Oilseed rape GT73

Organisation: The European GMO-free Citizens (De Gentechvrije Burgers)
Country: The Netherlands
Type: Others...

Comments:

Back in 2007 the European GMO-free Citizens wrote the following about access onto the EU market of oilseed rape GT73: Plea against genetically modified oilseed rape GT73, Ministry of Housing, Spatial Planning and the Environment (VROM) hearing, 10 May 2007, The Hague, Netherlands.

Everything we wrote at that time is still applicable.

Written plea

NB

This plea was supported in 2007 by 567 consumers, farmers and foundations.

Subject: concerns and objections regarding the intention to obtain a market authorisation;

Roundup Ready (glyphosate tolerant) oilseed rape, event GT73

Decision reference DGM/SAS/C/NL/98/11 Monsanto.

'The genetically modified organisms to be placed on the market as or in products for importing, processing and use as feed (non-cultivation) are grains of oilseed rape (Brassica napus L.), with tolerance to the herbicide glyphosate, derived from the oilseed rape GT73 line, which has been transformed with Agrobacterium tumefaciens, using the vector PV-BNGT04.'

(text of the Notification of the Decision, published in the Volkskrant newspaper on 28 February 2007).

Hearing on the market authorisation of oilseed rape

We, the GMO-free Citizens, do not want this genetically modified rapeseed, or any other GM crop, seed or other derivatives thereof to be imported, placed on the market, cultivated (planted) or traded in the Netherlands. The Netherlands should remain GMO-free so that the environment is protected from any accidental mixing or cross-fertilisation of organic, conventionally produced and GM seeds and pollen or derivatives thereof or any other unforeseen events. Organic and conventional farming can then continue to be practised. We also want to shield the soil, livestock and humans from the unexpected consequences inherent in planting, trading

and consuming GMOs (for our health!), now and in the future. As consumers, Stichting Ekopark [Ekopark Foundation], Stichting VoMiGEN [VoMiGEN Foundation], Platform Belangen van Consument (BeVaCo) [Consumer interests platform] and farmers, we are directly affected.

First and foremost, we wish to confirm the following:

Brussels (the Commission) and you have taken a decision to admit this crop to the market following a tie in voting by the Member States and thus take informed responsibility.

We would now like to address Articles 3 and 4 of the Decision. These read as follows:

Article 3

'Marketing requirements

The product may be put to the same uses as any other oilseed rape, with the exception of cultivation and uses as or in food...'

This rapeseed will be used as animal feed. This must under no circumstances be allowed, because after cold pressing of the rapeseed, the animal feed still contains herbicide residues (the GMOs are not usually destroyed), which enter the human food chain through animal feeding.

The oilseed rape is therefore not in any way the same as "conventional rapeseed"'.

Genetically Engineered Crops May Produce Herbicide Inside Our Intestines

By Jeffrey M. Smith

Spilling the Beans, May 2006

Fragment

'The only human GM-feeding study ever conducted did show that genetic material can transfer to our gut bacteria.' This study, published in 2004, confirmed that portions of the Roundup-tolerant gene in soybeans transferred to microorganisms within the human digestive tract. '[29]

Netherwood, et al, Assessing the survival of transgenic plant DNA in the human gastrointestinal tract, Nature Biotechnology, Vol 22 Number 2 February 2004.

During a symposium in New Orleans it was revealed that more than 90% of the herbicide used in labelled substances is regenerated into the original herbicide in the digestive tract of cattle. (New Orleans, 25 March 1996.)

Huang, M.N. and Smith, S.M. 1995b. Metabolism of [14C]-N-acetyl glufosinate in a lactating goat. AgrEvo USA Co. Pikeville, PTRL East Inc., USA. Project 502BK. Study U012A/A524. Report A54155. Unpublished.

This does not seem to us to be healthy for livestock or consumers. We do not want GM products, GM DNA and herbicides ending up via dairy products on our plates or in our glasses (of milk). And definitely not because it does not need to be labelled.

Luckily it has not been cultivated! So there will be no aminomethylphosphonic acid (AMPA) in our groundwater exceeding the high norms set!

Article 4

Monitoring

1. 'Throughout the period of validity of the consent the consent holder shall ensure that the monitoring plan, contained in the notification, to check for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented.'

The Netherlands Commission on Genetic Modification (COGEM) advisory report of 21 October 1998 and that of 1 January 2001 stated the following (quite a long time ago):

'However, in respect of any incidental feeding or consumption, the summaries are sufficient and an estimated minimum safety factor of 40 in combination with the dietary studies and the low stability of GOX protein also provides a comprehensive guarantee of safety. On this basis, any (acute) toxic effects that would preclude authorisation under [Council Directive] 90/220/EEC are not expected in the event of incidental feeding and/or consumption.'

Note: Directive 90/220/EEC has in the meantime been replaced by Directive 2001/18/EC.

The following is a letter from the State Institute for Quality Control of Agricultural Products – RIKILT-DLO – to the VROM dated 29 July 1999.

Page 6: 'These acute toxicity studies are of little or no relevance to an assessment of feed safety because, among other things, the studies were carried out with insufficiently characterised and impure formulations but in particular because the studies do not provide an insight into the potential effects of chronic consumption by target animals.'

On page 8 we read: 'The question is to what extent the studies carried out in animal experiments are relevant to predicting the safety of target animals (ruminants, pigs, poultry and fish).'

'Are expected' - is this based on laboratory studies? No, this is based on an assumption, an opinion. This same is true of the statement 'In an acute mouse study (gavage), no effects were found at a high dosage' (COGEM letter of 21 October 1998).

We would refer here to The Acute Mouse Gavage Study, Merriman 1996. (Dossier 97/17).

Crops sprayed with glyphosate do however pose a risk to humans and animals. Glyphosate is not that innocent (see my objection). It is incorrect to say that the risk falls under the responsibility of the CTB [Pesticide Authorisation Committee]; the final product, the genetically modified oilseed rape, is delivered with the herbicide, not without it. https://www.gentechvrij.nl/wp-content/uploads/2017/07/koolzaad-73-bezwaren.pdf

‘.....In such a crop, that of Roundup Ready soya, changes in the concentration of substances made possible by this enzyme have been detected. This is particularly the case when the plant is sprayed with glyphosate. The authorisation procedure does not take account of the fact that spraying changes the composition of the plant: at that time, they only released the measurements taken on the unsprayed plants. There are people who believe that this happened knowingly to create the impression that the manipulated soya is “essentially equivalent” to ordinary soya’ (e.g. Professor Benbrook (www.biotech-info.net/troubledtimes.html)).

From this document:

‘In order that the bacteria are not killed by the antibiotic that they themselves create, the strains also produce specialized enzymes which transform the antibiotic to a non-toxic form called NAG (N-acetyl-L-glufosinate).

The problem is that the NAG, which is not naturally present in plants, remains there and accumulates with every subsequent spray. Thus, when we eat these GM crops, we consume NAG. Once the NAG is inside our digestive system, some of it may be re-transformed back into the toxic herbicide. In rats fed NAG, for example, 10% of it was converted back to glufosinate by the time it was excreted in the faeces. [9] endnote_9) Another rat study found a 1% conversion. [10] endnote_10) And with goats, more than one-third of what was excreted had turned into glufosinate. [11] endnote_11)

It is believed that gut bacteria, primarily found in the colon or rectum, are responsible for this re-toxification. [12]

endnote_12) Although these parts of the gut do not absorb as many nutrients as other sections, rats fed NAG did show toxic effects. This indicates that the herbicide had been regenerated, was biologically active, and had been assimilated by the rats. [13]

endnote_13) A goat study also confirmed that some of the herbicide regenerated from NAG ended up in the kidneys, liver, muscle, fat and milk.’

[14]).
(http://www.talk2000.nl/mediawiki/index.php/NPG%3B_Herbicide_resistente_planten_zouden_herbicide_in_lichaam_kunnen_produceren# endnote_14) Hearing on the market authorisation of GM oilseed rape. From this website.

Austria, which objects to the authorisation of GT73, agrees with its contention that this rapeseed should not be placed on the market. For example, insufficient and inadequate toxicity and allergy tests have been carried out over too brief a period of time.

3. Conclusion

‘Both the toxicological and allergological risk assessments of GT73 oilseed rape are considered to be inadequate regarding the choice of methods. The data provided by the notifier do not give enough evidence that the use of GT73 oilseed rape is safe from a toxicological and allergological point of view.’

Other countries also object because of insufficient and inadequate toxicity and allergy tests, and too brief a period of time, as well as Greenpeace, Dr Mae Wan Ho, and many other scientists.

2. 'The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental grain spillage.'

The fine grains of the rapeseed may be released into the environment during transport, as Monsanto itself points out. Rapeseed is an indigenous plant here. Unintended GM rapeseed plants and cross-fertilisation with wild variants, which can become 'superweeds', can be the result of resistance to Roundup, for instance. This creates a threat to the environment, as greater quantities of more aggressive pesticides need to be used against this superweed. It also poses a risk to organic farming and conventional agriculture.

'Therefore an unintended release would be more likely to occur during import, processing and transportation of GT73 grain.' Van; SNIF – Placing on the market Roundup Ready oilseed rape derived from line GT73 Blz.5

http://gmoinfo.jrc.it/csnifs/C-NL-98-11.pdf

Austria also agrees with its contention that this rapeseed should not be placed on the market. They are afraid of inadvertent cross-fertilisation. (This is also true of the situation in the Netherlands.) Similarly, Austria considers that the problem of coexistence between unintentionally dispersed and emerging GT73 GM and conventional oilseed rape has not yet been resolved.

3. Conclusion

'Additionally, the monitoring plan does not take into consideration accidental spillage and its environmental consequences. Unprocessed oilseed rape is transported to Austria in considerable amounts, feral oilseed rape populations can be found along transport routes where Glyphosate is applied and oilseed rape seeds can establish and are likely to build up persistent populations.

Therefore it can be considered as highly likely that imported GT73 oilseed rape will spread and persist in certain habitats in Austria. Due to the fact that GT73 oilseed rape is herbicide tolerant the application of Glyphosate in these habitats would confer a selective advantage to feral GT73 oilseed rape plants. For a complete risk assessment the knowledge of the frequency distribution of seed spills is therefore inevitable. Neither a monitoring plan nor an emergency plan was provided by the notifier in order to monitor the presence of GT73 oilseed rape in case of accidental spillage. Finally, co-existence issues of accidental seed spills of GT73 oilseed rape with conventional oilseed rape production are still unsolved.'

(Bundesministerium für Gesundheit und Frauen, Vienna, received by VROM on 13 July 2006).

(3) In February 2005, the Japanese Environmental Studies Institute published a report referring to the accidental presence of oilseed rape genetically modified for tolerance to a herbicide in the vicinity of five of the six port facilities where sampling had been carried out.

from: Commission Recommendation 2005/637/EC.

You surely cannot ignore this fact!

We read the following:

(45) 'Means should be sought for providing possibilities for facilitating the control of GMOs or their retrieval

in the event of severe risk.' Directive 2001/18/EC of the European Parliament and of the Council

How are you going to implement it? GMOs can never be retrieved once they have been released into the environment!

Even in the case of prohibited GM maize gluten, detected by Greenpeace in May 2007, it cannot be retrieved, it is mixed with ordinary maize gluten. Animals are now allowed to eat this, but we are still waiting for scientific data from the authorisation providers. (Volkskrant, 4 May 2007).

(47) 'The competent authority should give its consent only

after it has been satisfied that the release will be safe for

human health and the environment.'

Directive 2001/18/EC of the European Parliament and of the Council

of 12 March 2001

Once again: Brussels (the Commission) and you(!) took the decision to admit this crop to the market following a tie in voting (in 2007) by the Member States and you therefore need to take informed responsibility.

In addition to the objection, we wrote the following to the Minister

Those objecting question the following: 'How is it that 80-90% of the US bee populations died this spring? This is known as Colony Collapse Disorder (CCD). In any event, USA bee expert Professor Dr Eric Mussen from the University of California attributes this to malnutrition. Bees depend on healthy pollen for their diet, from which they also extract their cholesterol. (See our objection and click on the link to the radio broadcast). Bees are indispensable to at least 100 crops. As Albert Einstein once said: 'If the bee disappeared off the surface of the globe then man would have only four years of life left.'

Miep Bos, spokesperson and Stichting Ekopark, both in Lelystad, NL

www.gentechvrij.nl

https://www.gentechvrij.nl/bezwaarschriften/pleitnota-tegen-gentech-koolzaad-gt-73-hoorzitting-vrom-10-mei-2007/

Organisation: Testbiotech e.V. - Institute for Independent Impact Assessment of Biotechnology
Country: Germany
Type: Non Profit Organisation

Comments:

Introduction

The EFSA GMO panel assessed GT73 oilseed rape for renewal of authorisation. GT73 expresses the proteins GOXv247 and CP4 EPSPS conferring resistance to herbicides containing glyphosate (EFSA, 2022a).

1. Systematic literature review

A systematic literature review as required in Regulation (EU) No 503/2013 was provided. However, this review only considered a fraction of the relevant studies. According to comments submitted by experts from Member States (EFSA, 2022b), even highly relevant studies, e.g. Swiss studies on spillage and persistence of transgenic oilseed rape, were excluded from the literature review simply because Switzerland is outside the EU.

Testbiotech agrees with Member States' experts that the "applicant's exclusion criteria are neither appropriate nor comprehensible since these publications provide new data and information that need further consideration."

Studies that should have been considered include i.a. Hecht et al., 2014; Laforest et al., 2022; Nishizawa et al., 2016; Pandolfo et al., 2016, 2018; Schoenenberger et al., 2012; Schulze et al., 2014, 2015; or Sohn et al., 2021.

It is in general necessary to also review literature which might indicate indirect, delayed or cumulative long-term risks, including interaction with other genetically engineered plants, which might occur due to spillage and further crossings. Literature research should, therefore, take particular account of potential persistence, spread and crossings with other transgenic plants already in the environment due to spillage along transport routes etc. The biological characteristics of potential offspring are also relevant for the application. Literature research should further include all relevant publications concerning the crop species and relatives. Any environmental risk assessment should take indirect, unintended, delayed and long-term cumulative effects of animal excretions into account.

Interactions with other genetically engineered plants which might be mixed into the diet are a further aspect of food and feed safety which needs to be considered. Implementing Regulation 503/2013 (3.2.3) requests that "the applicant shall evaluate the data generated to estimate possible short-term and long-term risks to human or animal health associated with the consumption of genetically modified food or feed with respect to the expression of new proteins/metabolites, as well as significantly altered levels of original plant proteins/metabolites." Apparently, this legal request is not limited to the specific event. It requires that the risk assessment of mixed diets must be equivalent to the risk assessment of stacked events, as the risks are equivalent. This would require a much more comprehensive literature review of potential interactions with other regulated GMOs.

There is also no information in the literature review on studies investigating the unexpected effects (e.g. higher fitness) of transgenic plants containing epsps genes (see chapter on environmental risk assessment).

The systematic literature review provided by the applicant and accepted by EFSA is completely unacceptable.

2. Molecular characterisation and gene expression

There is a complete lack of more recent data on genetic stability and gene expression in the context of ongoing climate change. Regulation 503/2013, however, requests data on changes in gene expression. Therefore, experiments must be conducted under controlled and defined conditions in order to expose the plants to all relevant biotic or abiotic stressors, and to gather sufficiently reliable data on gene expression and functional genetic stability.

Herbicide-resistant oilseed rape is known to tolerate extremely high concentrations of glyphosate (Nandula et al., 2007). Due to increasing pressure from herbicide-resistant weeds, it is likely that the dosages of glyphosate currently applied are much higher compared to agricultural practice ten or twenty years ago. It is probable that these higher and/or repeated dosages of herbicide applications will also influence gene expression. Regulation 503/2013 requests data from realistic agronomic practices. Therefore, data should have been requested which take all relevant patterns of complementary herbicide application and the highest dosage of glyphosate that can be tolerated by the plants into account, including repeated spraying.

The generation of data on meteorological and agronomic conditions should also take a number of different genetic backgrounds into account, and also represent a broad range of the relevant varieties. The data should further include so-called 'Omics'.

3. Comparative assessment of plant composition and agronomic and phenotypic characteristics

According to the requirements set out in Implementing Regulation 503/2013, there should have been a request for recent data on genetic stability and gene expression under ongoing climate change. Experiments under controlled and defined conditions should also have been conducted in order to expose the plants to biotic or abiotic stressors representative of the full range of expected agricultural and bioclimatic conditions.

Herbicide-resistant oilseed rape is known to tolerate extremely high concentrations of glyphosate (Nandula et al., 2007). Due to increasing problems with herbicide-resistant weeds, it is probable that the dosages applied to the plants are now much higher compared to

agricultural practice ten or twenty years ago. It is also to be expected that higher and/or repeated herbicide application dosages will influence gene expression, plant composition and phenotypical characteristics (for comparison see Miyazaki et al., 2019). Therefore, data should have been requested which take all relevant patterns of application of the complementary herbicide into account, including the highest dosage of glyphosate that can be tolerated by the plants and repeated spraying.

The generation of data on meteorological and agronomic conditions should also take into account a number of different genetic backgrounds, representing a broad range of the relevant varieties. The data should include so-called 'Omics'.

It is known that the genomic background of the varieties can influence both the expression of the inserted genes and plant metabolism (see, for example, Lohn et al., 2020; Trtikova et al., 2015). Therefore, EFSA should also have requested additional data on transgenic plant varieties.

Such data were not made available, therefore no conclusion can be drawn from the comparative assessment.

4. Toxicity

Implementing Regulation 503/2013 asks applicants to perform 90-day subchronic studies with genetically engineered plants for reliable toxicological hazard identification and characterization. However, as yet, no 90-day feeding study in rodents using whole feed or feed from GT73 oilseed rape has been conducted or provided (EFSA, 2022b). Therefore, no final conclusion can be drawn on the food and feed safety of oilseed rape GT73.

Effects of residues from spraying with complementary herbicides specific to GE plants and their mixed toxicity

The residues from spraying were (again) considered to be outside the remit of the GMO Panel. However, without detailed assessment of these residues, no conclusion can be drawn on the safety of the imported products: due to specific agricultural management practices in the cultivation of the herbicide-resistant plants, there are, for example, specific patterns of spraying, exposure and occurrence of specific metabolites that require special attention.

Both EU pesticide regulation and GMO regulation require a high level of protection for health and the environment. Therefore, in regard to herbicide-resistant plants, specific assessment of residues from spraying with complementary herbicides must be considered a prerequisite for granting (renewal) authorisation.

The described effects, which may enhance the uptake of DNA from the transgenic plants into gut bacteria, are not assessed under pesticide regulation, they have to be assessed within GMO risk assessment. The reason: the effects are highly dependent on the specific dosages of applications on the GE plants, as well as their metabolism and the resulting pattern of exposure in food and feed. Cumulative effects (mixtures of GE plants in a diet) may also play a decisive role. Under Directive 2001/18/EC, such effects could be considered to be indirect effects which may be immediate, delayed or cumulative. Implementing Regulation 503/2013 (1.4.2) requires "testing of new constituents other than proteins". It is our opinion that this requirement also

includes the assessment of residues from the complementary herbicides, which necessarily become constituents of all genetically engineered plants with this resistance.

As far as food and feed safety is concerned, EFSA (2020) considers microbiomes to be highly relevant to the health status of their hosts. Therefore, it is desirable to understand the importance of their role in risk assessment. EFSA expects that gut microbiome research (not in relation to GE plants) will play a relevant role in regulatory science with potential implications for future risk assessment and predictive risk models. As EFSA states: "considering that the gut microbiome is a biological component directly and indirectly involved in the metabolism of food/feed components and chemicals and in the protection of the host against adverse environmental exposure, it would be useful to establish criteria on how to evaluate the potential adverse impacts of perturbators on this defensive barrier, and consequently, on human/animal health."

In general, antibiotic effects and other adverse health effects might occur from exposure to a diet containing these plants, as they were not assessed under pesticide regulation. These adverse effects on health could be triggered by residues from spraying with the complementary herbicide. Further attention should be paid to the specific toxicity of the metabolites of the active ingredients in the pesticide, which might occur specifically in the GE plants, and therefore might escape pesticide regulation.

However, no attempts have been made to integrate the microbiome into the risk assessment of food and feed derived from the GE plants. This is in direct contradiction to Regulation 1829/2003 which requests "genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest possible standard, to be undertaken under the responsibility of the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment." (Recital 9).

It should not be overlooked that Implementing Regulation 503/2013 (point 3.2.3) requires that "the applicant shall evaluate the data generated to estimate possible short-term and long-term risks to human or animal health associated with the consumption of genetically modified food or feed with respect to the expression of new proteins/metabolites, as well as significantly altered levels of original plant proteins/metabolites." We conclude that this requirement, which, for example, also comprises long-term accumulated effects, is not fulfilled and safety was not demonstrated.

5. Environmental risk assessment

During the consultation process, several experts voiced concerns about spillage and the persistence of GE oilseed rape. For example, the Finnish authorities demanded more data and stricter measures, as recent studies had confirmed feral and persistent GM oilseed rape populations, including in Europe (EFSA, 2022b).

Oilseed rape (Brassica napus) can spread via pollen and seeds, and seeds can remain viable in the soil for more than ten years (seed dormancy). Europe is the centre 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. Brassica 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, Brassica napus growing in the wild 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., 2013). A recent publication (Sohn et al., 2021) shows that the uncontrolled spread of genetically engineered (GE) oilseed rape is already happening in 14 countries on five continents. These are countries which either allow the cultivation of GE oilseed rape (such as the USA and Canada), or have tested it in experimental releases (such as Germany), or allow the import of kernels (such as Japan). Moreover, it has to be assumed that there is a high number of undetected cases, as many regions do not have systematic monitoring. In many cases, the plants have persisted for several years in or around the fields and along of transport routes, and have been found to have a higher potential for environmental spread than previously assumed.

In the case of GT73, it is likely that the plants will persist in the environment after spillage and also start to propagate. This would allow next generation effects to emerge that were neither assessed by the applicant nor by EFSA (Bauer-Panskus et al., 2020). They may also cross with other GE oilseed rape that had previously entered the environment via spillage. However, EFSA did not risk assess the direct or indirect effects, which maybe immediate, delayed or accumulated, as set out in Directive 2001/18/EC for environmental risk assessment.

In addition, there is a need to consider other ways of distribution and spread. For example, a recent report (COGEM, 2022) lists several unpublished studies from Switzerland showing that bird feed sold in Europe appears to be contaminated with genetically engineered oilseed rape. Such unforeseen routes of spread are not reflected in the EFSA risk assessment.

Findings in a further recent publication revealed the hybridisation of genetically engineered herbicide-tolerant oilseed rape (GT73) into the related weed species Brassica rapa (bird rape mustard) in Canada (Laforest et al. 2022). Oilseed rape and B. rapa are intercrossable, and hybrids of genetically engineered (GE) oilseed rape and bird rape mustard have already been detected along transportation routes and near ports in countries that import GE oilseed rape. However, it was assumed that the hybrid plants had reduced fertility and were, therefore, unable to establish in the environment permanently. The current study shows that the genetically engineered trait is now detectable in purebred and weedy B. rapa plants in Canada, presumably through multiple backcrosses of the hybrids.

The paper also indicates hybridisation of GE oilseed rape and field radish (Raphanus raphanistrum), another wild relative of oilseed rape with weedy characteristics. Although the two species had been crossed in the laboratory, this is likely the first proven case of hybridisation under natural conditions.

There have been various studies in recent years showing that plants engineered to be resistant to glyphosate can exhibit unexpected biological effects. These effects may give the genetically engineered plants a survival advantage even if no glyphosate is sprayed at all (see, for example, Beres, 2018; Beres et al., 2019; Fang et al., 2018; Wang et al., 2014; Yang et al., 2017).

Overall, new evidence presented in COGEM (2022) and Laforest et al. (2022) as well as the unresolved questions regarding unexpected effects caused by epsps genes, should result in

much greater scrutiny regarding environmental risk assessment than is presented in the EFSA opinion.

6. Others

If approval for import is given, the applicant has to ensure that post-market monitoring (PMM) is developed to collect reliable information on the detection of indications showing whether any (adverse) effects on health may be related to GM food or feed consumption. Thus, the monitoring report should, at very least, contain detailed information on: i) actual volumes of the GE products being imported into the EU; ii) the ports and silos where shipments of the GE products are unloaded; iii) the processing plants where the GE products are transferred to; iv) the amount of the GE products used on farms for feed and v) transport routes for GE products. Environmental monitoring should be run in regions where viable material of the GE products, such as kernels, are transported, stored, packaged, processed or used for food/feed. Where there are losses or spread of viable material (such as kernels), all receiving environments need to be monitored. Furthermore, environmental exposure through organic waste material, by-products, sewage or faeces containing GE products, during or after the production process, and during or after human or animal consumption, should all be part of the monitoring procedure (see also comments submitted by experts from Member States experts, EFSA, 2022b).

7. Conclusion

Scientific evidence relevant for the environmental risk assessment of GT73 oilseed rape was deliberately not considered by EFSA, thus massively impairing the outcomes of the opinion. Further, no conclusion can be drawn on food and feed safety, as experimental data is still missing. The EFSA opinion should therefore be rejected since the safety of GT73 oilseed rape was not demonstrated.

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