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# Comments to the "Scientific advice to the European Commission on the internal review submitted under Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention against the Commission Implementing Decision 2015/687 to authorise genetically modified oilseed rape MON88302" (EFSA, August 2015)

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## Content



## Summary & Conclusion

This document addresses some of the arguments presented by EFSA regarding the environmental risk assessment of MON88302.

- EFSA failed to properly assess new information regarding the potential invasiveness and persistence of oilseed rape in general.
- EFSA failed to investigate the specific invasiveness and persistence of MON88302.
- EFSA did not assess the environmental risks as required by law and by EFSA´s own guidance.
- Proposed monitoring and risk management measures will not enable the removal of oilseed rape MON88302 from the environment if this is urgently required.

EU regulation only allows releases of genetically engineered organisms after an application has been filed and authorisation given for a deliberate release for a defined period of time. However, EFSA is of the opinion that in this case, an application for import can be extended to also allow the permanent release of genetically engineered organisms into the environment, without conducting a full environmental risk assessment and for an indefinite period of time.

The approach of EFSA is biased. In order to avoid a full environmental risk assessment, EFSA is ignoring existing knowledge about the invasiveness and persistence of oilseed rape, and is, instead, selectively choosing parts of new publications that appear most beneficial to the defence of its previous opinion.

EFSA is thereby not only undermining EU regulation 2001/ 18, it is also undermining the precautionary principle, which is the basis of EU GMO regulation. The precautionary principle presupposes that genetically engineered plants can be removed from the environment if new evidence of risks emerges. However, if the EFSA advice is followed it would mean that genetically engineered plants could be released into the environment even though they cannot be controlled in their spatio-temporal persistence.

## (1) EFSA is ignoring new scientific information

In a technical dossier prepared by Testbiotech (2015), new information was provided to EFSA and the EU Commission on the invasiveness and persistence of oilseed rape in the environment. Most relevant in this context is a publication by Banks (2014), a researcher who led the first long-term study over a period of 11 years on feral oilseed rape populations. He 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."*

In its response to the Testbiotech technical dossier EFSA (2015) refers to Banks (2014) several times. However, EFSA has selectively chosen arguments from the study without presenting and discussing Banks' most relevant findings. EFSA simply says that:

> *"The scientific arguments put forward in the technical background of Testbiotech's complaint reveal no new information that would invalidate the previous risk assessment conclusions and risk management recommendations made by the EFSA GMO Panel."*

EFSA did not assess Banks' (2014) actual findings in detail. On the contrary, EFSA followed Monsanto´s false claim that the consequences of spillage and feral distribution of MON88302 can safely be ignored (Monsanto 2012):

> *"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."*

In the following paragraphs, Banks' (2014) new findings on the potential invasiveness and persistence of oil seed rape are briefly summarised and contrasted to EFSA *technical advice.*

## (2) New findings on invasiveness

Contrary to the original *opinion* of EFSA (2014) and EFSA´s *technical advice* (EFSA 2015), 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. Distinct from 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."*

EFSA failed to properly analyse these new findings regarding potential invasiveness of feral oilseed rape populations. Instead, EFSA states:

> *"Consequently, to behave as a successful invading species, any annual, partially domesticated and poorly competitive plant, including oilseed rape would have to change its behaviour fundamentally; otherwise, it will be restricted to frequently disturbed (ruderal)*

*habitats."*

This statement is likely to have been driven by intended ignorance. First of all, if genetically engineered oilseed rape becomes successfully established in ruderal areas, this can have substantial ecological impacts, since ruderal areas are of ecological relevance in the European landscape and agriculture. For example, as Banks shows, if wild Brassica species are diminished this can have implications for the diversity of insects and pest infestations in and outside the fields. However, as Banks himself (2014) states, so far the relevant data are mostly missing:

> *"No study to date has assessed feral oilseed rape to see if it has an ecological impact on other ruderal crucifer species, or the insect communities associated with them. Such analysis is necessary for environmental risk assessment (EFSA 2010a) as the information would provide a baseline against which the likely impact of GM feral oilseed rape on naturally occurring plant species and associated insect communities could be assessed."*

Furthermore, the assessment of EFSA, 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 assess the specific invasiveness of oilseed rape MON88302. 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 leading to fitness advantages.

But EFSA seems to assume that glyphosate application is not a major problem, despite a high likelihood of glyphosate being sprayed in ruderal areas. Thus, EFSA (2015) states:

> *"Furthermore, the herbicide tolerance trait conferred by the cp4 epsps gene is unlikely to provide a selective advantage in unmanaged ecosystems, but rather only in settings where GLY is being applied for weed control. Therefore, oilseed rape MON88302 is no more likely to form feral populations than conventional oilseed rape, nor is it more likely to be more invasive or competitive or persistent in habitats where the target herbicide is not applied."*

Finally, EFSA risk assessment did not sufficiently assess whether the invasiveness of MON88302 is changed by unintended effects due to genetic engineering. As reported, a difference and lack of equivalence in days-to-first flowering was identified, but the cause for this observation was not finally identified. Thus, this finding has to be seen as a possible indication for changes in the biology of the plant that go beyond those parameters examined. However, most relevant characteristics to assess the specific invasiveness of MON88302 such as pollen, seed characteristics (secondary dormancy) and duration of flowering were omitted, based on the purely formal argument that the application would be for import and processing for food and feed uses only:

> *"(…) given that the scope of the application excludes cultivation, the EFSA GMO Panel did not consider the data on pollen viability, duration of flowering and seed dormancy essential for the risk assessment of oilseed rape MON88302.*
> *For GM plant applications for import and processing for food and feed uses, the EFSA GMO Panel does not require data on flowering duration, and considers data on days to flowering sufficient to assess potential differences in the periodicity of flowering (EFSA, 2015)."*

EFSA further fails to take into account the potential impact of climate change. EFSA (2015) states:

> *"In addition, the genetic transformation of oilseed rape MON88302 is not designed to target abiotic stressors, and therefore the EFSA GMO Panel considered protein expression measurements under typical environmental conditions as sufficient."*

EFSA seems to intentionally ignore that genetically engineered plants, which are not meant to resist specific abiotic stressors, will be exposed to conditions of climate change such as drought or overwatering. As Banks mentions, climate change is indeed likely to impact the relevant characteristics of oilseed rape:

> *"Warmer temperature would increase the rate of germination of seed, but high diurnal cycling is also needed in spring to release dormancy."*

## (3) New findings on persistence

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 concerning 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.”*

As Banks (2014) shows, the persistence of single populations on specific sites in combination with the seed bank (which EFSA does consider to some extent), is not the only criteria that has to be taken into account if persistence of feral populations is to be assessed:

> *“Ferals had, by the end of the study, become persistent, having the characteristics of a weed or ruderal that enables it to take advantage of disturbance in a range of environments. Persistence occurred at a large scale, however. The common pattern over the whole study region was for most feral populations to disappear after one or two years. Whereas Pessel et al. (2001) found that feral oilseed rape could persist in the seedbank on road verges in France for at least 8 years, this sort of persistence via the seedbank seemed to be uncommon here.”*

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 found 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).

EFSA (2015) does not doubt in general, that oilseed rape can become a persistent species in ruderal areas:

> *“On a larger scale in the landscape, feral oilseed rape can thus be considered long-lived, with a proportion of the populations founded by repeated fresh seed spills from both agricultural fields and transport, and the remainder resulting from the continuous recruitment of seeds from local feral soil seedbanks (Pivard et al., 2008a,b).”*

However, EFSA tries to give the impression that feral populations are only likely to occur under cultivation conditions:

> *However, if habitats are disturbed on a regular basis by anthropogenic activities such as mowing, herbicide applications or soil disturbance, or natural occurrences such as flooding, then feral populations can persist for longer periods (Claessen et al., 2005a; Garnier et al., 2006). Under these circumstances feral oilseed rape plants could become part of the vegetation in ruderal habitats under cultivation conditions (Banks, 2014).*[1]

EFSA apparently is trying to insinuate that persistence in ruderal habitats can only occur under cultivation conditions. But at the same time, EFSA cannot show that spillage from oilseed rape is not able to give rise to persistent feral populations in the absence of large-scale cultivation. There is, indeed, 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

1 For References see EFSA, 2015

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."*

In conclusion, it is likely that the cultivation of MON88302 is fostering the emergence of persisting ruderal populations, but there is no evidence that cultivation is a prerequisite. Consequently, it has to be assumed that MON88302 plants stemming from the spillage of kernels can persist in the environment by becoming part of feral populations.

## (4) What has to be considered in risk assessment?

In its *technical dossier*, Testbiotech argues that if persisting feral populations of oilseed rape inheriting the genetic conditions of MON88302 cannot be excluded, no clear distinction can be made between environmental risk assessment for cultivation and those for import and spillage. EFSA (2015) responded as follows:

> *"The EFSA GMO Panel does not share Testbiotech's view that no clear distinction can be made between the environmental risk assessment for GM plant applications for import and processing and those for cultivation. Depending on the scope of the application (and thus the intended uses of a GM plant, such as import and processing for food/feed uses, and/or cultivation), the pathways and levels of exposure of the GM plant will vary (EFSA, 2010b). When evaluating the likelihood and seriousness of harm to the environment following the cultivation of a GM plant, the environmental risk assessment assumes 100% exposure over an extended period of time. However, for GM plant applications for import and processing, substantially less GM plants will be present in the environment, compared to cultivation conditions, as these plants only derive from import spills. The exposure of the environment to oilseed rape MON88302 plants will thus be substantially less under import conditions than cultivation conditions."*

This statement has some substantial weaknesses in its arguments. Environmental risk assessment as performed by EFSA (EFSA, 2010) requires several steps. One of them, at an early stage, is risk characterisation. Exposure is considered at a later stage. But in this case, EFSA has largely confined its environmental risk assessment to the assessment of exposure. Since risk characterisation was not completed (data on all parts were not assessed, data on seed dormancy, pollen characteristics and duration of flowering were available etc.), any discussion about exposure is premature and cannot be used to assess worst case scenarios as EFSA is suggesting (EFSA 2015).

There is no doubt that risk assessment has to investigate the risks and dynamics of feral populations inheriting the genetic conditions of MON88302, whether or not these originate from large-scale cultivation or spillage from transport, before exposure can be discussed. For example, in the light of existing evidence, the following have to be considered:

- If MON88302 can persist in ruderal areas for a longer period of time, gene flow to native populations and within the feral populations is not unlikely. Thus, the genetic construct can spread within populations with genetic backgrounds that were not taken into account during risk assessment.

- Since genetic conditions within the feral populations might evolve further, MON88302 plants might achieve more weedy or invasive characteristics than previously thought. Depending on interactions between the inserted DNA, the various genetic backgrounds and the environment, these characteristics can be distinct from those of other oilseed rape plants.
- Due to ongoing climate change, the plants and their offspring are likely to be exposed to a wide range of environmental stressors, which can, for example, impact the period of flowering and seed dormancy. Depending on interactions between the inserted DNA, the various genetic backgrounds and the environment, these characteristics can be distinct from those of other oilseed rape plants.
- In ruderal areas, application of glyphosate is likely in some regions. Thus, MON88302 persisting in ruderal areas is likely to have advantages in fitness and is likely to replace other plants that are not resistant.
- The pattern of distribution and persistence as described by Banks makes it likely that long-range dispersal can occur after a period of time. This dispersal can be facilitated by wild life species, unintended transport via traffic, wind and agronomic activities. Thus, risk assessment of feral populations must not be restricted to areas adjacent to harbours, transport routes and processing plants.

None of the above scenarios were discussed or assessed by EFSA.

It also has to be mentioned that EFSA´s assumption on exposure is not sufficiently based on scientific evidence. Conditions for spillage might vary substantially from region to region, thus environmental exposure to transgenes, resulting gene flow and introgression caused by spillage has to be assessed in much more detail in regard to specific regional conditions. As EFSA states:

> *"Seed spillage of GMHT oilseed rape will occur wherever it is transported, and feral plants are likely to be present along transportation routes in all countries receiving imports of viable grains of GMHT oilseed rape. Seed spillage is a random event, and therefore the levels of seed immigration can vary substantially. Overall, the EFSA GMO Panel considers that the occurrence of feral GMHT oilseed rape resulting from seed import spills is likely to be low and mostly confined to port areas and processing points."*

Basically, the rate of spillage will depend on criteria such as the amount of import, transport routes and transport vehicles, as well as on the diligence of the company responsible. None of these variables is covered by regulation, imposed management rules or technical conditions. Thus, the expectation of EFSA that the overall conditions for the transport of MON88302 will be predictable, is not justified. Rather, one can expect – especially if import rates are increasing – that at least in some regions a higher rate of spillage will occur than expected by EFSA.

A further EFSA assumption is that spillage will not occur in the fields near to where oilseed rape is cultivated. Since transport routes, amount of import, usages and sites of cultivation can vary substantially, this assumption appears to have a low level of certainty. Oil mills and processing factories can be sited in regions where oilseed rape is grown. It cannot be excluded that in some regions transports with MON88302 will also target these oil mills, for example, if regional demand increases or yields are lower than expected in some regions. Thus, a scenario in which spillage will happen close to fields where oilseed rape is cultivated, cannot be excluded.

In conclusion, there is no alternative to performing environmental risk assessment and taking adequate worst case scenarios into account. These should include the wide-range distribution of feral populations inheriting the MON88302 construct that can evolve further to make the plants more weedy, persistent and invasive than originally expected.

Risk assessment also has to take a sufficiently long period of time into account. As Banks (2014) shows, a ten-year time frame will not be sufficient. However, EFSA (2015) is claiming that no long-term assessment needs to be made since the application for MON88302 does not formally apply to cultivation:

> *"The EFSA GMO Panel therefore performs its environmental risk assessments accounting for a ten year timeframe perspective. Given the scope of application EFSA-GMO-BE-2011-101, which excludes cultivation, the EFSA GMO Panel did not see the need to consider changes in climate, as the exposure of the EU environment to oilseed rape MON88302 plants will be substantially less under import conditions than cultivation conditions. Moreover, the intended trait in oilseed rape MON88302 is not designed to confer increased tolerance to biotic or abiotic stressors."*

This statement also highlights a major legal problem in the approach that EFSA is taking. Formally the application only refers to import. But, in fact, the application also implies the release of the plants via spillage which hardly can be seen as unexpected. Since it can be expected that feral populations can emerge and persist from the import of MON88302, the release of these plants via spillage – from a legal perspective - has to be regarded as intended. Thus, in this case, an application for deliberate release followed by full environmental risk assessment should be required. Adequate risk assessment would, at the very least, require the assessment of all parts of the plants which are part of the release. However, this was explicitly rejected by EFSA, because formally the application is for import only. As EFSA states:

> *"Because mainly the seeds of oilseed rape are used as a food and feed source and given that the scope of the application EFSA-GMO-BE-2011-101 excludes cultivation, the EFSA GMO Panel did not see the need to request compositional data on plant parts other than seeds. Forage and roots were not analysed, since oilseed rape roots are not consumed and oilseed rape forage is rarely consumed by animals, and because these materials are not expected to be imported."*

Furthermore, key plant characteristics concerning persistence and invasiveness should have been included. However, again, this was rejected by EFSA, because formally the application is for import only.

> *"(…) given that the scope of the application excludes cultivation, the EFSA GMO Panel did not consider the data on pollen viability, duration of flowering and seed dormancy essential for the risk assessment of oilseed rape MON88302.*
> *For GM plant applications for import and processing for food and feed uses, the EFSA GMO Panel does not require data on flowering duration, and considers data on days to flowering sufficient to assess potential differences in the periodicity of flowering (EFSA, 2015)."*

EU regulation only allows releases of genetically engineered organisms after a full environmental risk assessment, after application and authorisation for a deliberate release and for a defined period of time. However, following EFSA reasoning in this case, it appears that an application for import can be extended to also allow the permanent release of genetically engineered organisms into the environment without a full environmental risk assessment, without filing an application, with no authorisation for deliberate release and for an indefinite period of time.

## (5) Monitoring and risk management strategies

EFSA and the EU Commission did not request any specific monitoring or any risk management strategies as foreseen by EFSA Guidance (2010a) in cases where spillage or release of viable seeds is noticed.

Consequently, it is likely that spillage of MON88302 will occur without being noticed and this can give rise to feral populations. This will have serious consequences for any risk management measures aiming to remove the plants from the environment if necessary. Banks (2014) summarises current knowledge as follows:

> *"Management of ferals would also be a daunting prospect. As Knispel & McLachlan (2010) have argued, the ephemeral nature of individual populations, and the more permanent nature of the whole meta-population, makes management very difficult, if not practically impossible. While large, obvious feral populations can be controlled, it is the many small and medium sized ones that cannot be managed because, even if they are controlled one year, it is highly uncertain where they will arise in any subsequent year. Management by increased cutting or spraying could itself have deleterious ecological impacts (Devos et al. 2012)."*[2]

In its response to the Testbiotech complaint EFSA (2015) mentions several obstacles to the effectiveness of any risk assessment measures:

> *"A range of studies concluded that targeted control of roadside feral oilseed rape plants can be achieved mechanically (e.g., mowing) or chemically at a local scale (Beckie et al., 2004; Warwick et al., 2004; Simard et al., 2005; Gruber et al., 2008; Lutman et al., 2008), provided that monitoring systems are in place to detect where significant populations of feral oilseed rape exist (Beckie et al., 2010) and that targeted control measures taken are timely (Yoshimura et al., 2006).*[3]
>
> *Management efforts exclusively focused on controlling adult plants may not be sufficient to drive feral oilseed rape populations to local extinction in the short-term, and may even be counterproductive. The pattern and timing of mowing may vary, with varying effects on the reproductive success of feral plants. Further, ecological models predict that the regular mowing of vegetation and soil disturbance encourage the establishment of annual weed species including oilseed rape due to the creation of competition-free germination sites with reduced competition by perennial vegetation where new seed can establish and contribute to new feral plants (Claessen et al., 2005a,b; Garnier et al., 2006; Bagavathiannen et al., 2012). Therefore, management efforts may also have to focus on limiting seed immigration from fresh seed spills (Bagavathiannen et al., 2012; Bailleul et al., 2012). If total control of a feral population is warranted at a local scale, repeated mowing and/or herbicide applications may be required until the exhaustion of the soil seedbank, as the presence of dormant seeds in the soil seedbank may contribute to new recruits over time (Bagavathiannen et al., 2012). The implementation of appropriate communication means for the timely reporting of control failures of feral oilseed rape populations may help to reveal the occurrence of feral GMHT oilseed rape plants, and may serve as a trigger for specific management."* [4]

2 For References see EFSA, 2015
3 For References see EFSA, 2015
4 For References see EFSA, 2015

Consequently, if no targeted monitoring and specific management measures are imposed, Monsanto and EFSA together will be paving the way for the long-term uncontrolled spread of MON83302 into the environment. If the advice from EFSA (2015) is accepted then any risk management strategies to remove feral populations of transgene plants where urgently required will become impossible or ineffective and/ or extremely costly (in regard to economic and ecological impact). In this case, if the removal of the plants is urgently required, there would simply be no effective measures available where they have become established as feral populations over a large area such as that described by Banks (2016) in Scotland or Schafer et al. 2011.

Ultimately, seen from the perspective of the precautionary principle, the advice from EFSA is completely unacceptable.

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