Oilseed_rape_MON88302

Organisation: Life
Country: Germany
Type: Individual

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a. Assessment:
Molecular characterisation

Don't you agree, that it is unfair to ask the opinion on a GMO molecular characterisation of the public when 99% of the public can not answer this question. And should you not educate the public instead of leaving them in the dark?

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

Don't you agree that genetically modified plants compare to old climatized seeds?

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b. Food Safety Assessment:
Toxicology

Don't you agree, that genetically modified plants are not thoroughly researched, like Asbest wasn't?

Allergenicity

Don't you agree, that allergy rate in children and adults went up in the past 20 years, and instead of genetically modifying plants we should educate young and old on how to eat healthy and that you can survive on less animal products?

Nutritional assessment

Don't you agree that nature gives us all the nutrition, and instead of genetically modifying plants, we should grow our old climatized plants?

Others

I am tired of worrying, why cant we all be reasonable people that want to protect people, animals and the environment. Why is profit always so important?

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3. Environmental risk assessment

Cross-contamination? Don't you agree?

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4. Conclusions and recommendations

Please do not continue to allow GMO, instead tell people to eat less animal products, buy less clothes, use tax-money to educate people instead of making them more and more stupid.

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6. Labelling proposal

Please label all GMO products, and at the same time tell people why you label them.

Organisation: keine PRIVAT
Country: Germany
Type: Regulatory body

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a. Assessment:
Molecular characterisation

Stop Monsanto! Die genveranderten Pflanzen und deren Saatgut ist WEDER für Menschen noch für Tiere gut! Auch SIE sind letztendlich Verbraucher! Auch SIE müssen durch Ihre Beschlüsse diese verseuchten Dinge essen!!!

Organisation: Testbiotech
Country: Germany

Type: Non Profit Organisation

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a. Assessment:
Molecular characterisation

The data as presented are not conclusive. The additional DNA in the plant genome was inserted between two transcriptional areas, but no investigation was carried out to see whether this has changed plant gene activity.

So-called open reading frames (ORF), which can give rise to various new gene products, were identified at the site of insertion. But the relevant DNA sequences were only assessed for potential new proteins and not in regard to other biologically active DNA products such as micro-RNA. These 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). Its effects on health and environment are a matter of huge uncertainty. In its opinion, EFSA completely ignored this issue.

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.

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. Essentially 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 genetically engineered plant and its derivation.

Lukasik, A., & Zielenkiewicz, P. (2014) In Silico Identification of Plant miRNAs in Mammalian Breast Milk Exosomes – A Small Step Forward? PLoS ONE 9(6): e99963.

Zhang, L., Hou, D., Chen, X., Li, D., Zhu, L., Zhang, Y., Li, J., Bian, Z., Liang, X., Cai, X., Yin, Y., Wang, C., Zhang, T., Zhu, D., Zhang, D., Xu, J., Chen, Qu., Ba, Y., Liu, J., Wang, Q., Chen, J., Wang, J., Wang, M., Zhang, Q., Zhang, J., Zen, K., Zhang, C.Y. (2011) Exogenous plant MIR168a specifically targets mammalian LDLRAP1: evidence of cross-kingdom regulation by microRNA. Cell Research, 22(1): 107-126.

Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)

(1) Choice of comparator The variety Ebony, which is described as having a very similar

genetic background to MON88302, was used as a “comparator”. But it is unclear whether Ebony really is as 'isogenic' with MON88302 as it should be. In order to have a correct basis for comparison of plant composition and agronomic characteristics, the only genetic difference between the conventional and the genetically engineered plants should be the additional DNA as inserted. The comments from EFSA show this does not appear to be the case with Ebony.

Further questions arise from the fact that around a dozen plant varieties were used as additional 'references' without them having a similar genetic background to MON88302. By introducing this large number of additional varieties, a lot of unspecific data have been introduced into the comparison with the genetically engineered plant that can be used to mask relevant differences between MON88302 and Ebony.

The plants used as references and comparators for comparative analysis, were partially contaminated with MON88302. But no further tests for contamination with other genetically engineered traits were conducted.

All in all doubts remain about whether the comparators used for the investigations were suited to the purpose at all.

(2) Compositional analysis The compositional analysis revealed many statistically significant differences between oilseed rape MON88302 and its conventional counterparts. 14 of 52 parameters were identified (carbohydrates, ash and total fat, amino acid lysine, several fatty acids, mineral calcium and vitamin E). These differences can indicate unintended effects in the plants caused by the process of genetic engineering, and should have been assessed in detail. For example, interactions between the genome and the environment should have been explored to find the true range of variations in plants composition. This kind of investigation requires that the plants are subjected to various defined stressful conditions. However, no such investigations were required.

Risk assessment should also require data from all parts of the plants, 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. However, this lack of compositional analysis data from all other parts of the plants makes it more likely that unintended effects that are relevant for the safety of any derived food and feed, will be overlooked.

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 real conditions. This problem was also raised by experts from the Member States. 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. Consequently, the whole of the risk assessment is fundamentally flawed throughout.

(3) 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. Significant 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 avoid more detailed investigations, 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. 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. This gives reason to assume that the EFSA risk assessment is not sufficiently based on empirical findings and has an underlying bias aimed at avoiding more thorough investigations.

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. And - 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.

In addition, no data were made available regarding a sufficiently broad range of stress conditions that can impact the agronomic characteristics of the plants. For example, it is known that drought, heat, cold and soil conditions as well as pest infestations can change the plants´ interaction with the environment and in some cases also trigger unintended effects in genetically engineered plants. But in its reply to experts from Member States who had requested more data on the environmental impacts, EFSA simply states that “no unusual weather conditions at the selected locations were reported”. This statement again shows to that EFSA deliberately seems to ignore relevant questions to avoid more thorough investigations. In this context, relevant data on fertiliser, agrochemicals and irrigation applied on the fields are missing.

(4) Conclusion on the comparative assessment In the application as filed by Monsanto, 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...”

Apparently this statement is an assumption that is not based on scientific facts and can be considered wrong. This view is also endorsed by several experts from Member States. Nevertheless, EFSA comes to a very similar conclusion to Monsanto regarding the comparative assessment: “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.”

In its highly questionable interpretation of the scientific findings (“not of biological relevance”, “can be contributed to the variability in the genetic background”) EFSA more or less confirms the Monsanto conclusions. These conclusions are indicative for all the other parts of the MON88302 risk assessment. If comparative analysis does not reveal relevant differences, EFSA does not request further detailed testing for toxicology, allergenicity and nutritional effects. The plants are generally regarded as safe as their conventional counterparts. In reality, the plants are only subjected to a quick inspection, but not to detailed empirical studies.

The process as performed by EFSA is nothing other than a system to avoid more detailed risk assessment, and thus might be in line with the interests of industry. However, it 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. As EFSA 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.”

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b. Food Safety Assessment:
Toxicology

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

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.

Allergenicity

Digestion of the additional proteins was not assessed under practical conditions. Changes in the expression of endogenous genes (allergenes) were not assessed. Thus, the risk assessment for allergenicity cannot be regarded as conclusive.

Nutritional assessment

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

Others

EFSA agrees with Monsanto that no targeted case specific monitoring of the uncontrolled spread of MON88302 and related gene flow is necessary if import is allowed. Monsanto and other members of the industry lobby EuropaBio would be the ones to oversee the import and report potential unanticipated adverse effects.

The duration of this monitoring would be restricted to the duration of the authorisation. But as the case of transgenic oilseed rape produced by Bayer shows (Bauer-Panskus et al., 2013b, EU Commission 2012), contamination with transgenes are likely to occur even many years after the authorisation has expired, if once established.

Several experts from EU Member States such as the experts from Germany (BfN) voiced concerns that this is not a sufficiently robust approach. They believe there is a need for much more targeted case specific monitoring of factual gene flow. According to some experts from Member States, this monitoring should also include the health risks emerging from residues in the plants sprayed with glyphosate herbicides.

Bauer-Panskus, A., Hamberger, S., Then, C. (2013b) Transgene Escape –Global atlas of uncontrolled spread of genetically engineered plants, Testbiotech, http://www.testbiotech.org/en/node/944

EU Commission (2012) COMMISSION IMPLEMENTING DECISION of 3 February 2012 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape, Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape as well as their derived products. www.fsai.ie/uploadedFiles/Legislation/Food_Legisation_Links/Genetically_Modified_Organisms_%28GMOs%29/Dec2012_69.pdf

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3. 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 hybridise with cultivated B. rapa and B. oleracea, hybridisation with B. rapa is the most probable.

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).

EFSA is fully aware of the inevitability of MON88302 escaping into the environment during transport and processing. However, EFSA 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: "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 largely misleading and not based on scientific facts:

(1) Is there any evidence that MON88302 plants do not show enhanced fitness, persistence or invasiveness compared to conventional oilseed rape? As stated above, 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 plants have enhanced fitness. Further, it did not assess in detail the impact of the delay in flowering and possible outcrosses to wild relatives of the plant. Significant differences were observed in seed maturity and lodging, but set aside as not of biological relevance and therefore not assessed further. In conclusion, there are no sufficiently reliable data to assess fitness, persistence or invasiveness

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

(2) Is the occurrence of feral MON88303 oilseed rape resulting from seed import spills likely to be low? The assumption that occurrence of feral MON88032 oilseed rape resulting from seed import spills is likely to be low is not based on facts. French experts have said that 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.

(3) Can we expect hybridisation with wild relatives to be a rare event and the hybrids not to be persistent? 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)."

Furthermore, EFSA overlooked 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 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 & Hacker, 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.

According to Wang et al. (2013), EPSPS overexpression in crop plants may also foster the fitness of glyphosate resistance in weeds. "However, it seems possible that several mechanisms for glyphosate resistance could evolve in the same species, together or separately, and perhaps in different regions (Powles et al., 1997; Dinelli et al., 2008). If so, selection favoring greater expression of a plant's endogenous epsps gene(s) could complement or substitute for other mechanisms. This could occur as a result of any genetic mechanism that leads to overproduction of EPSPS, perhaps causing downstream fitness benefits, as observed in the current study."

As stated by EFSA, 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: 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.

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.

(4) What about cross-contamination of fields?

EFSA does not believe that cross contamination with conventional oilseed rape grown on the fields is a matter for concern. As EFSA 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 confers resistance to an ALS herbicide called imazamox. 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.

(5) What impact should we expect from applications with glyphosate? 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 (see Monsanto´s annual reports). According to recent estimates, around one million tons of glyphosate are sprayed in Germany 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. EFSA is trying to give the impression that this is only a minor problem by saying that spillage will be a rare event. However, as the example of Japan shows, this cannot not be assumed in general. The frequency of spillage is likely to increase with a higher volume of imports. 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.

(6) To which extent is environmental risk assessment needed in this case? As EFSA 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. The current application should therefore have been subjected to a full environmental risk assessment. Uncontrolled spread of these transgenes can pose risks to pollinators such as honey bees and butterflies which were completely omitted from risk assessment by EFSA.

(7) What kind of long term effects have to be considered? 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.

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: The control of weedy species can become more complicated with the proliferation of genetically engineered plants with herbicide tolerance. 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 both the adaption and spread of a new species within an ecosystem and the spread of technically inserted genetic information within the pool of genes of a 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 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 are not subject to the natural self-regulation of gene expression 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.

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 evolutionary dimensions into account. 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.

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. Therefore, market authorisation for the import of viable kernels of MON88302 would be in conflict with EU regulations since a substantial risk of permanent uncontrolled gene flow to the environment cannot be ruled out.

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4. Conclusions and recommendations

Importing viable whole kernels of MON88302 cannot be allowed. The opinion of EFSA has to be rejected due to major flaws and substantial gaps.
