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Testbiotech comment on EFSA GMO Panel Scientific Opinion on application EFSA-GMO-NL-2013-119 for authorisation of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MON 88302 x MS8 x RF3 and subcombinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience.

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Oilseed rape MON 88302 x MS8 x RF3 is genetically engineered to be resistant to the combined application of glyphosate and glufosinate. 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. The stacked plants as notified for import are supposed to help to overcome the problems with herbicide-resistant weeds resulting from large-scale cultivation of genetically engineered plants in countries, such as the USA. In addition, of the parental plants MS8 expresses Barnase conferring male sterility, while RF3 expresses Barstar restoring male fertility. If authorisation is granted, viable whole kernels would be allowed for import into the EU, thereby risking the uncontrolled spread of the plants into the environment.

Further, the EFSA opinion on this genetically engineered oilseed rape suffers from general weaknesses inasmuch as the plants are a stacked combination of three different events. According to the EFSA opinion (EFSA, 2017a), it is sufficient to assess the risks of “the three-event stack oilseed rape (OSR) MON 88302 x MS8 x RF3 and its three subcombinations, independently of their origin.” However, this statements lacks substance since the parental plants MS8 and RF3 did not undergo detailed assessment as single events. According to EFSA´s own guidance, the assessment of single parental plants is necessary before stacked events can assessed. Therefore, the opinion cannot be accepted. Further deficiencies in the EFSA opinion are discussed in the following paragraphs.

Molecular characterisation

The data presented in the assessment are not conclusive.

The expression of the additional DNA constructs showed significant combinatorial effects compared to the parental plants, but no further investigations were carried out. The assessment was made without any systematic investigation of the impact of stressful environmental conditions that may impact gene expression.

Further, there were several so-called open reading frames (ORF) identified in the parental plants; they were found at the site of insertion and can give rise to various new gene products. Nevertheless, 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 without being translated into proteins. There are publications showing miRNA might pass from plants to animals and humans (Zhang et al., 2011, Lukasik & Zielenkiewicz, 2014). Their effects on health and the environment are uncertain. In its opinion, EFSA completely ignored this issue.

Comparative analysis

Agronomic and phenotypic characteristics

Data that are crucial for the assessment of persistence and invasiveness, such as data on the duration of flowering, pollen production, pollen viability, as well as seed dormancy were not investigated. Thus, as also stated by experts from Member States (EFSA 2017b), the selected agronomic characteristics cannot sufficiently indicate differences in reproduction, dissemination and survivability of MON 88302 x MS8 x RF3 oilseed rape compared to conventional oilseed rape.

Several significant findings were observed on plant height, pod shattering, seed moisture and final stand count, as well as on yield. These differences should have been investigated in more detail under various defined stress conditions and after introgression into other genetic backgrounds.

In addition, observations made on the parental plants, such as a delay in the first day flowering of MON88302, were not reported in the stacked event.

Compositional analysis

59 endpoints were used for comparison. According to EFSA, for oilseed rape MON 88302 x MS8 x RF3 (not treated) statistically significant differences with the conventional counterpart were identified for 28 endpoints. For oilseed rape MON 88302 x MS8 x RF3 (treated), statistically significant differences with the conventional counterpart were identified for 13 endpoints. These differences, despite their high number, were not investigated further.

The complementary herbicides were not applied in high dosages as might be expected in fields under pressure from herbicide resistant weeds. Furthermore, the herbicides were only applied in combination, but not separately. Consequently, many of the potential effects that might have occurred under real conditions in the fields were not assessed by EFSA.

EFSA failed to require further studies e.g.

- A detailed comparison of the observations made on the single parental plants compared to the stacked events.
- Omics studies (proteomics, transcriptomics, metabolomics) to assist the compositional analysis and the assessment of the phenotypical changes.
- Investigations of changes in content of miRNA which can be taken up at from the gut and render biological effects across border of life domains.
- Exposing the plants to a wide range of defined biotic or abiotic stressors to assess the true range of possible changes in the plants´ composition.
- More varieties inheriting the trait should have been included to investigate how the gene constructs interact with the genetic background of the plants.

- Several dosages and formulations of the complementary herbicide should have been applied to the plants.

Toxicology

No feeding studies with the whole food and feed derived from parental plants were presented, nor from the stacked events. This is surprising because since 2014, 90-day feeding studies are requested at least for the assessment of the single plants (Commission Implementing Regulation (EU) No 503/2013). While there might be formal reasons not to apply this request for a specific notification, from the point of view of food and feed safety such deficiencies cannot be justified.

The lack of detailed toxicological investigation is highly relevant in this case. Testing of whole food and feed is especially relevant for assessing potential effects on health from the combination of the residues from spraying with high dosages of glyphosate and glufosinate.

The application of the complementary herbicide is part of regular agricultural practice in the cultivation of herbicide resistant plants. Therefore, it can be expected that residues from spraying are always present in the harvest and could be seen as inevitable “constituents”.

In general, EFSA considers residues from spraying with the complementary herbicide to be outside the remit of the GMO panel. However, clearly from a scientific and regulatory point of view, there is no justification for carrying out an assessment of herbicide-resistant genetically engineered plants for health risks and leaving out the residues from spraying with complementary herbicides. Health risk assessment cannot be reduced to what is required under Regulation 396/ 2005 (Pesticide Regulation) since this assessment does not take the specific pattern of exposure and relevant cumulative effects into account.

Due to the specific agricultural practices in the cultivation of herbicide-resistant plants, there are specific patterns of applications, exposure and occurrence of specific metabolites and an emergence of combinatorial effects that require special attention. For example, large-scale commercial cultivation of these plants results in a strong selective pressure on weeds to develop resistance to the herbicides (Sammons et al., 2014). This problem is also relevant for health risk assessment since it has led to increasing amounts of glyphosate being sprayed (Benbrook, 2016) and subsequently more residues in the harvest (Cuhra, 2015). Herbicide-resistant plants are meant to survive the application of the complementary herbicide while most other plants will die after short time. Thus, residues of glufosinate and glyphosate, their metabolites and additives to the formulated product might accumulate and interact in the plants.

As a publication by Kleter et al. (2011) shows, using herbicides to spray genetically engineered herbicide-resistant plants does indeed lead to patterns of residues and exposure that are not taken into account in regular pesticide registration. Further, according to a reasoned legal opinion drawn up by Kraemer (2012), from a regulatory point of view, residues from spraying with complementary herbicides have to be taken into account in the risk assessment of genetically engineered plants.

In regard to the pending application, there are specific reasons for concern. At present, there are continuing discussions about glyphosate being “probably carcinogenic” (IARC, 2015). Furthermore, in 2015, EFSA presented the result of the risk assessment of glyphosate. In its opinion, EFSA (EFSA 2015a) stated that not enough data were available on the applications of glyphosate to genetically engineered plants resistant to the herbicide. As a result, EFSA was unable to deliver a conclusive risk assessment on the actual risks of residues from spraying with glyphosate and the various glyphosate formulations (see also EFSA, 2015b). Glufosinate is suspected of having negative impacts on health (EFSA, 2005) and was already about to be phased out in the EU (EU Pesticides

Database, 2017) because of being classified as showing reproductive toxicity.[1] Meanwhile their approval periods were extended.[2] It is also known to cause residues from spraying if used as a complementary herbicide on genetically engineered plants.

Therefore, the safety of the genetically engineered oilseed rape sprayed with glyphosate and glufosinate cannot be proven by EFSA´s assessment.

In addition, there are many other substances such as oestrogens, allergens, antinutritional compounds present in the plants that in interaction with trait-related characteristics might act as stressors: There is a considerable amount of literature indicating that glyphosate formulations can act as so-called endocrine disruptors (see, for example, Thongprakaisang et al., 2013; Çağlar & Kolankaya, 2008; de Liz Oliveira Cavalli et al., 2013; Omran & Salama, 2013). Endocrine effects were found when young rats were exposed to soy milk in combination with glyphosate (Nardi et al., 2016). There may be synergistic or additive interactions of plant components (see for example de Lemos, 2001) with the residues from spraying with glyphosate formulations.

There are other relevant issues: For example, the potential impact on the intestinal microbiome also has to be considered. Such effects might be caused by the residues from spraying since glyphosate was shown to have negative effects on the composition of the intestinal flora of cattle (Reuter et al., 2007) and poultry (Shehata et al., 2013). Further, Bremmer and Leist (1997) examined the possible conversion of NAG to glufosinate in rats. Up to 10% deacetylation occurred at a low dose of 3 mg/kg bw as shown by the occurrence of glufosinate in the faeces. The authors concluded, however, that most of the conversion was caused by bacteria in the colon and rectum although toxicity findings indicate partial bioavailability.

As a result, there is a huge gap in the safety assessment of the genetically engineered plants that cannot be filled by adjustments to the MRLs applicable under the Pesticide Regulation. Consequently, the impact of residues in the plants from spraying with the herbicides must be assessed before the plants can be declared safe. The failure to do so poses real safety risks to humans, animals and the environment generally.

In any case, both the EU pesticide regulation and the GMO regulation require a high level of protection of health and the environment. Thus, in regard to herbicide-resistant plants, specific assessment of residues from spraying with complementary herbicides must be considered to be a prerequisite for granting authorisation. In addition, cumulative effects have to be investigated if a plant contains or produces other compounds of potential toxicity.

It should be acknowledged, that no new methodology is needed to assess the health risks emerging from the combinatorial application of the herbicides and their potential interaction with the other plant constituents. There is, for example, no need to apply methods such as the Monte Carlo Risk Assessment (MCRA) because the majority of potential stressors can be expected to occur in a fixed combination and follow a specific pattern of exposure. Rather, the methods currently available (*in vivo* and / or *in vitro*) are sufficient to assess the health effects. Regulation (EC) No 1907/2006 (REACH), for instance, provides guidance on how substances that are in fact mixtures (isomeric mixtures, MCS (multi-constituent substance) and UVCB (substances of unknown or variable composition, complex reaction products or biological materials) should be assessed for their PBT/vPvB (persistent, bioaccumulative and toxic) properties. In general, due to the nature of “substances of unknown or variable composition, complex reaction products or biological materials” it is not possible to make reliable predictions about additive, or synergistic, or antagonistic modes of effects.

1 http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
2 COMMISSION IMPLEMENTING REGULATION (EU) 2015/404, Official Journal of the European Union L 67/6, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2015.067.01.0006.01.ENG

Therefore, such substances have to be tested as a mixture, not as single compounds. For example, chronic feeding studies are a well-established method of generating the relevant data.

Environmental risk assessment

Europe is the centre of origin and genetic diversity for the group of *Brassica* plants to which oilseed rape belongs. Thus, there are several wild relatives that can interbreed with *Brassicus napus*. Oilseed rape (*Brassica napus*) can spread via pollen and seeds. 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 establishing volunteer plants even many years after the first sowing. The plants are mostly pollinated by insects such as flies, honey bees and butterflies, which can also carry the pollen over many kilometres. 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). 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).

The EFSA (EFSA 2014) opinion on the assessment of the parental plant MON88302 states that the import and transport of MON88302 (which they summarise as genetically modified herbicide tolerant – GMHT - oilseed rape), is likely to establish volunteer plants alongside transport routes and processing facilities. However, EFSA does not consider this to be a problem:

> *"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."*

As reasoned in EFSA´s current opinion, the GMO panel is of the opinion that the occurrence of feral MON88302 oilseed rape resulting from seed import spills is likely to be low, as is the likelihood of gene flow to wild relatives.

However, these assumptions are questionable. In general, the amount of spillage will be largely dependent on the amount of imports, the transport routes and the transport vehicles. The frequency of spillage is likely to increase with a higher volume of imports. Demands for import might vary over the years and will be driven by various markets, not only for usage in food and feed but also for energy production.

Several publications show that spillage from transport can occur in amounts that give rise to populations that can persist in the environment over several years; gene flow will also occur between these populations and wild relatives. 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 flow in neighbouring fields (Squire et al., 2011).

As seen in Japan, import can also lead to the emergence of self-sustaining populations. 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, in their publication 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.

Together with feral oilseed rape populations, transgenic volunteers can open up many opportunities for genetic recombination, stacking of genes and the evolution of genotypes that could lead not only to 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 the ALS-inhibitor herbicide known as 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.

There are several findings on crossings of wild and domesticated plants giving rise to transgenic offspring. The first transgenic hybrid plants between *B. napus* and *B. rapa* were 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 both glyphosate and glufosinate herbicides. Schafer et al. (2011) also reported crosses of transgenic plants giving rise to spontaneous stacked events.

Banks (2014), a researcher who led the first long-term study over a period of 11 years on feral oilseed rape populations, comes to the conclusion that feral oilseed rape populations:

> *"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."*

EFSA did not assess Banks' (2014) actual findings in detail, such as new findings on invasiveness. Contrary to the opinion of EFSA, Banks (2014) points to the potential invasiveness of oilseed rape in ruderal areas of Scotland. While the number of feral oilseed rape populations has increased substantially over the years, the number of other ruderal brassica species has decreased:

> *"By the end of the survey, however, feral oilseed rape had possibly become the most common crucifer in ruderal habitats. Its rise coincided with a widespread decline in wild crucifers such as Sinapis arvensis and Sisymbrium officinale that occupy similar habitats. Questions arise as to whether feral oilseed rape might be contributing to the decline of these crucifers or might be substituting for them in the ruderal food web. To date, no one has examined such interactions between feral oilseed rape and wild crucifers."*

He discusses several causes, finding indications for invasiveness but no final evidence. He states that:

> *"In total these are substantial changes that merit a re-assessment of feral oilseed rape as an invasive plant and of its role in the environmental risk assessment of GM crops."*

According to Banks, several issues have to be taken into account in assessing the potential invasiveness of feral populations of oilseed rape in ruderal areas:

- Feral populations can show significant changes in their biology, such as a change in the period of flowering. Consequently, feral populations can have a higher potential for invasiveness than the original varieties used for cultivation.
- Feral populations might become perennial (see also Kawata et al., 2009), which is unlikely under cultivation conditions. Perennial plants have a higher probability of spreading their genes because they persist for a longer period. This is a factor supporting higher fitness, which can render higher invasiveness.
- Comparisons with species that became weeds due to agricultural practices show that weedy characteristics can be acquired over a period of time even if they are not initially present.
- He also mentions that climate conditions can have a substantial impact on the competitiveness of feral oilseed rape populations.

Consequently, if oilseed rape is enabled to become a feral population, this can be a starting point for the plants to become invasive and / or acquire weed characteristics at a later stage. Unlike crop plants under cultivation these plants can start to evolve and adapt over a longer period of time. As Banks states:

> *"Nevertheless, the different behaviour of ferals in corridors and farmland demonstrate that the populations have to a degree arranged themselves in relation to local conditions beyond those just to do with transport. This is further evidence that ferals may be becoming established like weeds and other ruderals and finding preferred sub-habitats."*

Further, in comparison to some other weeds, he showed that weediness of ruderal populations can be acquired over a longer period of time. As Banks states:

> *"To illustrate this, feral oilseed rape is compared with several of the major agricultural weeds (...). None of these plants were 'weeds' originally, but all have become serious weeds because they fit into the various cycles of grassland and arable land. All began at some time in local or restricted habitats."*

The EFSA assessment, which is based on the biology of annual oilseed rape grown as crops in the fields, is not sufficient to assess the long-term dynamics of feral populations. As Banks shows, feral populations can show population dynamics that are largely distinct from those of cultivated crops. One of the relevant characteristics which can emerge in feral populations but is hardly likely in cultivation is perenniality. This has been reported by Kawata et al. (2009) as well as by Banks (2014):

> *"Feral oilseed rape is mostly a spring annual germinating in spring or a winter annual germinating in autumn. However, a few individuals have been found to survive into a third summer in Tayside, following cutting and re-growth from the cut stumps (written records of the Tayside Study 1993-1995; G. R. Squire, personal communication). Whether perenniality would become more common in feral oilseed rape is uncertain at present."*

In addition, EFSA failed to make a detailed assessment of the specific invasiveness of the herbicide-resistant oilseed rape. Since ruderal areas are the most relevant ecological areas for oilseed rape to persist and spread, its resistance to glyphosate is highly relevant when it comes to competitiveness with other brassica populations that can be found in overlapping ecological niches. As Banks states by referring to relevant literature, this can become a decisive issue:

"Under strong selection pressure, for instance if herbicide-tolerant feral genotypes were treated with the respective herbicide, evolved genotypes could increase rapidly, re-colonise fields and thereby join existing volunteer populations to increase the economic weed burden and the potential for impurity (Squire et al. 2011)."

In addition, according to Gressel (2015), "transgenic herbicide resistance poses a major risk if introgressed into weedy relatives." Gene flow from oilseed rape 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 oilseed crop plants may foster the fitness of glyphosate resistance in weeds and lead to fitness advantages.

Finally, the EFSA risk assessment did not sufficiently assess the invasiveness of the genetically engineered plants. Most of the relevant characteristics for assessing the specific invasiveness of MON88302, such as pollen, seed characteristics (secondary dormancy) and duration of flowering, were omitted.

Banks' research (2014) has uncovered substantial new findings on the persistence of oilseed rape in the environment. Contrary to the opinion of EFSA, the actual area on which oilseed rape is grown in a region does not necessarily impact the dynamics of the feral populations. Within the region investigated in Scotland, the area on which oilseed rape was grown was decreasing, while the number of feral oilseed rape populations was strongly increasing. Banks comes to following conclusions:

"The number of feral oilseed rape populations increased almost five-fold during a period when the number of fields and total area cropped with oilseed rape decreased. Ferals did not usually remain at the same location for more than one or two years, and did not spread by gradual movement out from the sites of initial colonization. They persisted and spread in the region by occurring at different places each year, most likely through long range dispersal."

Banks also presented new findings on the pattern of distribution in the environment:

"However, the demographic study reported here showed that feral populations increased in number, not just along transport routes but in farmland generally. The reason for the discrepancy between small-scale studies on risk assessment and the actual rise of ferals here is unclear."

Emergence of persistent feral populations of oilseed rape as described by Banks is in no way restricted to conditions under cultivation. In a publication by Mizuguti et al. (2011), it is concluded that populations of genetically engineered oilseed rape are able to self-sustain around Japanese harbours. These plants stem from spillage, since their cultivation is not allowed in Japan. Further, Katsuta (2015) found no clear tendency (decrease or increase) in populations of genetically engineered oilseed rape around Japanese harbours stemming from spillage between 2006 and 2011. At some sites, the populations of genetically engineered plants reported by Katsuta (2015) were found to remain stable for several years, even though there had been no further imports. Further, in the US and Canada, ferals occurred along routes that were sometimes distant from fields, and they increased in density towards storage depots and industrial sites (Knispel & McLachlan, 2010; Schafer et al. 2011).

There is sufficient evidence to show that spillage alone can give rise to persistent populations. As Banks (2014) shows, the number of feral populations was increasing while the cultivation sites were decreasing. Further, the examples from Japan and the US show that persistent feral populations emerged from import, and seem to be able to persist in some regions even if no further import and transport is taking place.

In general, according to Banks (2014) there are dynamics within the distribution of feral populations that cannot be predicted on the basis of currently available short-term investigations:

> *"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."*

As mentioned, EFSA did not request any data on seed dormancy, duration of flowering, number of pollen, viability of pollen, nor on any other parameter crucial to judging whether the plants have enhanced fitness. Further, no assessment was made of the potential impact of gene flow from the single parental plants MS8 or RF3 to native populations.

Furthermore, EFSA only took the characteristics as observed in the original event into account. Indeed, EFSA assumed that offspring and hybrids would show the same characteristics as the original event. In making this assumption, EFSA overlooked publications, such as those by Kawata et al. (2009) or Aono et al. (2006), which indicate unexpected changes in the fitness of transgenic plants that are unrelated to the intended trait. No crossing experiments with the genetically engineered plants were performed to investigate the effects of the transgenes on plants with other genetic backgrounds. It is therefore not possible to predict fitness, persistence or the invasiveness of hybrids from crossing with the genetically engineered oilseed rape.

Further, genome x environmental interactions were also ignored. For example, outcrossing into wild species could be enhanced by climate or other environmental changes. A higher amount of gene flow for oilseed rape under extreme climatic conditions has been reported (Franks & Weis, 2009). The study shows there was a change in the time for flowering resulting in matching of flowering between species.

In a worst case scenario, due to crossing with other transgenic oilseed rape of wild relatives, the resulting transgenic plants could become resistant to one or several herbicides. Further, the genetic background of the wild relatives is very different from that of the domesticated oilseed rape. Therefore, enhanced fitness in hybrids might emerge that was not observed in the original event. Once established in the environment, oilseed rape can persist over a long period of time and the transgenic plants can, for example, be exposed to climate change stress factors which might confer higher fitness than observed in the original events.

If such a worst case scenario, whether wholly or partially, became reality, teosinte plants might become a "superweed" with invasive characteristics that could endanger oilseed rape production in the EU and, if transgenic plants are established besides the fields, also impact the ecosystems.

In conclusion, EFSA´s risk assessment suffers from:

- No investigation of enhanced fitness of the original events; and no assessment of the single parental plants MS8 or RF3.
- Underestimating the likelihood and consequences of spillage and gene flow
- No assessment of the fitness in offspring and hybrids
- No assessment of genome x environmental interactions.
- No detailed assessment of whether applications of the complementary herbicide glyphosate might promote enhanced fitness of the transgenic oilseed rape.

Taking worst case scenarios into account, EFSA risk assessment is not sufficient to conclude on the risks associated with the import of viable kernels of oilseed rape MON88302 into the EU.

Monitoring

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

Several experts from EU Member States, such as those from Germany (BfN) (EFSA, 2017b), 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. Thus, case-specific monitoring should be run in regions where MON 88302 x MS8 x RF3 oilseed rape will be transported, stored, packaged, processed or used. In case of substantial losses and spread of MON 88302 x MS8 x RF3 oilseed rape, all receiving environments need to be monitored.

Recently, also in Europe studies on feral oilseed rape stemming from imports were conducted in vicinity of “hot spots” like oil mills and along transportation roads. Fertile engineered oilseed rape was found in Switzerland (Hecht et al., 2012, Schoenenberger & D’Andrea, 2012, Schulze et al., 2014). In Germany, large amounts of feral oilseed rape were found in the vicinity of oils mills and seed processing industries at the harbours along the river Rhine (Franzaring et al., 2016). Only one of the plants proved to be transgenic. Nevertheless, the findings indicate an urgent need for monitoring efforts.

Monitoring for genetically engineered oilseed rape should also be extended to other plant species when imports enter the EU: A study by Schulze et al. (2015) investigated the possible sources of herbicide tolerant oilseed rape along transportation routes in Switzerland. Analyses revealed that low level impurities of genetically engineered oilseed rape in imports of Canadian durum wheat is one source of feral genetically engineered oilseed rape in Switzerland. The researchers found traces of oilseed rape events GT73, MS8×RF3, MS8 and RF3 in imports of durum wheat from Canada. The reported results should be considered carefully as they may have far-reaching consequences for the regulation of genetically engineered crops.

In the light of the potential environmental risks, the monitoring plan as presented cannot be accepted.

Conclusions:

The import of viable whole kernels of the stacked event MON88302 x MS8 x RF3 cannot be allowed. The opinion of EFSA has to be rejected due to major flaws and substantial gaps.

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