU legislation, EFSA has adopted a "don't look – don't find" approach – finding that there is nothing to suggest that MON88302 is unsafe rather than requiring Monsanto, in accordance with in particular the GM Regulation to prove that it is so. EFSA's approach, adopted and endorsed by the Commission, was to overlook the fact that crucial data had and have not been obtained and/or t fail to investigate or require Monsanto to further investigate concern disclosed by or raised by the limited data made available. Consequently, EFSA's opinion should have been rejected and the importing of MON88302 should not have been authorized by the Commission.

EFSA also failed to recommend, and the Commission failed to impose, any monitoring requirements pursuant to the GM Regulation on the use of MON88302 as food and feed as a result of its flawed risk assessment.

Moreover, the environmental risk assessment carried out by EFSA, and upheld by the Commission, fails to meet the requirements of Directive 2001/18. The Decision also upheld EFSA's flawed conclusion that Monsanto had proposed an adequate monitoring plan in accordance with the Directive.

Accordingly, the Decision is unlawful because it is based on a flawed and unlawful assessment of the risks posed by MON88302.

The Commission should now reconsider the Decision and withdraw it. Authorising the importation of viable whole kernels of MON88302 on the basis of EFSA´s opinion cannot be allowed.

1. General Legal Framework

The GM Regulation on 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 authorization cannot be granted because it has not been proven that the genetically modified food/feed is unsafe – it has to be established 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.

In order to obtain an authorisation, an application must be made to the competent authority of a Member State: Articles 5(2) and 17(2) GM Regulation. That application should include, among other things (emphasis added):

- "*a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1) [/16(1)]*": Articles 5(3)(e) and 17(3)(e) GM Regulation; and

- "*either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in Article 13(2)(a), or a proposal for labelling the food...*": Articles 5(3)(f) and 17(3)(f) GM Regulation.

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 makes clear 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 GM Regulation was adopted with a view to achieving these General Principles by giving special weight to the precautionary principle. Recitals (2), (3) and (9) make clear (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."*

In the context of these General Principles, EFSA is mandated to issue guidance on the manner in which it will assess applications for authorisations under the GM Regulation. In particular:

- Under Article 23(b) of the Food Safety Regulation, one of its tasks is that it must *"promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission";*

- Under Articles 5(8) and 17(8) GM Regulation, it *"shall publish detailed guidance to assist the applicant in the preparation and presentation of the application"*;

EFSA has issued four guidance documents of particular relevance to the present application, as follows:

(a) The Guidance on the environmental risk assessment of GM plants. EFSA Journal 2010; 8(11):1879 (EFSA 2010 a).

(b) The Guidance for the risk assessment of food and feed from GM plants. EFSA Journal 2011 (EFSA 2011 a).

(c) The Guidance on the post-market environmental monitoring (PMEM) of genetically modified plants. EFSA Journal 2011 (EFSA 2011 b).

Further EFSA published statistical considerations for the safety evaluation of GMOs - EFSA Journal 2010 (EFSA 2010, b).

These guidance documents outline the European Food Safety Authority's own view of how, in practice, it will discharge its obligation to conduct a *"scientific evaluation of the highest possible standard"* (Recital (9) GM Regulation), and to do so using a *'uniform methodology'* (Article 23(b) Food Safety Regulation) and *"based on the available scientific evidence and... in an independent, objective and transparent manner"* (Article 6(2) Food Safety Regulation).

(a) Particular provisions of the 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 an application 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"*. Furthermore, such an application shall be accompanied by *"a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/187EC..."* (Article 5(5)(b)).[1]

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 <u>all appropriate measures</u> are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs…"*

Under, Articles 5(3)(k) and 17(3)(k) of the GM Regulation an application for marketing authorisation has to contain a proposal for post-marketing monitoring regarding the use of the food for human consumption and feed for animal consumption *"where appropriate"*. Similarly, in giving a positive opinion in relation to an application EFSA has to include such post-marketing monitoring requirements *"where applicable"* (Articles 6(5)(e) and 18(5)(e) of the GM Regulation.

The authorisation of a genetically modified food is granted by the Commission by way of the so-called comitology procedure (Article 7 and Article 35). The authorisation has to include the particulars referred to in Article 6(5), which includes, where appropriate, a monitoring plan. In its decision, the Commission is not bound by the opinion of EFSA. Instead, the Commission has to take the EFSA opinion into account, as well as *"any relevant provision of Community law and other legitimate factors relevant to the matter under consideration"* (Article 7(1)).[2] In other words, the

[1] For such cases, Articles 13 to 24 of Directive 2001/18 are declared inapplicable.

[2] Further, under Article 7(1) the Commission has to provide an explanation for the difference, where its decision is

Commission has to determine, whether the monitoring plan has to include the control of potential adverse effects of the genetically modified plant during the use and consumption stage. Even when EFSA, in any of its opinions, does not comment on the need for such a control, the Commission is obliged to decide on that issue.

The provisions on feed containing or consisting of GMOs mirror the provisions on genetically modified food: A provision corresponding to Article 5(5) of the GM Regulation is laid down in Article 17(5), a provision corresponding to Article 6(4) is found in Article 18(4). In addition, where appropriate EFSA also has to give the particulars of the relevant monitoring plan (Article 18(5)(g)). The Commission, when authorising the genetically modified feed, also has to refer to the monitoring plan (Article 19(2)).

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 occasionally did add supplementary conditions on the placing on the market of genetically modified food products[3].

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 establish whether it is safe.
The Court of Justice confirmed this interpretation and stated that[4] (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".*

not in accordance with EFSA's opinion.

[3] 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.

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

The issue that EFSA, and then the Commission, must determine before it grants an authorization is whether the genetically modified food or feed is safe – it is not sufficient for either institution to determine that the available literature does not show that the food or feed to is unsafe – it must be safe in the light of the assessment undertaken pursuant to this important additional level of control because the goods are to be consumed by humans and animals.

(b) Particular provisions of the Directive[5]

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 shall 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 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, it 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"*[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. Further, section A of Annex

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

[6] 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.

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 on the EU in respect of the *"protection of the environment"*[7].

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, that 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 the occurrence of each 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)"*[8].

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

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

[8] 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.

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"*[9], 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"*[10]*and, as a catch-all formula "other potential interactions with the environment"*[11]. 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"*[12]; *"Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising rom the genetic modification, where the GMHP is intended to be used in animal feedstuffs"*[13]; and *"Potential interactions with the abiotic environment"*[14].

This wording with regard to the "other information" is thus again very broad and tries to cover all effects that the GMO product 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.

The monitoring plan

According to Article 13(2)(e) of the Directive, a monitoring plan has to accompany the notification; the plan shall be established in accordance with Annex VII to the Directive. Its objectives are underlined by recital 43 of the Directive which states (emphasis added): *"it is necessary to introduce into this Directive an obligation to implement a monitoring plan in order to trace and identify <u>any</u> direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOS as or in products after they have been placed on the market"*. The use of the word "any" both in the Recital 43 and in Annex VII itself demonstrates that the purpose of the monitoring plan is to discover all possible impacts of adverse effects of GMOs, including those effects not foreseen in the environmental risk assessment ("unforeseen").

This interpretation is confirmed by the provisions in Annex VII on the design of the monitoring plan: the plan has to

1. be detailed on a case by case basis (Annex VII, C.1);
2. take into account the relevant environmental conditions where the GMO is expected to be released (C.2);
3. incorporate general surveillance for unanticipated adverse effects (C.3);
4. provide for case-specific monitoring, which can be through routine surveillance practices that *"were already established*" in appropriate cases (C.3.1 and C.3.2);
5. facilitate the observation *"in a systematic manner"* of the release of the GMO in the receiving environment and the interpretation of these observations *"with respect to human*

[9] Directive 2001/18, Annex III A, section II, C.2(i)
[10] Directive 2001/18, Annex IIIA, section IV B12.
[11] Directive 2001/18, Annex IIIA, section IV B.16.
[12] Directive 2001/18, Annex IIIB, section D no.7.
[13] Directive 2001/18, annex IIIB, section D no.8.
[14] Directive 2001/18, annex IIIB, section D no11.

health or the environment" (C.4).

In 2002, the Council adopted, by way of a Decision, guidance notes *"supplementing Annex VII"*[15]. The guidance notes "*shall be used as a supplement to Annex VII of Directive 2001/18/EC"* (Article 1). The guidance notes repeat in the introduction that the purpose of the monitoring plans is to *"trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market"*.

The guidance notes first repeat the objective and general principle of the monitoring plan of Annex VII to the Directive and then add: *"In addition, monitoring of potential adverse cumulative long-term effects should be considered as a compulsory part of the monitoring plan"* (part B). They clarify what is to be understood by the terms *"direct effects"*, *"indirect effects"*, *"immediate effects"* and *"delayed effects"*.

With regard to unforeseen effects, the guidance notes indicate: *"it is very difficult if not impossible to predict the appearance of potential, unforeseen or unanticipated effects that were not highlighted in the risk assessment. General surveillance for potential unforeseen or unanticipated effects should, therefore, be considered as a part of the monitoring strategy"* (part C). This statement indicates that the notifier may not limit his monitoring plan to those risks identified in the environmental risk assessment, which had to be made according to Article 13(2)(b) and Annex II section D to the Directive.

The guidance notes also expressly state that the time-period for monitoring would depend on the circumstances, but could extend to a number of years (part C- 1.5). This is another indication that potential cumulative effects of genetically modified plants hand herbicide residues are to be controlled.

Case-specific monitoring (part C-1.3.1) should focus on "*all the potential effects on human health and the environment identified in the risk assessment"*. It should begin with determining the case-specific objectives of the monitoring strategy, which *"include"* the identification of the occurrence and impact of potential adverse effects of the GMO or its use that were made in the environmental risk assessment. The strategy should indicate that these assumptions are to be confirmed by the case-specific monitoring. With regard to potential effects on human health, the guidance notes specify that such effects will depend on the inherent nature of a GMO and its specific genetic modification.

For unforeseen adverse effects that were not predicted in the risk assessment, the guidance notes make provision for a *"general surveillance"* (part C- 1.3.2) which consists of *"routine observation ("look – see") approach"*. Such surveillance should be carried out over a longer period of time and possibly a wider area than the case-specific monitoring, though the type of general surveillance would depend on the type of unforeseen adverse effects. The notes indicate that the general surveillance could make use of established routine surveillance practices *"where compatible"*; then the established routine surveillance practice should be described in the plan, including any necessary alignment to the general surveillance. *"Food surveys"* are expressly mentioned (part C -1.7) as one example of existing systems.

The guidance notes contain a number of other indications, such as the monitoring methodology (part C- 2) and analysis, reporting and review (part C-3) which will not be set out here.

[15] Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, OJ 2002, L 280 p.27.

Overall, the main purpose of the monitoring plan is to confirm the assumptions that were made in the environmental risk assessment on (the absence of) potential adverse effects. However, the guidance notes expressly indicate that the monitoring strategy should also include a strategy with regard to unforeseen events not assessed in the environmental risk assessment.

The competent authority has to give written consent for the placing on the market of a GMO as or in a product (Article 19). The consent has to specify, among other things, the monitoring requirements in accordance with Annex VII to the Directive (Article 19(3)(f)). This provision clarifies that the competent authority is not bound, in the monitoring conditions, which it puts on the consent with regard to monitoring, by the monitoring plan of the notifier. Rather, this plan is, legally, a mere proposal. Thus, the competent authority, which gives written consent, has a responsibility of its own to ensure that all direct and indirect, immediate and delayed, cumulative and unforeseen effects of the GMO on human and animal health and the environment are properly monitored.

Conclusion

Under the GM Regulation, the authorization 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 such adverse effects and, where appropriate, a suitable monitoring plan must be put in place.

It follows from all these provisions, that under 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. The monitoring plan must be case specific and also contain a strategy for monitoring events that were not foreseen in the environmental risk assessment.

Taken together, the purpose or part of the purpose of the GM Regulation and the Directive 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. Indeed, the development of allergies or other adverse effects, due to the consumption of genetically modified plants which are herbicide-resistant, and which possibly contain herbicide residues, are not so unlikely that the monitoring of such effects can be omitted.

2. Factual Background

The genetically engineered oilseed rape MON88302 is a herbicide resistant plant which has had a DNA sequence for glyphosate herbicide resistant protein "CP4 EPSPS" inserted into its genome.

According to Monsanto (2012 a),

> *"Monsanto Company has developed a second-generation glyphosate-tolerant oilseed rape product, MON 88302, designed to provide growers with improved weed control through tolerance to higher rates of glyphosate and greater flexibility for glyphosate herbicide application.*
>
> *MON 88302 produces (CP4 EPSPS) protein that via the incorporation of a tolerance to the herbicide agricultural herbicides. The same 5-enolpyruvylshikimate-3-phosphate synthase is produced in commercial Roundup Ready ®1 crop products, cp4 epsps coding sequence. The CP4 EPSPS protein confers [resistance to] glyphosate, the active ingredient in the family of Roundup 1.*
>
> *MON 88302 utilizes a FMV/Tsf1 chimeric promoter sequence to drive CP4 EPSPS expression in different plant tissues. By virtue of CP4 EPSPS expression in pollen, MON 88302 provides tolerance to glyphosate during the sensitive reproductive stages of growth, and enables the application of glyphosate at higher rates up to first flower with no detectable impact to male fertility."*

It can be concluded that MON88302 is part of Monsanto´s tailored strategy to combat herbicide resistant weeds that occur in many fields where genetically engineered glyphosate resistant plants are grown. Farmers who plant MON88302 oilseed rape will be able to apply higher dosages of glyphosate more frequently as required. In consequence the exposure to the herbicide will be higher for the environment and the plants will show higher levels of residue, which will subsequently be present in any food or feed derived thereof.

On 8 September 2011, the European Food Safety Authority (EFSA) received from the Belgian Competent Authority an application (Reference EFSA-GMO-BE-2011-101) for authorisation of oilseed rape MON 88302 (Unique Identifier MON-883Ø2-9), submitted by Monsanto within the framework of Regulation (EC) No 1829/2003 on GM food and feed.

The oilseed rape and the derived products, that the companies have applied for to bring into the EU, are genetically modified organisms, or food/feed containing genetically modified organisms, within Article 2 of Directive 2001/18 and Article 2(5) of the GM Regulation. The grains are biological entities capable of replication or of transferring genetic material, and are therefore "organisms" within Article 2(1) of Directive 2001/18. Their genetic material has been altered in a way that does not occur naturally, within Article 2(2) of Directive 2001/18.

EFSA considered the Application, in order to determine inter alia whether the oilseed rape would have adverse effects on human health, animal health or the environment, contrary to Articles 4(1)(a) and 16(1)(a) GM Regulation, if its placing on the Union market were to be authorised.

In accordance with Articles 6(4) and 18(4) of the GM Regulation, EFSA consulted the competent

national authorities of Member States on the Application.

Following that consultation, EFSA issued an Opinion on the Application in 2014 (EFSA 2014, **"EFSA Opinion"**). In its opinion from 2014 EFSA concluded (EFSA 2014):

> *"In conclusion, the EFSA GMO Panel considers that the information available for oilseed rape MON 88302 addresses the scientific issues indicated by the guidelines of the EFSA GMO Panel and the scientific comments raised by the Member States, and that oilseed rape MON 88302 is as safe as its conventional counterpart and other non-GM oilseed rape varieties, and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of this application"*

In the absence of a decision by the The Standing Committee on the Food Chain and Animal Health, the appeal committee, and on the basis of the EFSA Opinion, the Commission decided on 24 April 2015 to grant the market authorization, i.e. **"the Decision"** (Commission Implementing Decision (EU) 2015/687 of 24 April 2015, published on 30 of April 2015 in the Official Journal of the European Union[16]).

The Commission decided (Article 2 of the Decision):

> *"The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC)*
> *No 1829/2003 in accordance with the conditions set out in this Decision:*
>
> > *(a) foods and food ingredients containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;*
> > *(b) feed containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;*
> > *(c) MON-883Ø2-9 oilseed rape in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation."*

The Commission agreed with the plan of the applicant on the monitoring plan for environmental risks and did not request post-market monitoring requirements for the use of the food for human consumption.

[16] http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

3. Grounds for the complaint

Ground A: Failures in EFSA's molecular characterization: EFSA's asessment of the molecular data and gene expression is fundamentally flawed

Ground A relates to EFSA's flawed assessment of the molecular characterization of MON88302: see Section 3 of the Opinion.

Ground A1: Failures in assessing unintended gene products

The data presented by Monsanto are not conclusive. The additional DNA in the plant genome was inserted between two transcriptional areas. Several potential gene products such as eleven putative peptides were identified as possible plant constituents. So-called open reading frames (ORF), which can give rise to various new gene products, were identified at the site of insertion. It was concluded that it would be unlikely that unintended proteins are produced in the plants. Further if they were produced, it was concluded that it would be unlikely that these proteins would have any relevance for risk assessment:

> *"No empirical evidence exists to suggest that any of the 11 sequences are produced or found in planta. Likewise, other than translation of CP4 EPSPS, no evidence exists to indicate that any other sequence from the T-DNA is translated. Rather, the results of the flank junction and T-DNA bioinformatic analyses indicate that in the unlikely occurrence that any of the 11 peptides analyzed herein is found in planta, or translation of sequence other than CP4 EPSPS was to occur, none would share significant similarity or identity to known allergens and toxins, or other biologically active proteins that could affect human or animal health."* (Monsanto 2012b).

EFSA failed to assess this properly. First of all, EFSA failed to make a distinction between gene products that are proteins and gene products that are not proteins, but also relevant for risk assessment such as miRNA. As to the first category (unintended proteins), EFSA should have required Monsanto to carry out empirical investigations to find out if such unintended proteins can be found in the GM plants *de facto* or not.
Monsanto simply states that no empirical evidence exists for the emergence of such proteins. However, we are not aware of any targeted empirical investigations that have been carried out to assess whether such proteins occur.

As to second category (gene products that are not proteins), there are a lot of scientific uncertainties that were evidenced in a workshop carried out by EFSA in June 2014 on RNA interference in genetically engineered plants (RNAi) (EFSA 2014c). These uncertainties do not only concern plants that intentionally produce molecules like miRNA, but RNAi can emerge from any transgene inserted into plants. Its occurrence can not be assessed by looking to potential proteins but have to be assessed separately. But no or no adequate investigations were carried out about other gene products such as miRNA or other biological active molecules. Small RNA parts are likely to emerge from the open reading frames and interact with gene regulation with translation into proteins. There are publications showing miRNA might pass from plants to animals and humans (Zhang et al., 2011; Lukasik & Zielenkiewicz, 2014; Li et al., 2015). Its effects on health and environment are a matter of uncertainty (EFSA, 2014c). In its opinion, EFSA completely ignored this issue, did not request any data and did not address relevant uncertainties.

Ground A2: Failures in assessing intended gene products

There are substantial gaps in assessment of gene expression of the intended proteins.

1. Lack of assessment of the precursor protein

As Monsanto describes it, there is not only the CP4 EPSPS protein being produced in the plants, but also a precursor protein that is cleaved in the chloroplasts: (Monsanto 2012 b)

> *"The amino acid sequence of the CP4 EPSPS precursor protein was deduced from the full-length coding nucleotide sequence present in PV BNHT2672. The 76 amino acid CTP2, the transit peptide of the Arabidopsis thaliana EPSPS protein, is underlined. CTP2 targets CP4 EPSPS protein to the chloroplasts. At the chloroplast the CTP2 is cleaved producing the mature 455 amino acid CP4 EPSPS protein that begins with the methionine at position 77."*

However no data were presented to assess the safety of this precursor protein. Instead Monsanto in its general information claims that the intended protein in the plants would be identical to those produced in other Roundup-crops:

> *"The same 5-enolpyruvylshikimate-3-phosphate synthase is produced in commercial Roundup Ready ®1 crop products, cp4 epsps coding sequence."* (Monsanto 2012a)

Also EFSA did not perform risk assessment of this precursor protein - but given the description of description as provided by Monsanto it looks like there are two proteins that need to be assessed as intended DNA products – CP4 EPSPS and its precursor..

2. Expression data of EPSPS enzyme not sufficient

The expression of the artificial DNA construct was investigated in regard to the production of the EPSPS enzyme in the kernel, without taking into account the impact of stressful environmental conditions that may impact gene expression. While data were collected from field trial in Canada, US and Chile, Monsanto explicitly states that

> *"There were no unusual weather events at the sites that negatively impacted the quality of the study."* (Monsanto 2012 b)

It is known that stressful conditions can impact gene expression and content of the additional protein in genetically engineered plants (see for example Trtikova et al., 2015). Changes in gene expression of the additional gene construct can also affect the composition of the plant compounds. Thus more data would be needed to assess transcription rate and protein content under various environmental conditions.

Given the intended usage of these plants, one specific stressful condition that might affect gene expression in the plants are higher amounts of glyphosate being applied or glyphosate being applied several times during cultivation. However no such data were presented.

Such data were not requested to assess gene expression nor to assess changes in the compositional analysis nor in agronomic and phenotypical characteristics. Since the specific purpose of this GM plant is to be sprayed with higher dosages, the risk assessment of the plant was not performed in accordance with its intended usage in agriculture. Since this intended usage can affect the plants

gene expression as well as composition as well its agronomic and phenotypical characteristics, it can not be left aside in risk assessment for food & feed (see ground B).

3. Other relevant parts of the plant such as pollen were not investigated.
EFSA argues that the pollen and other parts of the plants are not relevant because Monsanto only applied for the import of the kernels. However (see below), it is highly likely that there will be some spillage of the kernels into the environment, especially at production sites and along transport routes, where the plants will start to grow and produce pollen. Thus all parts of the plants should have been subjected to risk assessment.
Likewise gene expression in all parts of the plant needs to be assessed to find out more about the overall functional and genetic stability of the inserted DNA and its interactivity with the plant's genome. Adequate risk assessment of food and feed undoubtedly necessitates an understanding of the overall quality of the whole genetically engineered plant.

Conclusion

In the light of the above, EFSA's opinion was fundamentally flawed and, accordingly, the Commission erred in granting the authorization.

Overall, the Commission granted an authorization via the Decision without ensuring that:

- the authorisation was issued on the basis of a risk assessment of the "*highest possible standard*": Recital (9) GM Regulation; and
- EFSA had complied with its duties, under Articles 6(3)(a) /18(3)(a) GM Regulation, to ensure that Monsanto had provided to it, and to EFSA, "appropriate" information and data to support the comparative analysis submitted with the application under Articles 5(3)(f) / 17(3)(f) GM Regulation.
- EFSA had carried out a sufficient comparative analysis of MON 88302 and/or failed to require Monsanto to provide adequate or any data at all in the light of concerns raised by the initial data submitted and/or in relation to points which Monsanto had inadequately investigated or failed to investigate.

Moreover, the Commission failed to act in accordance with its duty:

- under Articles 4(1)(a) and 16(1)(a) GM Regulation to ensure that food and feed that would have an adverse effect on human health, animal health, or the environment "must not" be placed on the Union market;
- under Articles 7(1) and 19(1) GM Regulation to take into account not only the EFSA Opinion but also "any relevant provisions of [Union] law", including the provisions of Union law that require Union institutions to comply with their own guidance;
- under Article 168 TFEU and reflected in Recital (2) GM Regulation to ensure a high level of protection for human health.

Furthermore, so far as relevant, the Commission has unlawfully defeated a legitimate expectation that EFSA would act in accordance with its own guidance in advising the Commission on applications for authorisation under the GM Regulation, and that the Commission would ensure such compliance by EFSA before reaching its authorisation decisions.

Ground B: *Failure to perform proper comparison*

Ground B1: Compositional analysis

Under treated and untreated conditions, the compositional analysis revealed many statistically significant differences between oilseed rape MON88302 and its conventional counterparts that were consistent in all field trials.. These differences concern components such as carbohydrates, ash and total fat, amino acid lysine, several fatty acids, mineral calcium and Vitamin E. (See EFSA 2014a page 13. See Monsanto 2012 b, page 71ff.)

EFSA concluded that these differences *"did not raise safety concerns for humans and animals"*. This judgement is based on statistical analysis showing for single components that equivalency is more likely (than unlikely) when compared to the conventional reference varieties (equivalency categories I and II). The significant differences found in regard to vitamin E and calcium fell into outcome "type 4". According to EFSA´s own Guidance (EFSA 2011 a), findings within this category indicate that:

> *"Non-equivalence cannot be rejected, but the appropriate conclusion is that equivalence between the GM plant and the set of non-GM reference varieties is more likely to be the case than lack of equivalence. Further evaluation may be required."*

These conclusions show a substantial level of uncertainty. The statistical test applied does allow to judge on single components, but not on the overall biological relevance of the significant findings. To sort out whether further evaluation is required, the overall biological relevance of the significant differences has to be assessed. In this regard it is most important that large group of significant differences was found to be consistent in all field trials (all locations, with and without spraying). Since these differences were consistent, it is highly likely that they are caused by the process of genetic engineering. This conclusion is backed by findings on the phenotypic and agronomic characteristics which also showed changes being consistent across the field trials. There is no doubt that these findings are in summary biological relevant and have to be assessed in regard to food & feed safety. But EFSA failed to draw this most relevant conclusion that would have caused further investigation such as more detailed compositional analysis and toxicological testing.

EFSA should have required Monsanto to carry out a further investigation to determine the real range of unintended effects before any conclusion was taken. For example, interactions between the genome and the environment should have been explored to find the true range of variations in plants composition. Thus the plants should have been subjected to various environmental and agricultural conditions and relevant agricultural practises that are known to influence gene expression and plants composition. However, no such investigations were required. The Commission should not have authorized MON88302 in the absence of an assessment of the outcome of such further investigations.

Further, data from all parts of the plants should have been required, to find out more about the more general pattern of the unintended effects. In this case, the kernels were the only part of the plant to be investigated. EFSA argues that other parts of the plants are not relevant since the company only applied for the import of the kernels. Thus in result, no data on other parts of the plants such as pollen, forage and roots were included (EFSA, 2014 a, page 13). However, since consistent differences in compositional analysis of kernels were observed, analysis of other parts of the plants are necessary to sort out uncertainties regarding the plants composition. Compositional analysis of other parts of the plants is also necessary to assess risks for the environment if plants escape to the

environment via spillage (see further below).

Furthermore, although MON88302 is designed to enable late and repeated spraying (after the first flowering) with glyphosate, the plants tested for the market application were only sprayed once and at an early stage of the vegetation period. It is known that the dosage and the frequency of spraying with herbicides can impact plant composition as well as agronomic characteristics. The data provided by Monsanto do not allow for reliable conclusions to be drawn on the composition of plant components and the safety of the products derived from MON88302 under those practical conditions the plants are likely to be grown. This problem was also raised by experts from the Member States (EFSA, 2014b). In response, EFSA simply states that

> *"The EFSA GMO Panel noted the relatively early spraying with the intended herbicide glyphosate and considered it within the normal agricultural practice."*

This statement shows that the EFSA risk assessment deliberately ignored the specific purpose for which the plants were developed.

As explained by Monsanto (Monsanto 2012b),

> *"the glyphosate treatment was applied at approximately 1.8 kg a.e./ha (kilograms of acid equivalent per hectare)."*

However, according to its US Patent 2015/0119248 A1, the purposed amount of glyphosate to be applied on the plants ranges up to 7,2 kg g acid equivalence / hectare (claim 40). Also on page 7 of the patent it is explained that

> *"an herbicidally effective dose of glyphosate for use in the fields as an in-crop application to control the growth of weeds in the field, should consist of a range from about 0,125 pounds of glyphosate per acre to about 6,4 pounds of glyphosate per acre total over a growing season."*

As described in the patent, the plants get sprayed several times. Further the patent reveals that targeted field studies were performed to compare MON88302 with other plants in regard to the maximum dosage that can be applied. However no such data were presented to EFSA.

In consequence, the comparative risk assessment in regard to the plants composition is fundamentally flawed. In result, no conclusions can be drawn on real range of variations and the content of potential toxicants such as erucic acid and glucosinolates, and anti-nutrient components such as phytic acid and sinapine.

Ground B2 Agronomic and phenotypic characteristics

In regard to agronomic and phenotypic characteristics, MON88302 showed a significant delay in days-to-first flowering. This was explicitly confirmed in the EFSA risk assessment (section 4.1.2.1 of the EFSA Opinion). Further significant and consistent differences were observed in seed maturity and lodging, but these were set aside as being not of biological relevance and no further assessment was carried out.

To sort out the reason for this observation (the days-to-first flowering), Monsanto performed field trials with 'negative segregant' plants. Such plants are not usually accepted as comparators in risk

assessment. In this case they were derived from MON88302 by further breeding to eliminate the trait for glyphosate resistance. These negative segregant plants also showed a delay in days-to-first flowering. Based on these data, EFSA suggested that the observed effects in MON88302 are not caused by the trait conferring glyphosate resistance. Instead EFSA assumes some general genetic variability might be the cause for the delay in flowering and did not request any more investigations. But this assumption is highly questionable since a plant derived from the breeding of genetically engineered plants can still inherit unintended effects caused by the genetic manipulation, even if the functional trait is no longer present in the plant. For example the process of genetic engineering can cause changes in parts of the DNA that can remain undetected because there not located at the place of the insertion of the additional construct. These unintended, additional changes can remain undetected in the plant, if the additional DNA construct is removed by further breeding. EFSA does actually express some uncertainties in its conclusions:

> *"The observed difference for days-to-first flowering could be attributed either to the variability in the genetic background of the Ebony population or to an unintended effect due to the genetic transformation process."*

However, as mentioned, the changes observed in agronomic and phenotypical characteristics were not investigated any further. In result the EFSA risk assessment is not sufficiently based on empirical investigations but merely on ad hoc assumptions (see above).

Monsanto presented some further very questionable data. Since the assessment of persistence and invasiveness of MON88302 is crucial in this case (see below), data on the duration of flowering, pollen production, pollen viability as well as seed dormancy (which shows how long the seed can remain in the soil and still germinate; also called seed bank) are very relevant parameters that should have been investigated. Changes in these agronomic and phenotypical characteristics can impact the general fitness of the plants and its potential to persist in the environment or become invasive.

However, no reliable data were made available. Kernels and the pollen were subjected to various temperatures to assess seed dormancy and pollen viability. But - as confirmed by EFSA - these experiments did not provide the data that was needed because the methods that Monsanto used were simply inadequate. Despite this observation, EFSA did not require any further, more reliable investigations. Again, the EFSA risk assessment process appears not to be governed by real scientific findings, but rather a fundamental bias to presuppose safety, mostly based on the absence of relevant data showing that it is unsafe.

Further data that are missing to come to reliable conclusions, concern applications of fertiliser, all agrochemicals and irrigation applied during the experimental field trials. Applications of glyphosate were not repeated and not in a range of high dosage applications as it will be under practicable conditions. Also experts from the Member States requested more data on environmental impact on the plants. In its reply to experts from Member States EFSA simply states that *"no unusual weather conditions at the selected locations were reported"*.

As it can be derived from McPherson & Ahmad (2012), the incidence of biotic and abiotic stressors was rather low and its infestions mostly of low intensity. Several parameters such as drought or watering are not defined, so no conclusions can be derived from these data how the plants will react to more stressful environmental conditions.

Taken together there is a quite high level of evidence that genetic engineering of MON88302

caused several unintended effects in the composition and its agronomic characteristics. The differences were consistent in all field trials and in treated and untreated plants. Thus the outcome of comparative assessment clearly shows that further investigations would be necessary (of other parts of the plants, broader range of environmental conditions, more data on other plants constituents, testing of seed dormancy and pollen viability etc). But EFSA failed to request such data without sufficient justification. In result the EU Commission should have rejected market authorisation.

Conclusion on the comparative assessment

In the application as filed by Monsanto (2012b), it is stated that

> *"MON 88302 is not different in composition, nutritional and agronomic characteristics relative to the conventional counterpart, except for the introduced tolerance to glyphosate..."*

EFSA concluded that (EFSA, 2014 a):

> *"Based on the agronomic and phenotypic characteristics of oilseed rape MON 88302 tested under field conditions, no biologically relevant differences were observed between oilseed rape MON 88302 and its conventional counterpart, except for days-to-first flowering. The observed difference for days-to-first flowering could be attributed either to the variability in the genetic background of the Ebony population or to an unintended effect due to the genetic transformation process. No differences in the compositional data of seeds obtained from oilseed rape MON 88302 requiring further assessment with regard to safety by the EFSA GMO Panel were identified.*
>
> *No biologically relevant differences were identified in the compositional characteristics of seeds obtained from oilseed rape MON 88302 that would require further assessment with regard to safety."*

In our view, this statement has to be considered to be wrong. This view is also endorsed by several experts from Member States.

In assessing the overall biological relevance of the data, EFSA did not pay enough attention to the fact that many significant differences were observed consistently in the field trials. This is a strong indication that these differences stemmed or stem from unintended effects caused by the process of genetic engineering. The same conclusion can be derived from significant differences consistently found in agronomic and phenotypic characteristics. In consequence, these differences are biologically relevant and cannot be set aside as purely statistical effects. But despite the actual findings and the comments from Member States, EFSA more or less simply confirmed the Monsanto conclusions.
Since - according to Monsanto and EFSA – the comparative analysis did not reveal relevant differences, EFSA did also not request further detailed testing for toxicology, allergenicity and nutritional effects (see further below). This is in contradiction to the overall requirements of EFSA´s Guidance (EFSA 2011 a):

> *"The comparative assessment of compositional, agronomic as well as phenotypic characteristics constitutes, together with the molecular characterisation, the starting point for the risk assessment of GM plants and derived food and feed. It aims to identify*

differences in composition, agronomic performance and phenotypic characteristics between the GM plants and derived food and feed and its comparator. If found these differences should be further assessed with respect to potential impact on human and animal health." (emphasis added)

The Commission granted the authorization without properly assessing these issues and/or without requiring the further investigations or analysis required before a lawful authorization could be granted.

In conclusion, risk assessment as performed by EFSA contravenes legal requirements. EU regulations such as 18929/2003, 178/20012 and Directive 2001/18 all request a high level of protection for human health and the environment, based on a precautionary approach. Instead EFSA is following a don´t look don´t find approach claiming evidence of safety based on the absence of reliable data. In particular:

- Contrary to the requirements of and Articles 6(3)(a) and 18(3)(a) GM Regulation, either EFSA has failed to consider whether the applicants´ analysis was supported by "*appropriate information and data*", or EFSA has unlawfully and manifestly incorrectly concluded that the information provided by the applicants was "*appropriate*".

- EFSA failed to carry out a sufficient comparative analysis of MON 88302 and/or failed to require Monsanto to provide adequate or any data at all in the light of concerns raised by the initial data submitted and/or in relation to points which Monsanto had inadequately investigated or failed to investigate.

- The errors outlined under Grounds A and B are also likely to be highly material to the conclusion that MON 88302 does not present a risk of adverse effects on humans and/or animal health, contrary to Articles 4(1) and 16(1) GM Regulation. EFSA's conclusion that MON 88302 is safe depends on its reasoning on the molecular characterisation and its comparative analysis i.e. the assumption that MON 88302 is substantially equivalent to its conventional counterpart. As such, it is fatally flawed. In particular, on the basis of its conclusion that the MON 88302 and its conventional counterpart are substantially equivalent EFSA concluded that it was not necessary to conduct a toxicological assessment of the whole food/feed. A properly conducted comparison of the field trial results with properly analysed literature might well have demonstrated that the statistically significant differences observed were biologically relevant, and required much more detailed analysis and further investigation.

Accordingly, the Commission should not have granted the authorisation of MON 88302 in this case. Overall, the Commission granted an authorization via the Decision without ensuring that:

- the authorisation was issued on the basis of a risk assessment of the "highest possible standard": Recital (9) GM Regulation; and

- EFSA had complied with its duties, under Articles 6(3)(a) /18(3)(a) GM Regulation, to ensure that Monsanto had provided to it, and to EFSA, "appropriate" information and data to support the comparative analysis submitted with the application under Articles 5(3)(f) / 17(3)(f) GM Regulation.

- EFSA had carried out a sufficient comparative analysis of MON 88302 and/or failed to require Monsanto to provide adequate or any data at all in the light of concerns raised by the initial data submitted and/or in relation to points which Monsanto had inadequately investigated or failed to investigate.

Moreover, the Commission failed to act in accordance with its duty:

- under Articles 4(1)(a) and 16(1)(a) GM Regulation to ensure that food and feed that would have an adverse effect on human health, animal health, or the environment "must not" be placed on the Union market;

- under Articles 7(1) and 19(1) GM Regulation to take into account not only the EFSA Opinion but also "any relevant provisions of [Union] law", including the provisions of Union law that require Union institutions to comply with their own guidance;

- under Article 168 TFEU and reflected in Recital (2) GM Regulation to ensure a high level of protection for human health.

Furthermore, so far as relevant, the Commission has unlawfully defeated a legitimate expectation that EFSA would act in accordance with its own guidance in advising the Commission on applications for authorisation under the GM Regulation, and that the Commission would ensure such compliance by EFSA before reaching its authorisation decisions.

Ground C: Inadequate food/feed safety assessment

According to the Guidance of EFSA (EFSA 2011 a),

> "*The toxicological impact of any biologically relevant change in the GM plant and/or derived food and feed resulting from the genetic modification (e.g. expression of introduced genes, gene silencing or over-expression of an endogenous gene) should be assessed.*"

Further the Guidance of EFSA requests:

> *"Toxicological assessment must consider:*
> *a) presence and levels of newly expressed proteins;*
> *b) potential presence of other new constituents;*
> *c) possible changes in the levels of endogenous constituents beyond normal variation;*
> *d) impact of other changes in composition due to the genetic modification."*

After EFSA (2014 a) wrongly concluded that no biological relevant findings can be derived from the level of comparative assessment, its toxicology assessment also failed to fulfill the requirement of its Guidance. For example, EFSA failed to assess the possible effects to the precursor protein, relevant biological components such as new miRNA, the residues from spraying as well as unintended effects that stem from the process of genetic engineering.

Ground C1: Toxicology

As EFSA (2014b) simply states in response to comments from experts from the Members States:

> *"No hazard was identified in the molecular characterization and comparative analysis. In line with the EFSA guidance, no animal feeding study is necessary."*

In result, not a single feeding study with the whole plants or food derived thereof was requested. EFSA ignored that in field trials the plants composition was significantly and consistently different compared to its isogenic comparator. Further the true range of variation in the composition of potential toxicants such as erucic acid and glucosinolates was not investigated. Relevant DNA products such as miRNA were left aside completely. On the basis of data provided, impact on human and animal health cannot be excluded.

Neither were residues from spraying assessed. Since MON88302 allows a higher dosage and/ or higher frequency of spraying, it would be necessary to run detailed investigations into residues, metabolites and possible interactions.

Further mixtures of the oilseed rape with other genetically engineered plants in food and feed should have been tested to investigate accumulative risks.

Ground C2: Allergenicity

Digestion of the additional proteins was not assessed under practical conditions. The only data provided were on in-vitro digestion of the isolated enzyme EPSPS. Not data were provided on the precursor protein.

The data provided suggest that the isolated enzyme is quickly digested. But in regard to real conditions during ingestion, these data are not sufficient. For example it is known that the whole viable kernel from oilseed rape can survive ingestion by wildlife species (Guertler et al., 2008). In result also the enzyme EPSPS will not be degraded during ingestion.

Furthermore, besides allergenic reactions, also other impacts on the immune system are known to be relevant in the context of genetically engineered plants. For example (Adel-Patient et al., 2011) stated that immune reactions might be provoked by bacterial proteins being produced in the plants. Even if such reactions are not provoked by the isolated protein, they still can emerge in combination with other plant constituents. But no assessment of such immune reaction was performed. In this context it is also a matter of concern that changes in the expression of endogenous genes (allergenes) were not assessed.

In conclusion, the risk assessment for allergenicity and immunotoxicity cannot be regarded as conclusive.

Ground C3: Nutritional assessment

Not a single feeding study with the whole plants or food derived thereof was requested.

Since in field trials the plants composition was significantly and consistently different compared to its isogenic comparator, further investigations such as as feeding studies would have been necessary. The true range of variation in the content of potential toxicants such as erucic acid and

glucosinolates was not investigated. The same is true for the true range of variation of anti-nutrient components such as phytic acid and sinapine. Relevant DNA products such as miRNA were left aside completely.

Further mixtures of the oilseed rape with other genetically engineered plants in food and feed should have been tested to investigate accumulative risks.

On the basis of data provided, negative nutritional effects in humans and animals cannot be excluded.

Conclusion on toxicology assessment

The toxicological assessment is part of the "risk characterisation" as required by the Guidance of EFSA (2011 a):

> *"Uncertainties identified at any stage of the risk assessment should be highlighted and quantified, to the extent possible (...). The estimated risk and associated uncertainties should be as precise as possible."*

But EFSA did not determine the actual level of uncertainties and failed to fulfill the requirements for toxicological testing. In contradiction to the real findings, Monsanto and EFSA assumed that the comparative analysis did not reveal relevant differences – this assumption was flawed for the reasons given above. In the light of EFSA's reliance on this flawed assumption, EFSA did not request further detailed testing for toxicology, allergenicity and nutritional effects. Thus the plants were only subjected to a quick inspection, but not to detailed empirical studies.

But contrary to the opinion of EFSA, the outcome comparative risk assessment should have been a starting point for further investigations concerning risks for human and animal health. The outcome of the the comparative assessment provides evidence or at least strong indications that unintended effects in the plants caused by the process of genetic engineering. In result feeding studies or other more detailed investigations would have been necessary.

Further, despite MON88302 is supposed to be sprayed with much higher dosages of herbicides compared to other genetically engineered herbicide resistant oilseed rape, the impact of these higher dosages of herbicides much more sprayings on plant metabolism and plant constituents was not taken into consideration. Thus EFSA failed to take into account "Issues to be considered for risk characterisation" as described by the Guidance of EFSA (2011 a):

> *"Risk assessment of GM plants and derived food and feed should be carried out in an integrative manner and, on a case-by-case basis depending on the type of genetic modification, should take into consideration environmental factors including cultivation practice that may influence food and feed quality."*

Further plant constituents such as residues from spraying and combinatorial effects between MON88302 and other genetically engineered crops in food and feed should have been tested to assess accumulated risks. For example, MON88302 was authorised together with 18 other genetically engineered plants to be imported and used in food and feed. But no assessment of potential accumulated effects was performed.

Overall: the Commission granted an authorization via the Decision without ensuring that:

- the authorisation was issued on the basis of a risk assessment of the "highest possible standard": Recital (9) GM Regulation; and

- EFSA had complied with its duties, under Articles 6(3)(a) /18(3)(a) GM Regulation, to ensure that Monsanto had provided to it, and to EFSA, "appropriate" information and data to support the comparative analysis submitted with the application under Articles 5(3)(f) / 17(3)(f) GM Regulation.

- EFSA had carried out a sufficient comparative analysis of MON 88302 and/or failed to require Monsanto to provide adequate or any data at all in the light of concerns raised by the initial data submitted and/or in relation to points which Monsanto had inadequately investigated or failed to investigate.

Moreover, the Commission failed to act in accordance with its duty:

- under Articles 4(1)(a) and 16(1)(a) GM Regulation to ensure that food and feed that would have an adverse effect on human health, animal health, or the environment "must not" be placed on the Union market;

- under Articles 7(1) and 19(1) GM Regulation to take into account not only the EFSA Opinion but also "any relevant provisions of [Union] law", including the provisions of Union law that require Union institutions to comply with their own guidance;

- under Article 168 TFEU and reflected in Recital (2) GM Regulation to ensure a high level of protection for human health.

Furthermore, so far as relevant, the Commission has unlawfully defeated a legitimate expectation that EFSA would act in accordance with its own guidance in advising the Commission on applications for authorisation under the GM Regulation, and that the Commission would ensure such compliance by EFSA before reaching its authorisation decisions.

Ground D: Monitoring

Moreover, in the light of the failures discussed above, EFSA, and consequently, the Commission failed to ensure that appropriate monitoring obligations were imposed on Monsanto, contrary to Articles 5(3)(k), 17(3)(k) and Articles 6(5)(e) and 18(5)(e) of the GM Regulation.

Ground E: Environmental risk assessment

Oilseed rape (*Brassica napus*) can spread via pollen and seeds, its seed can remain viable for more than ten years in the soil (seed dormancy). Similar like Mexico is the centre of origin for maize, Europe is the center of origin and genetic diversity for the group of Brassica plants to which oilseed rape belongs. Some native plant populations such as *Brassica rapa* (turnip) can hybridise with oilseed rape. *Brassic napus* itself occurs mainly as a cultivated plant, but still maintains significant characteristics of a wild plant. Disturbed soil promotes the establishment of *Brassica napus* beyond the fields whereas dense vegetation will hinder establishment. However, wild growing *Brassica napus* is found primarily in habitats where wild relatives of the Brassica genus and related genera grow. In addition, many related species which can hybridise with oilseed rape occur in environments such as road verges, industrial or feral sites. Gene flow to wild relatives is possible and likely to happen, even if *Brassica napus* itself only has a reduced potential to spread in a densely vegetated environment (Bauer-Panskus et al., 2013a).

The plants are mostly pollinated by insects such as flies, honey bees and butterflies which can also carry the pollen over many kilometers. Wind is also relevant for pollen drift: The farthest pollen-mediated outcrossing distance measured to date is 26 kilometres, recorded in a field trial with sterile male plants (Ramsay et al., 2003). Further, the seed remains viable in the soil for more than ten years (Lutman et al., 2003). Consequently, oilseed rape has a high potential for volunteer plants even many years after the first sowing.

Oilseed rape can appear in ruderal populations along field edges and roadsides. Pivard et al. (2008) found that ruderal populations are self-sustaining in a semi-permanent form. According to Munier et al. (2012), herbicide tolerant oilseed rape is a weed. There are weedy forms of *B. rapa* and *B. olereracea*. The wild relative species *Sinapis arvensis*, *Raphanus raphanistrum* and *Hirschfeldia incana* are also considered to be weeds (OECD, 2012).

According to EFSA´s Guidance (EFSA 2010 a), genetically engineered plants meant for import have to undergo environmental risk assessment, taking into account the possible routes of exposure:

> *“Depending upon the intended uses of a GM plant, such as import, processing, food, feed and/or cultivation, the pathways and levels of exposure of the GM plant to the environment will vary. In the case where the use of GM plant does not include cultivation in the EU, the problem formulation will consider exposure (1) via the accidental release into the environment of propagules, such as seeds, of the GM plant during transportation and processing potentially leading to sporadic feral GM plants and (2) indirect exposure, for example, through manure and faeces from the gastrointestinal tracts mainly of animals fed the GM plant, and/or (3) organic plant matter either imported as a fertiliser or soil amendment or derived from other bioproducts of industrial processes.”*

In this context at least the receiving environments, specific uncertainties, long term and accumulative effects and possible impact on non-target organisms have to be considered. If feral populations are expected to emerge, an additional set of informations has to be provided.

In regard to the receiving environments the following is requested by the Guidance of EFSA (EFSA, 2010 a, 2.3.2):

"The receiving environment(s) is the environment into which the GM plant(s) will be released and into which the transgene(s) may spread. The receiving environment(s) is characterised by three components (see Figure 3):

- The GM plant (e.g. plant species, genetic modification(s) and intended uses(s));
- The Geographical Zones (e.g. the climate, altitude, soil, water, flora, fauna, habitats....);
- The Management Systems (e.g. land use and production systems, other cultivated GM plants, cultivation practices, integrated and other pest management, non-production activities and nature conservation activities).

(…)

The three components listed above result in biotic and abiotic interactions that shall be considered by applicants when establishing representative scenarios considering receiving environment(s) for carrying out the ERA of a GM plant (Figure 3 and Table 2). A broad range of environments in terms of fauna and flora, climatic conditions, habitat composition and ecosystem functions and human interventions occurs in the EU. Accordingly, GM plants will potentially interact with those differing environments."

Furthermore, as part of the receiving environment, there might be other GM plants being placed on the market already, that have to be considered in regard to cumulative effects:

"Applicants shall take into account the potential risk implications of the presence of any other GM plants that have been placed on the market in the same receiving environments, including interactions between the specific cultivation characteristics (e.g. use of plant protection products) associated with the different GM plants. In addition, applicants shall consider likely and/or predicted trends and changes to receiving environments, and how these might interact with the GM plants."

Applicants should not only investigate the most likely scenarios but also the worst case scenarios:

"Applicants should initially consider representative scenarios for the GM plants, including a worst-case scenario where the exposure and impact are expected to be the highest. The receiving environment(s) is characterised by the GM plant, the geographical zones and the management systems (including production systems)."

In regard uncertainties (EFSA, 2010 a, 2.3.3.8.), environmental risk assessment goes beyond the risk assessment as performed under food and feed:

"ERA has to take into account uncertainty at various levels. Uncertainties may arise from problem formulation, limitations in the data (e.g. limited exposure data), gaps in the effect database, model choice, the limitation of the test systems and measurement endpoints selected, inadequacy of study designs and the uncertainties in extrapolating between species.

(…)

Although it may be impossible to identify all the uncertainties, the assessment shall include a description of the types of uncertainties encountered and considered during the different risk assessment steps. Their relative importance and their influence on the assessment outcome shall be described (...). Any uncertainties inherent in the different steps of the ERA (steps 1 to 5) shall be highlighted and quantified as far as possible; (…) The absence of data essential for the environmental risk assessment shall be indicated and the quality of existing data shall be discussed.

(…)

It is recognised that an ERA is only as good as our state of scientific knowledge at the time it was conducted. Thus, under current EU legislation, ERAs are required to identify areas of uncertainty or risk which relate to areas outside current knowledge and the limited scope of the ERA. These include such factors as the impact of the large-scale exposure of different environments when GM plants are commercialised, the impact of exposure over long periods of time and cumulative long-term effects."

Specific emphasis by EFSA (2010 a, 2.3.4) is given in regard to long-term effects, taking into account the impact of possible spillage deriving from imports:

"The consideration of long-term effects in the ERA should address effects that might arise up to a minimum of 10 years after the start of cultivation for annual plants, i.e. corresponding to the time frame of the consent authorisation (...), but possibly longer for perennial species, and should in all cases cover the time period over which progeny of the GM plant might persist and appear as volunteers or ferals.

To cover all relevant receiving environments of the GM plant and its compatible relatives, problem formulation should address not only the conditions of the production system under which the GM plant will be grown, but also relevant semi-natural and natural habitats. It should also consider viable GM plant seeds or propagules spilled during import, transportation, storage, handling and processing that can lead to feral plants that colonize and invade ruderal, semi-natural and natural habitats.

If feral populations are likely and/or if hybridisation is plausible, then stage 3 requires information to establish if GM traits will alter the fitness of feral plants, or of transgenic (introgressed) wild relatives. Since feral plants, or transgenic (introgressed) wild relatives may exhibit fitness differences across a wider range of environmental settings, stage 3 also consists of providing information that enables assessing the ability of these plants to occupy larger ecological niches than their conventional counterparts. It is possible that certain GM traits may enable the GM plant to expand its geographical range, and to grow in new areas close to wild relatives from which it was previously isolated, so the potential for this should be considered.

For GM plant applications for food and feed uses, import and processing, the ERA on persistence and invasiveness is concerned mainly with the environmental consequences of accidental release of viable GM seeds or propagating material during import, transportation, storage, handling and processing. Therefore, the ERA needs to consider the scale of environmental exposure, and if this could ultimately lead to GM plants

being established in receiving environments.

For the stabilisation of the transgene into the genome of the recipient (introgression), genes must be transmitted through successive backcross generations or selfing. Therefore, the risk characterisation should consider features such as the proximity of and flowering synchrony of wild relatives, and the viability, fertility, genetic compatibility and fitness of hybrid and backcross plants."

In the case that viable seeds are imported that might give rise to feral populations, the following specific informations (stage 1- stage 3) are required (EFSA, 2010 a, 3.1.2.2. - 3.1.2.4):

"Stage 1 information requirements:

All GM plant applications, including those for import and processing of viable propagating plant material, should provide general background information describing the parental species. Species-specific information on the following characteristics should be given in order to summarise existing knowledge of that species.

a) Seed germination characteristics. Growth chamber experiments or information collected during field trials enable assessment of seed germination characteristics of the GM plant under various conditions. The comparison of germination characteristics between the GM plant and its conventional counterpart might identify potential unintended changes, resulting from the transformation process, in the GM plant that require further analysis.

b) Phenotype under agronomic conditions. The general phenotypic and agronomic characteristics of the GM plant should be assessed in multi-location field trials representative of the different environments where the GM plant may be grown in order to establish intended or potential unintended differences between the GM plant and its conventional counterpart (see e.g. Horak et al., 2007, Garcia-Alonso, 2009, Raybould et al., 2009). Characteristics under consideration include plant establishment and vigour, time to flowering and maturity, growth, plant height and dry matter production, seed and yield characteristics, vernalisation requirement, attractiveness to pollinators, and pollen shed, viability, compatibility and morphology.

In addition to plant growth, development and reproduction observations, any visually observable response to naturally occurring insects, diseases and/or abiotic stressors (such as heat, drought, and excess of water) should be recorded during the growing season, as these observations provide indications of biotic and abiotic stress responses and thus susceptibility/adaption to stresses.

The comparison of phenotypic and agronomic characteristics between the GM plant and its

conventional counterpart might identify potential unintended changes, resulting from the

transformation process, in the GM plant that require further analysis.

c) Reproductive biology. When considering the potential impact of gene transfer from GM plants, it is important to assess whether the GM plant has any different capacity for gene transfer than its conventional counterpart. The gene(s) inserted may modify the potential for plant to plant gene transfer due to altered flower biology (e.g. altered flowering period), attractiveness to pollinators, fertility, or changed pollen viability and compatibility.

d) Seed persistence leading to volunteer occurrence. Measurements or observations such as volunteer number in subsequent crops/plantations indicate the potential for seeds and vegetative propagules from a GM plant to give rise to volunteer populations. Post-harvest field inspection data in which volunteer numbers are reported can serve as an information source and provide indications on the overwintering potential of the GM plant seeds. Seed burial experiments can also give indications of changes in dormancy and seed persistence (e.g. Hails et al., 1997).

Stage 2 information requirements

Stage 2 information will be required for plants that could overwinter in some parts of the EU under production system (e.g. agricultural) conditions, and/or transmit genes to compatible relatives that could overwinter. The risk assessment should consider whether the GM trait (or unexpectedphenotypic trait) could cause the plant to become a more serious weed within the production site. (…)

Data on relative persistence and fitness of the GM plant under production conditions may be available in the scientific literature, or new data may be required in the form of (1) monitoring of existing GM plants in comparable climatic conditions 20 ; (2) manipulative field experiments comparing GM and conventional plant fitness under a range of environmental conditions representative of EU production receiving environments; and/or (3) population models parameterised by appropriate field data to explore the long-term persistence of GM traits in relevant crop rotations. (…)

Persistence or enhanced fitness of volunteers or hybrids should be considered in the context of typical crop rotations. For example, herbicide tolerant Brassica napus, may be used as a break crop one year in four and could transmit herbicide tolerance genes to weedy Brassica rapa. The presence of herbicide tolerant B. rapa in years 2-4 may be relatively inconsequential as this weed, and crop volunteers, may be controlled by alternative herbicides. However, persistence of transgenic weedy B. rapa x B. napus hybrids in year 5 could have consequences for the following B. napus crop.

Crops vary considerably in their ability to form feral populations and this is extensively recorded in the scientific literature (e.g. Bagavathiannan and Van Acker, 2008). If the conventional crop forms feral populations, then this will allow the GM trait to persist outside production systems, and the consequences of this will need to be assessed (stage 3).

Stage 3 information requirements:

Stage 3 information will be required for plants that can form feral populations in semi-natural habitats, or for which there are sexually compatible wild relatives that are likely

to be recipients of transgenes. The risk assessment will need to evaluate whether feral plants, or compatible relatives containing the GM trait, will exhibit changed fitness in semi-natural habitats. If fitness is enhanced, populations may increase; if fitness is reduced, outbreeding depression may occur. The potential for changes in fitness may be estimated through: (1) observations from regions growing the GM plant; (2) manipulative field experiments (Crawley et al., 1993, Crawley et al., 2001); (3) greenhouse, microcosm or growth chamber experiments with additional field data and/or models to aid interpretation; or through (iv) knowledge of the ecology of feral crops and wild relatives and the phenotypic consequences of the presence of the GM trait. Fitness will vary depending upon the environmental context (including anthropogenic influences like mowing), particularly upon the presence of inter and intra-specific competitors, the presence of herbivores and pathogens, and the abiotic conditions. The variation in fitness according to biotic and abiotic conditions is often referred to as a genotype-by-environment interaction. It is therefore important that an appropriate range of environmental conditions is considered.

Detailed knowledge of the ecology of feral crops and wild relatives and the phenotypic consequences of carrying the GM trait may lead to the conclusion that the GM trait is extremely unlikely to confer a fitness advantage in semi-natural habitats. This may be supported by information from other events of the same GM trait. For example, it is unlikely that herbicide tolerant genes will influence fitness unless in the presence of the herbicide. There is now a body of evidence to support this conclusion (Crawley et al., 1993, Crawley et al., 2001, Warwick et al., 2008).

However, in some cases, the existing evidence may be insufficient to draw firm conclusions, and further experiments may be required. The most direct way to measure relative fitness is via manipulative field trials in a range of suitable habitats and over a minimum of two years. In designing such experiments, field sites should be representative of the receiving environments. The timescale should be sufficient to ensure a range of abiotic conditions are experienced by the experimental plants.

The number of seasons should also be sufficient to ensure that a range of biotic pressures (pathogen and herbivore pressure for example) are experienced, although this may also be enhanced by experimental treatments (see below). Treatments should always include disturbance, in which perennial vegetation is removed before experimental seed is sown, as many crops are not strong competitors with species in semi-natural habitats, but may be able to exploit disturbed areas in the manner of ruderal species. (…) The parameters measured should include survival in the seed bank as well as survival and fecundity of adult plants, to allow the lifetime fitness to be estimated."

In regard to Non-Target Organisms, the Guidance of EFSA requires the following (3.4.1.3.):

"The overlap of the life cycle and developmental stages of the focal species and the phenology of the GM plants needs to be evaluated. Exposure may also happen after the transgene has moved via dispersal of pollen and grain/seed in and away from the cultivation site of the GM plant (e.g. pollen deposited on leaves of host plants for non-target Lepidoptera and Coleoptera). Moreover, gene flow via outcrossing may result in gene expression in related species and result in additional levels of exposure to other

NTO species.

The level of exposure of NTOs to the GM plant will depend on the intended uses of a GM plant:

- In cases where the application does not include cultivation in the EU, direct environmental exposure of NTOs to the GM plant is via the accidental release into the environment of seeds or propagules of the GM plant during transportation and processing. This may result in sporadic occurrence of feral GM plants and therefore exposure of NTO populations is likely to be negligible. The ERA will then focus on indirect exposure to products of the GM plant (e.g. through manure and faeces from the animals fed the GM plant; and other by-products of industrial processes);

- In cases where the application includes cultivation in the EU, the level of environmental exposure is estimated on a case-by-case basis depending upon several factors. These included the biological and ecological characteristics of the GM plant and its transgene(s), the range of expected scales and frequencies of GM plant use, the receiving environment(s) where the GM plant is likely to be cultivated, and the interactions among these factors.

If gene flow to cross-compatible wild/weedy relatives and feral plants inside or outside the areas of cultivation is likely to occur then exposure of NTOs to these GM plants and their products over life cycles and seasons should be assessed."

EFSA is fully aware of the inevitability of MON88302 escaping into the environment during transport and processing which will give rise to feral populations. However, EFSA (2014a) is of the opinion that the dispersal of the plants does not cause environmental risks or hazards because the plants do not show a higher fitness compared to other oilseed rape plants. Consequently, EFSA believes that gene flow to crops in the field or to native plant population is not a cause for concern. It further assumes that the overall likelihood of MON88302 spillage is low. According to EFSA, even where glyphosate has been applied to the plants and rendered an advantage to MON88302 and its hybrids, there is no need for concern at all (section 6.1.1.1 of the EFSA Opinion):

"Glyphosate-based herbicides are frequently used for the control of vegetation along railway tracks, on arable land, in open spaces, on pavements or in industrial sites (...). In these areas, the glyphosate tolerance trait is likely to increase the fitness of GMHT plants (be it feral plants or progeny from hybrids of oilseed rape and wild relatives) relative to non-glyphosate-tolerant plants when exposed to glyphosate-based herbicides (...). However, both the occurrence of feral GMHT oilseed rape resulting from seed import spills and the introgression of genetic material from feral oilseed rape to wild relatives are likely to be low under an import scenario. Therefore, feral oilseed rape plants and genes introgressed into other cross-compatible plants would probably not create any additional agronomic or environmental impacts, even after exposure to glyphosate-based herbicides (…)."

These statements are flawed and not based sufficiently on scientific facts:

Ground E1: No reliable data to assess real fitness, persistence and invasiveness of MON88302 and its hybrids

As stated by EFSA (EFSA 2014a), the import and transport of MON88302 (which they summarise as genetically modified herbicide tolerant – GMHT - oilseed rape), is likely to establish volunteer plants along transport routes and processing facilities (section 6.1.1.2(b):

> "*The EFSA GMO Panel confirms that feral GMHT oilseed rape plants are likely to occur wherever GMHT oilseed rape is transported. However, there is no evidence that the herbicide tolerance trait results in enhanced fitness, persistence or invasiveness of oilseed rape MON 88302, or hybridising wild relatives, unless these plants are exposed to glyphosate-based herbicides. Escaped oilseed rape plants and genes introgressed into other cross-compatible plants would therefore not create any additional agronomic or environmental impacts."*

In this context, EFSA did not consider recent publications that indicate unexpected changes in the fitness of transgenic plants that is unrelated to the intended trait. For example, according to research from Japan, the properties of feral transgenic oilseed rape plants that are herbicide resistant might have changed under the influence of climatic conditions and showed that some of the plants found were larger than normal. These plants have also become perennial (Kawata et al., 2009). This is a major change in the biology of the plants, as oilseed rape and all other Brassica species cultivated in Japan are annual. Perennial forms of oilseed rape might have a significant impact on population dynamics. Perennial plants could have a higher probability of spreading their genes because they persist for a longer period. This could be seen as a factor supporting a higher fitness.

Other publications show unexpected higher fitness in transgenic oilseed rape that is not related to the specificity of the trait. According to Claessen et al. (2005), transgenic modifications for modified oil content might provide oilseed rape with fitness advantages. Simulations show that related wild species such as *B. rapa* und *Raphanus sativus* most probably have higher fitness with the introgression of Bt genes through hybridisation (Letourneau & Hagen, 2012). This might also be the case for *Raphanus raphanistrum* (Meier et al. 2013). Gene flow to related species was recently discussed by Garnier et al. (2014) and Liu et al. (2013). Both studies highlight the aspect of uncertainty in the risk assessment of such events.

Since the outcome of the comparative assessment showed several significant differences being consistent across the field trials there is enough reason to assume that MON88302 or its hybrids show unintended effects that also might affect its potential to persist and invade. These plant characteristics should have been investigated further taking into account several generations of volunteer generation and hybrids that inevitability will emerge in feral populations and in the fields if spillage and cross contamination occur as expected.

EFSA should have followed the requirements of the EFSA Guidance (2010 a) in regard to stage 3 data, before any conclusion was drawn upon persistence and invasiveness:

> *"The most direct way to measure relative fitness is via manipulative field trials in a range of suitable habitats and over a minimum of two years. In designing such experiments, field sites should be representative of the receiving environments. The timescale should be sufficient to ensure a range of abiotic conditions are experienced by the experimental plants.*

> *The number of seasons should also be sufficient to ensure that a range of biotic pressures (pathogen and herbivore pressure for example) are experienced, although this may also be enhanced by experimental treatments (see below). Treatments should always include disturbance, in which perennial vegetation is removed before experimental seed is sown, as many crops are not strong competitors with species in semi-natural habitats, but may be able to exploit disturbed areas in the manner of ruderal species. (…) The parameters measured should include survival in the seed bank as well as survival and fecundity of adult plants, to allow the lifetime fitness to be estimated."*

In this context, further investigations are also required by EFSA (2010 a) to assess long-term effects:

> *"For the stabilisation of the transgene into the genome of the recipient (introgression), genes must be transmitted through successive backcross generations or selfing. Therefore, the risk characterisation should consider features such as the proximity of and flowering synchrony of wild relatives, and the viability, fertility, genetic compatibility and fitness of hybrid and backcross plants."* (emphasis added)

But no such investigations were performed. No crossing experiments with MON88302 were performed to investigate the effects of the transgenes in plants with other genetic backgrounds such as wild relatives. It is therefore not possible to predict fitness, persistence or the invasiveness of hybrids from crossing with oilseed rape MON 88302.

Further, EFSA did not request any data on seed dormancy, duration of flowering, number of pollen, viability of pollen nor on any other parameter which is crucial to judge whether the plant and its hybrids have enhanced fitness.

Finally, it also has to be taken into consideration, that application of glyphosate has steadily increased within last decade. Glyphosate is the most used herbicide worldwide with an upward trend in demand including the European market. According to recent estimates, around one million tons of glyphosate are applied every year. Applications are not restricted to agriculture but are also used on non-cultivated areas, for example areas along transport routes. Thus, the likelihood that feral MON88302 and its hybrids will repeatedly come into contact with the herbicide is very high - and with current practice being what it is - MON88302 and its hybrids will definitely have an advantage to persist and spread into the environment.

In conclusion, EFSA did not address the exact level of uncertainties as requested and no sufficiently reliable data to assess fitness, persistence or invasiveness of oilseed rape MON 88302 were made available.

Ground E2 No data available to conclude on the occurrence of feral MON88302 oilseed rape resulting from seed import spills

The assumption that occurrence of feral MON88302 oilseed rape resulting from seed import spills is likely to be low is not based on facts. As experts from Member State France mentioned, no reliable information to predict spillage in the EU was provided and experience in Japan shows that spillage along transport routes can indeed become a major problem:

> *"It is difficult to assess the potential scale of the dispersal and persistence of this oilseed rape and the associated consequences without having precisely located these potential areas of dispersal along import routes, i.e. without having located seed storage facilities and crushing plants in relation to seed entry ports, and without knowing the precise means of transport and exact routes to be taken by the GM oilseed rape seed. (…) The applicant ought therefore to obtain accurate data to make a quantitative assessment of dispersal risks with full knowledge of the facts instead of offering general predictions for the whole of the European Union without any basis in actual data. We may note that the presence of feral populations of oilseed rape in the vicinity of Japanese ports (...) is the result of seed spillage from trains and lorries upon arrival of the seed at the port and its transport to the crushing plant."*

Japan is especially relevant in this context because even though transgenic oilseed rape is not commercially cultivated in this country genetically engineered oilseed rape has been found growing and attributed to imports. The first studies on the presence of transgenic oilseed rape in Japan were published in 2005 (Saji et al., 2005). Plants that proved to be resistant to glyphosate or glufosinate were found in the proximity of ports like Kashima, Chiba, Nagoya and Kobe as well as along transportation routes to industry plants where oilseed rape is processed. Follow-up studies found ruderal populations along further transportation routes (Nishizawa et al.,2009) and in areas close to all other major ports (such as Shimizu, Yokkaichi, Mizushima, Hakata, or Fukushima) (see for example Kawata et al., 2009; Mizuguti et al., 2011). Further, the publication of Mizuguti et al. (2011) came to the conclusion that oilseed rape populations are able to self-sustain over time. Obviously, the percentage of transgenic oilseed rape in ruderal populations is constantly growing. In 2008, 90 percent of all tested plants in the proximity of Yokkaichi port proved to be genetically engineered. The first transgenic hybrid plants between *B. napus* and *B. rapa* was found in Yokkaichi (Aono et al., 2011). Aono et al. (2006) also detected herbicide tolerant transgenic oilseed rape plants that had hybridised with each other and were thus tolerant to glyphosate and glufosinate herbicides.

Monsanto (Monsanto 2012 b) is simply denying those problems by making simplistic statements that were not put in question by EFSA:

> *"Some incidental spillage of oilseed rape may occur during import, handling, storage and processing of oilseed rape. However, modern methods of grain handling minimize such losses. Furthermore, the locations of spillage will be predictable, since they will be near the storage facilities and along transportation routes. Environmental conditions at these sites are unlikely to be conducive to germination, growth and reproduction of oilseed rape destined for food and feed use. Thus, the exposure of organisms in the environment to the import of MON 88302 in the EU would be negligible."*

This statement was accepted by EFSA as a crucial element in its risk assessment. However from a scientific point of view the Monsanto position cannot be accepted:

(1) It is not explained what "modern methods" have to be used and to which extent this will lead to a reduction in spillage.
(2) No matter which method is used to reduce spillage, the amount of spillage will be dependent on the amount of oilseed rape kernels being imported. In general, the frequency of spillage is likely to increase with a higher volume of imports. However no statistical analysis was made available to draw any conclusion on spillage in relation to the amount of viable kernels being imported. Demands for import might vary over the years are driven by various markets, not only for usage in food and feed but also for energy production. This was not discussed and assessed by EFSA at all.
(3) While the location of spillage to some extent might be predictable it is wrong to assume that germination is unlikely. There is at least evidence from Japan and Switzerland (Hecht et al., 2013: Schulz et al., 2014) that germination will occur. Further seeds (for example via animal dung) and pollen (via wind and insects) can widely be distributed and therefore can lead to uncontrolled spread that is no longer predictable.
(4) Completely overlooked by EFSA were other sources for environmental releases such as the normal spillage during transport. For example in case of accident (like breakdown of transport vehicles) large quantities of MON88302 kernels might enter the environment. Further misuse of the kernels like usage for sowing cannot be excluded and have to be integrated in risk assessment if viable kernels are imported.

In this context, EFSA overlooked that its own Guidance (2010 a) requests that applicants should not only investigate and consider most likely scenarios but also worst case scenarios:

> *"Applicants should initially consider representative scenarios for the GM plants, including a worst-case scenario where the exposure and impact are expected to be the highest. The receiving environment(s) is characterised by the GM plant, the geographical zones and the management systems (including production systems)."*

In conclusion the conclusion of EFSA is not based on any scientific evidence. Based on data available, the occurrence of feral MON88302 oilseed rape resulting from seed import spills can not be predicted. On the other side, there is overwhelming evidence that substantial spillage will occur, the seeds will germinate and feral population will occur that can be a starting point for further uncontrolled geneflow into the environment.

These flaws in the risk assessment are also relevant in regard to the frequencies of possible hybridisation with wild relatives. In response to comments from experts of EU Member States, EFSA considers the likelihood of gene flow to wild relatives to be low:

> *"Introgression of genetic material from feral oilseed rape to wild relatives, while theoretically possible, is likely to be very low due to the combined probabilities of spillage of GMHT oilseed rape in areas where wild relatives (e.g., B. rapa) are present, germination, survival of oilseed rape plants, hybridisation with its wild relatives, survival and the low fertility of interspecific hybrids restricting backcrossing with the wild relative."*

But as the experts from France explain, this assumption is highly questionable:

> *"The main species for which gene flow has been demonstrated is clearly wild turnip (B. rapa), but the applicant does not mention that introgressions into the genome of this weed occur easily and frequently; although the hybrids may be less fertile than oilseed rape, recombination easily permits introgression of oilseed rape genes (Leflon et al., 2007; Leflon et al., 2010). We may note that Ammitzbøll et al. (2005) show that F1 hybrids of B. rapa and B. napus can have a reproductive fitness similar to that of their parents in certain environments (Ammitzbøll et al., 2005). Calculation of hybrid frequency and of hybrid persistence, which depends on parental genotypes, environment, and transgene characteristics, cannot therefore be generalised from the findings of a single study as presented in the applicant's dossier."*

French experts summarised current knowledge and showed that persistence of the transgenes in the environment and in native populations does have to be expected:

> *"Studies have shown that oilseed rape seed can produce progeny in semi-natural habitats. Feral oilseed rape populations can persist for several years (Pessel et al., 2001; Schafer et al., 2011). While they persist mainly through the soil seed bank (Pivard et al., 2008a; Pivard et al., 2008b), they can in fact constitute transgene reservoirs. Knispel & Lachlan (2010) have found that feral herbicide-resistant populations have now become a permanent feature of agricultural landscapes in western Canada (Knispel and McLachlan, 2010). Under selection pressure (for example glyphosate treatment for glyphosate-tolerant oilseed rape), these populations can grow in number and contribute to gene flows in neighbouring fields (Squire et al., 2011). The presence of two transgenes in populations in Japanese ports already suggests flows between oilseed rape fields and feral populations (Aono et al., 2006)."*

Further, outcrossing into wild species could be enhanced by climate or other environmental change. There are cases published showing that especially hybrids of cultivated species with wild species develop a higher fitness under stress (Mercer et al., 2007). A higher amount of gene flow for oilseed rape under extreme climatic conditions was reported (Franks & Weis, 2009). The study shows there was a change in the time for flowering resulting in matching of flowering between species.

In conclusion there are clearly major gaps in EFSA risk assessment, and it further ignores relevant findings regarding the frequency of gene flow and indications for unintended effects rendering higher fitness to transgenic oilseed rape and its hybrids. Since no empirical investigations about the fitness of following generations stemming from spontaneous crosses between oilseed rape carrying the relevant trait with wild relatives were performed, no conclusions can be drawn upon frequency of gene flow to wild relatives and the persistence of the hybrids. Accordingly, the Commission should not have granted Monsanto the market authorization.

Ground E3: Cross-contamination in the fields was not taken into account

EFSA does not believe that cross contamination with conventional oilseed rape grown on the fields is a matter for concern. As EFSA (2014b) states in response to comments from Member States:

> *"The EFSA GMO Panel indicated that feral oilseed rape MON 88302 plants arising from spilled seeds could pollinate crop plants of non-GM oilseed rape if feral populations are immediately adjacent to field crops. Shed seed from cross-pollinated crop plants could emerge as GM volunteers in subsequent crops. However, the EFSA GMO Panel considered that the frequency of such events was likely to be extremely low and concluded that this route of gene flow would not introduce significant numbers of GM plants into farmland or result in any environmental consequences."*

This statement ignores facts on the biology of oilseed rape. For example, honey bees are known to transport pollen for several kilometers thereby enabling gene flow to fields much further away. Some animal species such as deer are also known to transport the seed. A large portion of the oilseed rape kernels remain viable after passage through the intestines of these animals (Guertler et al., 2008). This might also be the case in other animals which have not so far been investigated.

This issue not only raises economic problems, but also ecological concerns, since transgenic volunteers in the fields can become a source of enhanced gene flow to the environment. Together with feral oilseed rape populations these volunteers can open up many opportunities for genetic recombination, stacking of genes, and the evolution of genotypes that could lead to not only an increase in the cost of weed control in the future, but also to phenotypes with new environmental risks such as enhanced invasiveness. For example, new combinations of herbicide resistant traits can emerge such as crossings with Clearfield oilseed rape, which is grown in the EU and was made resistant by mutagenesis to ALS-inhibitor herbicide called imazamox. By crossing, oilseed rape could become a multi-resistant weed with a much higher fitness (at least under current agricultural practices) compared to other oilseed rape plants. Clearfield oilseed rape has to be considered as GMO, even if not being subjected to regulation (see Directive 2001/18). Thus it is covered by EFSA´s Guidance that requests

> *"Applicants shall take into account the potential risk implications of the presence of any other GM plants that have been placed on the market in the same receiving environments, including interactions between the specific cultivation characteristics (e.g. use of plant protection products) associated with the different GM plants"*

Once more, EFSA overlooked that its own Guidance (2010 a) requests that applicants should not only most likely scenarios but also worst case scenarios:

> *"Applicants should initially consider representative scenarios for the GM plants, including a worst-case scenario where the exposure and impact are expected to be the highest. The receiving environment(s) is characterised by the GM plant, the geographical zones and the management systems (including production systems)."*

In conclusion, the problem of cross contamination in the fields was largely ignored by Monsanto,

EFSA and the EU Commission. Once established in the fields, MON88302 the legal, economical and ecological consequences could be tremendous.

Ground E4: Failure to apply adequate environmental risk assessment

As EFSA (2014b) states in response to comments from experts of EU Member States, none of the environmental risk assessment was conducted in the way that it would have been if the application had been for cultivation:

> *"The EFSA GMO Panel considered that there is no requirement for scientific information on possible environmental effects associated with the cultivation of oilseed rape MON 88302 in Europe, as the application EFSA-GMO-BE-2011-101 covers the import, processing and food and feed uses of oilseed rape MON 88302, and excludes cultivation."*

But in this case no such clear distinction can be made between risk assessment for import and cultivation. As the example of Japan shows, large populations of transgenic oilseed rape plants can be established just by spillage without commercial cultivation in the fields. Further, one established in the fields, gene flow to the environment would be multiplied. Uncontrolled spread of these transgenes might for example pose substantial risks to pollinators such as honey bees and butterflies which were completely omitted from risk assessment by EFSA.

According to the Guidance of EFSA (2010 a), the requirements for environmental risk assessment are for example depending on the biology of the plants, the routes of exposure and the existing uncertainties. In any case, the receiving environment, specific uncertainties, long term and accumulative effects have to be considered as well as potential effects on non-target organisms.

EFSA completely failed to assess the risks and uncertainties regarding interactions with the the receiving environment as well as long term and accumulative effects.

In any case, risk assessment cannot be restricted to kernels used for processing, but has to take into account the whole plants with all parts. Further effects on non-target organisms have to be assessed in detail. As the Guidance of EFSA (2010 a) requests

> *"If gene flow to cross-compatible wild/weedy relatives and feral plants inside or outside the areas of cultivation is likely to occur then exposure of NTOs to these GM plants and their products over life cycles and seasons should be assessed."*

This requirement is valid in regard to plants applied for cultivation as well as for plants that can build feral populations. However, risks for pollinators and wild life species were not discussed at all.

Ground E5: Failure to perform proper risk assessment of long-term effects

EFSA´s Guidance (EFSA 2010 a) puts a lot of emphasis on long-term risk assessment.

> *"The consideration of long-term effects in the ERA should address effects that might arise up to a minimum of 10 years after the start of cultivation for annual plants, i.e. corresponding to the time frame of the consent authorisation (...), but possibly longer for perennial species, and should in all cases cover the time period over which progeny of the GM plant might persist and appear as volunteers or ferals.*

As mentioned, in its risk assessment, EFSA admits that feral MON88302 plants are likely to occur wherever this oilseed rape is transported. In its application Monsanto gives the impression that it would be easy to control the uncontrolled spread of MON83302:

> *"Exposure to the environment will be limited to unintended release of the viable GM commodity destined for processing into animal feed or human food products, which could occur for example via substantial losses during loading/unloading. Such exposure is highly unlikely to give rise to an adverse effect and can be easily controlled by clean up measures and the application of current practices used for the control of any adventitious plants such as manual or mechanical removal and the application of appropriate herbicides."* (Monsanto 2012d)

But looking at existing experience, such as from the spread of transgenic oilseed rape along the transport routes in Japan and in other parts of the world, there is a high likelihood that spillage, gene flow and introgression into fields and the environment can result in a loss of spatio-temporal control of these plants – at least in the long-term. There is a considerable and partly irreducible uncertainty about potential environmental concern and potential damage which could be caused by an uncontrolled spread of transgenes. Some risks are obvious and some of them concern the tasks of the risk manager:

- The control of weedy species can become more complicated with the proliferation of herbicide tolerance amongst native or feral populations. This could increase the pesticide use in the environment and the shift to more toxic substances. It can lead to higher workload for farmers and to an increase in operational costs.
- Genetically engineered organisms, which are no longer allowed on the market for economic or ecological reasons, cannot be removed efficiently if they proliferate in the environment. They can also contaminate harvests and cause substantial economic damage.
- The biodiversity in the centres of diversity are an important genetic resource for plant breeding. Future plant breeding might be hampered substantially if transgenes spread into these resources.

In general, the overall long-term impact on ecosystems is hard to predict. In this regard, transgenic plants can be compared to alien species. Even if the biological characteristics of a species are known, its potential to persist or invade under new environmental conditions very often cannot be predicted (BfN, 2005). Some of the alien species only persist in distinct local regions and do not spread substantially over a longer period of time (i.e. lag-phase) but even after many years they may still become invasive. It is also difficult to predict the ecological impacts of invasiveness (BfN,

2005). The fact that climate change and disturbed ecological systems can foster invasiveness (Clements & Ditommaso, 2011) could cause even further uncertainty.

The comparison between the spread of genetically engineered organisms and the invasive potential of alien species also shows major differences. In the case of MON88302, one must consider the spread of technically inserted genetic information within the pool of genes of Brassica plants in the field and in the environment that are already adapted to the environment. The dynamics of proliferation within established species can be completely different from the pattern of the ecological potential of alien species within a new environment.

In the context of genetic engineering, specific attention should be given to the genetic stability and functionality of the inserted DNA. Unlike alien species, genetically engineered crops contain technical DNA constructs, very often composed from elements such as promotors and stop codons that can escape the normal gene regulation in the plant cells. Under the influence of climate change or in their interaction with other stress factors, this can have unexpected effects in the crops (Meier et al., 1992; Matthews et al., 2005; Zeller et al., 2010) that may also imply new risks for the environment. This issue was completely ignored by risk assessment of EFSA.

Contrary to the opinion of EFSA (2014 a), feral oilseed rape can not only persist for a short period of time and only in a disturbed environment such as rural areas. For example in Scotland, Banks (2014) showed that feral oilseed rape

> *"can persist and flower outside the range of cropped oilseed rape plants. It has become part of the native weed and wildflower community, but to date has had no major ecological impact. The long term demographic changes in feral oilseed rape that were found in the 11 year study could not have been predicted from the initial early years when there were few populations or from prior estimates of risk carried out at small spatial scales."*

Consequently, it is very difficult to predict the long-term ecological impact of transgenes that escape spatio-temporal control, and it may be exacerbated by genetic re-arrangements and newly occurring mutations in combination with environmental (biotic as well as abiotic) changes. Therefore, risk assessment must take into account evolutionary dimensions. Evolutionary processes make it possible to turn events with a low probability of ever happening into events that may feasibly happen (Breckling, 2013).

For example, outcrossing into wild species could be enhanced by climate or other environmental change. There are cases published showing that especially hybrids of cultivated species with wild species develop a higher fitness under stress (Mercer et al., 2007). A higher amount of gene flow for oilseed rape under extreme climatic conditions was reported (Franks & Weis, 2009). The study shows there was a change in the time for flowering resulting in matching of flowering between species.

There are further big gaps in the data available: For example no information was made available how the gene construct of MON88302 will interact with the genome of wild relatives if gene flow occurs. Since feral populations at least can be self-sustaining for several years, many interactions, combinatorial effects and spontaneous evolutionary effects might occur that were not assessed and are unpredictable without reliable data.

There are several other factors that might influence the long term dynamics in wild populations. For example, according to Londo et al. (2013), a factor potentially contributing to gene flow of the glyphosate tolerance trait to related Brassica species are sublethal doses of glyphosate that

> *"could be subject to very different pollination patterns and an altered pattern of gene flow that would result from changes in the overlap of flowering phenology between species. Implications include the potential for increased glyphosate resistance evolution and spread in weedy communities exposed to sub-lethal glyphosate."*

EFSA´s Guidance (2010 a) requests to point out these uncertainties in detail:

> *"Although it may be impossible to identify all the uncertainties, the assessment shall include a description of the types of uncertainties encountered and considered during the different risk assessment steps. Their relative importance and their influence on the assessment outcome shall be described (...). Any uncertainties inherent in the different steps of the ERA (….) shall be highlighted and quantified as far as possible; (…) The absence of data essential for the environmental risk assessment shall be indicated and the quality of existing data shall be discussed.*
>
> *(…)*
>
> *It is recognised that an ERA is only as good as our state of scientific knowledge at the time it was conducted. Thus, under current EU legislation, ERAs are required to identify areas of uncertainty or risk which relate to areas outside current knowledge and the limited scope of the ERA. These include such factors as the impact of the large-scale exposure of different environments when GM plants are commercialised, the impact of exposure over long periods of time and cumulative long-term effects."*

But EFSA failed to identify and address these uncertainties.

Where there are uncertainties, the precautionary principle provides a rational management strategy for the admission of transgenes. In the EU, the precautionary principle is part of the regulatory system. It has to be taken into account before decisions on experimental release or commercial cultivation are made (EU Directive 2001/18).

In this context, it is important to understand that environmental risk assessment in the EU is an iterative process. If new information on the genetically engineered plants and their effects on human health or the environment becomes available, the risk assessment may need to be re-addressed in order to determine whether the risk characterisation has changed and whether it is necessary to amend the risk management. The EU Directive 2001/18 foresees the monitoring of environmental impact (Article 20) and the admission of a specific GMO has to be renewed after ten years. Its outcome should indicate whether the genetically engineered organism can remain on the market or whether the authorisation should expire (Article 17). Article 8 and 23 cover cases where stopping the release of a genetically engineered plant may be deemed a matter of urgency immediately after new information about risks becomes available.

In conclusion, the EU can allow the import, release and commercial growing of plants inheriting transgenes. However, there is a caveat. If new information becomes available, the authorisation can be revoked. Then the release of the transgenes must be terminated. However, if genetically

engineered plants have escaped spatio-temporal control by dispersing in natural self-sustaining populations, they might no longer be retrievable as stipulated (Kraemer, 2013).

As previously mentioned, EU Directive 2001/18 foresees that emergency measures must be taken if new information is made available about serious risks (Article 8 and Article 23). Furthermore, market authorisation has to be monitored and reassessed after 10 years (Art. 15,4 and Article 17). If there is new information on adverse impacts, the market authorisation can be terminated. If a genetically engineered organism no longer has authorisation it must be removed from the market (Art . 4 (5)) – and thus also from the environment. The release of genetically engineered organisms, which cannot be controlled in spatio-temporal dispersal conflicts with these provisions. The precautionary principle as established in Directive 2001/18 is operational only if efficient measures exist that can assure the removal of the genetically engineered organism from the environment is feasible if required becomes a matter of urgency. Therefore, spatio-temporal control is a prerequisite for implementing precaution. There is no doubt that under current EU regulation this principle also has to be applied for applications filed under EU Regulation 1829/2003.

In conclusion, market authorisation for the import of viable kernels of MON88302 is in conflict with EU regulations that require spatio-temporal control.

Table 1: Tabled overview on some topics being relevant for environmental risks and its assessment by EFSA

Issue	level investigation	assessment by EFSA	comment
Interaction with various environmental stressors	Data from field trials	Accepted without detailed discussion	Data not conclusive since incidence and level of intensity of stressful conditions during field trials was very low and definitions were not defined sufficiently.
Seed dormancy	Investigated as germination rate	EFSA is correct in stating that the methods were not adequate	No conclusion can be derived from data provided
Pollen viability	Investigated by Alexander‘s stain which is a preliminary test assessing pollen grain maturity, but does not directly measure pollen viability or germination capacity.	EFSA is correct in stating that the methods were not adequate	No conclusion can be derived from data provided
Survival rate of viable seeds after ingestion by relevant wildlife species	No data provided	Not requested by EFSA	Not discussed at all
Statistical data on spillage	No data provided	Not requested by EFSA	Assumptions that spillage is likely to be low not based no data and is in contradiction to findings in Japan and elsewhere. In general, amount of

Issue	level investigation	assessment by EFSA	comment
			import might vary over the years are driven by various markets, not only for usage in food and feed but also for energy production.
Statistical data on gene flow under specific conditions (for example unnoticed large scale contamination in the fields)	No data provided	Not requested by EFSA	No general conclusions can be drawn form data presented. Under specific conditions such as unnoticed large scale contamination in the fields, a high frequency of gene flow to other fields and feral populations has to be expected.
Interaction of the transgene with genetic backgound of wild relatives	No data provided	Not requested by EFSA	Assumptions that gene flow will not lead to persistence of the transgene used in MON88302 are not based on empirical data. On the opposite, data available show that persistence at over several years has to be expected.
Functional genetic stability and potential effects of the transgene in spontaneous crossings over several generations within populations of several species.	No data provided	Not requested by EFSA	Not discussed at all
Risks for insects, pollinators, wild life species if feral populations establish.	No data provided	Not requested by EFSA	Not discussed at all
Accumulated and combinatorial risks (for example crossing with other herbicide resistant plants)	No data provided	Not requested by EFSA	Not discussed at all

Ground E6: Post-market environmental monitoring

As shown above, if MON88302 is being imported in large bulks over longer periods of time, it is likely to trigger gene flow to oilseed rape fields and also wild relatives. Further in case of accidental releases (like breakdown of transport machines) and misuse of the kernels for sowing, large scale contamination of fields and massive gene flow can occur within a short period of time. Thus it cannot be denied that case specific monitoring to collect data on any release of MON88302 by spillage or any other reason as well as on any potential gene flow has to be conducted. Further the risk manager has to make sure that immediate action is taken as soon as any release of MON88302 is noticed, to prevent further spread of the transgene. Also several experts from EU Member States such as the experts from Germany (BfN) voiced concerns demanding much more targeted case specific monitoring of factual gene flow.

But EFSA and the EU Commission did not request any specific monitoring in combination nor any risk management strategies as foreseen by EFSA Guidance (2010 a) in case of if spillage or release of viable seeds is noticed.

Further, according to experts from some Member States, the monitoring should also include the health risks emerging from residues in the plants sprayed with glyphosate herbicides. Since the MON88302 oilseed rape is supposed to tolerate higher concentrations of glyphosate than other oilseed rape before, the request for specific monitoring of the residues is a must in case of any imports.

Finally, according to Monsanto, the duration of this monitoring would be restricted to the duration of the authorisation. But it has to be expected that even after the authorisation expired, further contamination of the food chain is might to be observed for many years, especially if any gene flow into fields and feral or native populations occurred. Thus monitoring has to be prolonged as long as any viable material can be found in the environment.

In result, the monitoring plan as provided by Monsanto should not have been accepted by the EU Commission. The missing requirements for specific monitoring and for effective control mechanisms is a manifest violation of EU GMO regulations read together with the Directive: It can cause permanent uncontrolled and not authorised release of MON88302 into fields and the environment.

Conclusions:

The decision of the Commission has to be withdrawn. Importing viable whole kernels of MON88302 on basis of EFSA´s opinion cannot be allowed. EFSA risk assessment shows major flaws and substantial gaps. Further no requirements were made for specific monitoring and for effective control mechanism in case of unintended releases.

As a result, the Commission failed to ensure that a lawful environmental assessment was carried out and/or appropriate monitoring was put in place in accordance with the GM Regulation read together with the Directive. Furthermore, so far as relevant, the Commission has unlawfully defeated a legitimate expectation that EFSA would act in accordance with its own guidance in advising the Commission on applications for authorisation under the GM Regulation, and that the Commission would ensure such compliance by EFSA before reaching its authorisation decisions.

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