Vår ref:2017/H_RX_002
Deres ref: 2017/781

Høringsuttalelse av fornyelsessøknad om markedsføring av genmodifisert raps

GT73

EFSA/GMO/RX/002

Under EU forordning 1829/2003

Sendt til

Miljødirektoratet

av

GenØk-Senter for biosikkerhet
Mars 2017

GenØk – Senter for biosikkerhet
Adr.: Siva Innovasjonssenter, PB. 6418, 9294 Tromsø
Tlf.: 77 64 66 20 - post@genok.no
www.genok.no

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Miljødirektoratet
Postboks 5672 Sluppen
7485 Trondheim
Dato: 06.03.2017

Vedlagt er innspill fra GenØk – Senter for Biosikkerhet på offentlig høring av fornyelsessøknad **EFSA/GMO/RX002**, genmodifisert raps GT73, fra Monsanto Europe S.A under EU forordning 1829/2003. Søknaden gjelder bruksområdene fòr, import og prosessering.

Vennligst ta kontakt hvis det er noen spørsmål.

Med vennlig hilsen,

Idun Merete Grønsberg
Forsker II
GenØk – Senter for biosikkerhet
idun.gronsberg@genok.no

Bidragsytere:

Lilian van Hove
Forsker III
GenØk-Senter for biosikkerhet

Berit Tømmerås
Forsker III
GenØk-Senter for biosikkerhet

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Høringsuttalelse – fornyelsessøknad vedrørende genmodifisert raps linje GT73, EFSA/GMO/RX//002 under EU forordning 1829/2003.

Fornyelsessøknad EFSA/GMO/RX/002 omhandler genmodifisert raps til bruksområdene fôr, import og prosessering.

Den genmodifiserte rapsen har toleranse mot herbicider som inneholder glyfosat via de innsatte genene *cp4 epsps*, og *goxv247*.

Rapsen er ikke godkjent for noen av bruksområdene i Norge.

I EU er rapslinje GT73 godkjent for de omsøkte bruksområder.

GenØk – Senter for biosikkerhet
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OPPSUMMERING

GenØk–Senter for biosikkerhet, viser til høring av fornyelsessøknad EFSA/GMO/RX/002 om GT73 raps som omfatter bruksområdet import og prosessering og til bruk i fòr eller inneholdende ingredienser produsert fra denne rapsen.

Vi har gjennomgått de dokumenter som vi har fått tilgjengelig, og nevner spesielt følgende punkter vedrørende søknad om fornyelse:

- Genmodifisert rapslinje GT73 er ikke godkjent i Norge basert på potensiale for spredning og krysning med ville slektninger, at en ikke ønsker spredning av fremmede gener i norsk miljø samt at rapsfrø kan overleve i jorda i flere år og fremdeles være spiredyktige[1].
- Genmodifisert rapslinje GT73 er tolerant mot glyfosat, et sprøytemiddel med potensiell helse-og-miljø fare ved bruk.
- Genmodifisert raps GT73 er ikke funnet å utgjøre helsefare for mennesker eller dyr (basert på vurderinger fra Mattilsynet og VKM).
- Det er ikke fremkommet nye data som endrer evaluering fra Miljødirektoratet i 2008 (1) vedrørende samfunnsnytte og bærekraft.

SUMMARY

GenØk-Centre for biosafety refers to the re-application EFSA/GMO/RX/002 on GT73 oilseed rape for import, processing, and feed or ingredients thereof.

We have assessed the documents available, and highlights in particular the following points for the current re-application for GT73 oilseed rape:

- The genemodified rapeseed event GT73 is banned in Norway based on the potential for spread and hybridization with wild relatives in Norway, that spread of foreign genes is not wanted in Norwegian environments and due to rapeseed seeds being able to survive in soil and still be able to sprout after several years[1].
- Genemodified rapeseed event GT73 is tolerant to glyphosate, a herbicide with potential health and environmental damages upon use
- Genemodified rapeseed event GT73 has not been found to exert any risk towards animal and human health (made by Norwegian Food Authority and Norwegian Scientific Committee for Food Safety).
- No new data is provided that change the evaluation made by the Norwegian Environment Agency in 2008 (1) regarding social utility and sustainability.

[1] http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Nyhetsarkiv/2012/12/Forbyr-innforsel-av-genmodifisert-raps/

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Application on EFSA/GMO/RX/002

Oilseed rape
Oilseed rape, *Brassica napus*, (also reffered to as canola, rape, rapeseed etc.) is a crop with wild relatives in Norway, harboring an estimated number of 49 species. These wild relatives are able to grow throughout the country and as far north as Finnmark (2) and are potential hybridization partners for transgenic oilseed rape. Although there are challenges when it comes to the cultivation due to geography, climate, insects and also fungus-related pathogens, the trend is towards increasing the cultivation of oilseed rape in Norway.

As Norway is not able to keep up with the domestic needs of oilseed rape, most of it is imported.

For more information on oilseed rape situation in Norway, we refer to the report written by GenØk in 2015 (2).

From this report, we highlight the following:

"*The risk for spread of the transgenes are also highly present. Reports show that "unintentional stacking" of herbicide resistance genes in B. napus has taken place in the volunteers due to intraspecific pollen flow in and from the cultivation areas (3). This means that the volunteers detected have multiple herbicide resistant traits present in the same plant. Also spread of transgenes to wild relatives takes place naturally (4). Spread of transgenes will thus not only happen through spillage of OSR seeds but also along transport routes to and from cultivation areas, transport from the machinery involved in harvesting and by other routes (5).*"

Oilseed rape seeds are small and can live for many years in the soil after harvest. In addition, pollen from oilseed rape can travel over long distances with wind and insects. There is thus a potential for genes from gene modified oilseed rape to spread over distances and to wild relatives, as well as to non-modified oilseed rape crops.

This is also thoroughly described by the Norwegian Biotechnology Advisory Board in their report of 2013 (6) where they point to data showing that gene modified oilseed rape is growing beside roads and railway tracks, where they have been transported, in USA and Canada. Spread of oilseed rape during handling and transport is thus important to consider.

Previous evaluations
The oilseed rape event GT73 has been evaluated by the Norwegian Scientific Committee for Food Safety (vkm.no) in 2006 (7) and 2012 (8).

Evaluation in 2006: The committee evaluated the transformation process, the vector, nutrition value, minerals, toxins, anti-nutrients, allergens and the new proteins expressed. They concluded that it was not likely that the newly expressed proteins would damage health, and that the oil and feedstuff from oilseed rape event GT73 does not have more damage to health than other commercial oils and feedstuff from oilseed rape plants.

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Evaluation in 2012: The committee evaluated oilseed rape event GT73 for its use in foodstuffs, but not as processed oil. They commented that there should be a monitoring plan especially focusing on harbor areas, along transport routes and around import and processing facilities.

Also, they commented that if seed spillage is an issue, spread and hybridization of GT73 must be monitored, for outcrossing with cultivated, as well as wild populations of oilseed rape to avoid spread of transgenes, . A thorough environmental risk assessment, covering unintentional seed spillage during transport, handling, storage and processing must be in place.

In this evaluation, the Norwegian Scientific Committee for Food Safety also highlighted the following issues, to be answered by the applicant:

- Comparative assessment data did not meet the EFSA Guidance standards at that time.
- There is limited agronomic data for statistical analysis from field trials of agronomic and phenotypic analysis of GT73.
- The toxicology data are too old and not according to OECD guidelines.
- There is a lack of information regarding the 28 day feeding studies: are they performed with sprayed of unsprayed oilseed rape?

We do not know if the feeding studies were performed with sprayed and unsprayed oilseed rape. Based on the Technical report on GT73 from 2011 (Version Completeness check#2), this is still unclear.

The Norwegian Biotechnology Advisory Board has looked at the environmental concerns regarding the gene modified, herbicide tolerant oilseed rape event GT73. They comment that it is important prohibit spread of transgenes to wild relatives. And even though the application in question is not for cultivation, spread during transport and storage is difficult to avoid (9).

The Norwegian Environment Agency has evaluated oilseed rape event GT73 for cultivation purposes (1). Based on evaluations from other instances in Norway they commented that there probably was no harm to animal or human health, but that the Applicant had not provided any information on social utility, sustainability or ethical principles. Thus, the environment agency recommended that the application was prohibited based on the precautionary principle, a restricted attitude to spread of transgenes/foreign genes in the environment. The evaluation is based on a negative social utility.

EFSA (10) have commented that “oilseed rape GT73 is unlikely to have an adverse effect on human and animal health and environment”.

GenØK-Centre for biosafety have also assessed GT73 alone or in combination with other events in the following:

- EFSA/GMO/NL/2010/87: **GT73**

- EFSA/GMO/NL72009/75: **MS8 x RF3 x GT73**

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Social utility and sustainability issues on oilseed rape event GT73, EFSA/GMO/RX/002

In addition to the EU regulatory framework for GMO assessment, an impact assessment in Norway follows the Norwegian Gene Technology Act (NGTA) (11). In accordance with the aim of the NGTA, production and use of the GMO needs to be *ethically justifiable*, demonstrate a *benefit to society* and contribute to *sustainable development*. This is further elaborated in section 10 of the Act (approval), where it is stated that: "*significant emphasis shall also be placed on whether the deliberate release represent a benefit to the community and a contribution to sustainable development"* (See section 17 and annex 4 for more detail on the regulations on impact assessment). Recent developments within European legislation on GMOs allow Member States to restrict the cultivation of GMOs on their own territory based on socio-economic impacts, environmental or agricultural policy objectives, or with the aim to avoid the unintended presence of GMOs in other products (Directive 2015/412). Additionally, in recent years attention increased within academic as policy spheres to include broaden the assessment of new and emerging (bio)technologies to include issues that reach beyond human and environmental health. (12-17).

The assessment *ethically justifiability, benefit to society* and *sustainability* as in the NGTA, significant dedication is demanded as it covers a wide range of aspects that need to be investigated (e.g. Annex 4 within the NGTA, or 18). Nevertheless, the applicant has currently not provided any information relevant to enable an assessment of these criteria. Therefore, this section will highlight some areas that are particularly relevant to consider with oilseed rape GT73 and where the applicant should either provide data for in order to conduct a thorough assessment according to the NGTA. If no information will be provided to assess these criteria, the application should be refused.

Sustainability

The oilseed rape GT73 confers tolerance to glyphosate. Recent studies have shown negative effects from glyphosate, both on species present in terrestrial and aquatic ecosystems and on animals and cell cultures (for further elaboration and references on this issue see section on "Herbicides" (p.11). Consequently, glyphosate is now increasingly recognized as more toxic to the environment and human health than what it was initially considered to be. This is particularly a concern as the introduction of glyphosate tolerant GM plants has led to an increase in the use of glyphosate (19). As oilseed rape GT73 is genetically modified to possess *cp4 epsps* genes (providing glyphosate tolerance) and goxv247 genes, it is likely to assume that this GM crop is tolerant to higher doses of glyphosate and could potentially further increase the use of glyphosate.

Impacts of the co-technology: glyphosate

The evaluation of the co-technology, that is, secondary products that are intended to be used in conjunction with the GMO, is also considered important in the risk assessment of a GMO (20). Therefore, considerations of the co-products also warrant an evaluation of safe use and data required for such an assessment is, not provided by the Applicant.

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Impacts in producer countries

As already stated, the Applicant does not provide data relevant for an environmental risk assessment of oilseed rape GT73 as it is not intended to be cultivated in the EU/Norway. However, this information is necessary in order to assess the sustainability criteria as laid down in the NGTA which is referring to a global context, including the contribution to sustainable development in the producing countries with a view to the health, environmental and socio-economic effects in other countries, such as where the GMOs are grown or in this case where the oilseed rape GT73 is cultivated. When herbicides are used in agriculture, it is important to minimize the potential of weeds becoming resistant. Indeed, when crops are engineered to be herbicide resistant in order to maintain an agriculture practice that uses herbicide, it is essential to remain attentive to the amount of herbicide used, the potential consequences of this use for the area in which the crop is cultivated and develop management strategies to make sure that this does not create resistant weed. The Applicant has not provided information on whether the cultivation of oilseed rape GT73 could affect the emergence of glyphosate resistance in weeds, nor if there are already cases of this in the areas intended for cultivation of the variety. Indeed, this is also an important aspect to evaluate the ethical justifiability; it is not sufficient to only state that oilseed rape GT73 will not be cultivated in the EU. Additionally, no information is currently provided that demonstrates reflection on how the monitoring, assessment or evaluation of the GM crop in countries where the crop will potentially be cultivated is assessed, which is an important aspect for a sustainability evaluation. It is important to explain the process of evaluation of the environmental and socio-economic consequences for other countries.

In addition to the lack of information, there can also be ambiguity about how scientific conclusions may be achieved. For example, it is difficult to extrapolate on hazards or risks taken from data generated under different ecological, biological, genetic and socio-economic contexts as regional growing environments, scales of farm fields, crop management practices, genetic background, interactions between cultivated crops, and surrounding biodiversity are all likely to affect the outcomes. It can therefore not be expected that the same effects will apply between different environments and across continents. Hence, a proper evaluation of potential impacts that are relevant for this sustainability criteria is lacking, and sufficient information in this agricultural context needs to be provided. This should include information from an ERA concerning impacts on cultivation, management and harvesting stages, as well as the post-market environmental monitoring in the producing country.

Benefit to society

The criteria of ‘benefit to society’ in the NGTA should be interpreted on a national level. That means that the import of oilseed rape GT73 needs to demonstrate as to how it will benefit Norway. However, no information on this part is provided by the applicant. Moreover, before Norway allows for the import of GM produced feed, it is also important to evaluate what the attitude of Norwegian consumers are toward GM crops in general. This information will contribute to anticipate impacts at an early stage, as well as that it may demonstrate a need to assess the alternative options for transgenic canola (oilseed rape). However, the limited amount of empirical data on the attitude towards GM in Norway available (e.g. 21, 22) is outdated and more empirical research on this is warranted to investigate consumers’ attitude, demand and acceptance.

Assessing alternatives

When a new (bio-)technology is developed, it is important to reflect on what problem it aims to solve and to investigate whether alternative options may achieve the same outcomes in a safer and ethically justified way. After all, when a crop is genetically modified to tolerate a particular herbicide, it means that the crop is developed for a particular cultivation practice in which these herbicides are to be used. What is meant with alternatives, and what would benefit from being assessed could include alternative varieties (e.g. non-GM) for import, alternative sources to satisfy the demand, alternative ways of agriculture, or even explore alternative life visions. In fact, this corresponds with the increased trend within research and policy of science and innovation to anticipate impacts, assess alternatives and reflect on underlying values, assumptions, norms and beliefs (15, 23) to reflect on what kind of society we want, and assess how certain (biotechnological) developments may or may not contribute to shaping a desired future. Thus, in order to evaluate whether oilseed rape GT73 contributes to social utility, it is important to investigate current and future demands and acceptance of this in Norway and if there are alternatives sources that could be cultivated in Norway that may satisfy this demand, or are more desirable.

Ethical considerations: socio-economic impacts

As known, GM crops have been, and still are a hot topic for debate. A significant amount of this debate focuses on the safety of GMOs and currently no scientific consensus on this topic has been achieved (24). However, another substantial part of the debate is around the socio-economic impacts of GM productions and many questions for evaluating the above mentioned criteria in the NGTA are based on an assessment of the socio-economic impacts. These impacts can vary and range from seed choice for farmers, co-existence of different agricultural practices, changing power dynamics among stakeholders, new dependencies of farmers, intellectual property right on seeds, benefit sharing, the decreasing space for regional and local policy, and more organisational work and higher costs for non-GM farmers (e.g. for cleaning of sowing machines or transport equipment to avoid contamination). Although the examples of socio-economic impacts clearly indicate the complexity and extensive list of concerns beyond safety aspects, little empirical investigation on these kind of aspects has been done. For example a study performed by Fischer et al. (25) concerning social implications from cultivating GM crops found that from 2004 – 2015 there has only been 15 studies corning social implications of cultivating Bt-maize. The study demonstrates that published literature is dominated by studies of economic impact and conclude that very few studies take a comprehensive view of social impacts associated with GM crops in agriculture. Although this study focused on Bt-maize, the amount of research performed in this case and the minimal focus on social impacts strongly indicate a high need for further investigation on how the cultivation of GM crops affects different parties involved. It is therefore striking that no information on any of the above mentioned points is discussed by the applicant.

Conclusion

In order to meet the requirements for the NGTA, the regulator is encouraged to ask the Applicant to submit information relevant for the assessment of the criteria of ethically justifiability, benefit to society and sustainability assessment. The information provided by the Applicant must be relevant for the agricultural context in the producing country/countries. The

information should also include issues such as: changes in herbicide use, development of herbicide resistant weed, potential for gene flow and possible socio-economic impacts such as poor and/or small-scale farmers in producing countries and share of the benefits among sectors of the society. It is also important to stress the need for (information on) integrated weed management strategies in those countries. Moreover, the applicant does not attempt to demonstrate a benefit to the community or any reference on the consumer attitude and demand within Norway for oilseed rape GT73 and does therefore not provide sufficient information as required by the NGTA.

Environmental risk issues in a Norwegian context

Oilseed rape produces many small seed. These seed can live for many years in the soil after harvest. In addition, pollen from oilseed rape can travel over long distances with wind and insects. There is thus a potential for genes from gene modified oilseed rape to spread over distances and to wild relatives, as well as to non-modified oilseed rape crops. This is thoroughly described by the Norwegian Biotechnology Advisory Board in their report of 2013 (6).

Another issue is also described by COGEM (Commissie Genetische Modificatie, Netherlands) in their report on import and processing on GT73 (26), where they recommend that there must be a post monitoring plan involved along railways in order to monitor the occurrence of potential GM oilseed rape. Also, as cross-fertilization can occur, the issue on "stacking" several transgenes in the same oilseed rape plant is something that also should be monitored, according to COGEM. This would however not lead to an environmental risk as the selective advantage is not present. However, if spraying with herbicides containing glyphosate is performed, selection pressure could be of interest to follow further. They also write the following:

"*However, in view of future applications and to increase knowledge it is important to know whether stacked events arise in order to allow future risk assessments to take the putative presence of established GM oilseed rape with stacked traits into account. A putative stacked event would most likely occur in a location where herbicides are frequently used, such as railway tracks. Therefore, COGEM advises to monitor the occurrence of GM oilseed rape along railway tracks in addition to the monitoring of industrial sites that is usually carried out by operators involved in import and processing of GM crops.*

In conclusion, although COGEM is of the opinion that in view of the present conditions import and processing of GT73 oilseed rape poses a negligible risk to the environment, COGEM cannot finalize its opinion on import and processing of GT73 due to the absence of a post-market monitoring plan."

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Molecular characterization, expressed proteins and herbicide use -special issues to consider in the present application

The oilseed rape event GT73 contains two genes called *cp4 EPSPS* and *goxv247* encoding proteins involved in giving the plant tolerance towards glyphosate containing herbicides.

Molecular characterization
The two inserted genes in the oilseed rape event GT73 has been thoroughly described before. Here is a short description of their source and actions:

- The *CP4 epsps* gene (source: *Agrobacterium tumefaciens*) encodes a herbicide tolerant form of 5-enolpyruvulshikimate-3-phosphate synthase enzyme that confer resistance to glyphosate containing herbicides by decreasing binding affinitiy to it.
- The *gox gene* (source: *Ochrobacterium anthropi*) encodes a CS-glyphosate oxidoreductase enzyme promoting degradation of glyphosate to aminomethylphosphonic acid (AMPA).

Southern blot was used as a method for detection of the inserted genes in GT73. Some of the membranes (as figure 6, p47 in Technical dossier of GT73, version 2011 Check#2 October 2011) are still of poor quality as the molecular weight standard used can not specify the size of the fragments of interest. It is impossible to say anything but, “somewhat above 7.1 kb. This is to unspecific.

It also seem that there are additional bands on the southern blots that has not been investigated further. This can be exemplified by the blot represented on page 79-80 in in Technical dossier of GT73, version 2011 Check#2 October 2011. In addition, there is no molecular weight standard used to verify size of fragments analyzed.

As this GT73 line was produced by transforming it with a T-DNA plasmid with the inserted transgenes, it must be noted that recent publications, as the one by Glowacka et al (27) emphasize that it is important to routinely check T-DNA copy numbers in generation of transgenic plants. This is due to a “high frequency of genetically linked insertions” that they could not detect by segregation analysis. In this work, they compared southern blot, which is the method used for detection of inserted transgenes in GM-plants, with methods like thermal-asymmetric interlaced (TAIL)-PCR, quantitative (q)-PCR and digital droplet (dd)-PCR. In this work, they found that dd-PCR is the most suitable method in T-DNA copy number estimation.

Characterization of the newly expressed protein(s)

- No new expression studies have been performed of the cp4 epsps and gox proteins. Data provided with the renewal of application are from field trials performed 1992-1996 (p.19, summary of the dossier).
- The EPSPS protein is expressed throughout the plant. Expression data are as expected.
- The GOX protein is also expressed in the whole plant, and data are as expected.

GenØk – Senter for biosikkerhet
Adr.: Siva Innovasjonssenter, PB. 6418, 9294 Tromsø
Tlf.: 77 64 66 20 - post@genok.no
www.genok.no

Herbicides
The oilseed rape event GT73 contains CP4 epsps and goxv247 genes providing tolerance against glyphosate containing herbicides by two different mechanisms.

Herbicide use on GM plants
In this case, oilseed rape event GT73 is tolerant to the herbicide glyphosate.

HT plants are sprayed with the actual herbicide(s), leaving the weed to die whereas the plant with the inserted genes will survive. However, the issue on accumulation of herbicides in the HT plants, including metabolic pathways and metabolites of these, are often not tested as part of the risk assessment of HT plants. Bøhn et al. (28) documented high levels of glyphosate residues in HT GM soybeans grown in the USA, and the same research group have published papers showing that such residues have the potential for negatively to affect the feed quality of HT GM soybeans (29, 30). It is important to look at the potential metabolites of the herbicides in use and if these are documented to have a negative effect on health and environment.

Another issue is the development of resistance towards the herbicides (31) in use that is a relevant issue, but not discussed further here.

Glyphosate tolerance
Glyphosate kills plants by inhibiting the enzyme 5-enolpyruvoyl-shikimate-3-phosphate synthase (EPSPS), necessary for production of important amino acids. Some microorganisms have a version of EPSPS that is resistant to glyphosate inhibition.

Glyphosate has been announced as an ideal herbicide with low toxicity for operators, consumers and the environment surrounding agriculture fields (32, 33). However, it has received more risk-related attention due to its potential for negative effects on both aquatic and terrestrial ecosystems (34), as well as in studies in animals and cell cultures that have indicated possible negative health effects in rodents, fish and humans (35-37). Recent studies also indicate that agriculture of GM plants is associated with greater overall usage of pesticides than the conventional agriculture (38).

A restricted number of recent publications indicate unwanted effects of glyphosate on health (37, 39), aquatic (40) and terrestric (34, 41) organisms and ecosystems. Moreover, a study of Roundup effects on the first cell divisions of sea urchins (42) is of particular interest to human health. The experiments demonstrated cell division dysfunctions at the level of CDK1/Cyclin B activation. Considering the universality among species of the CDK1/Cyclin B cell regulator, these results question the safety of glyphosate and Roundup on human health. In another study (35) it was demonstrated a negative effect of glyphosate, as well as a number of other organophosphate pesticides, on nerve-cell differentiation. Surprisingly, in human placental cells, Roundup is always more toxic than its active ingredient. The effects of glyphosate and Roundup were tested at lower non-toxic concentrations on aromatase, the enzyme responsible for estrogen synthesis (43). The glyphosate-based herbicide disrupts aromatase activity and mRNA levels and interacts with the active site of the purified enzyme, but the effects of glyphosate are facilitated by the Roundup formulation. The authors conclude that endocrine

and toxic effects of Roundup, not just glyphosate, can be observed in mammals. They suggest that the presence of Roundup adjuvants enhances glyphosate bioavailability and/or bioaccumulation.

Additionally, the International Agency for Reseach on caner (IARC) released a report concluding that glyphosate is "probably carcinogenic to humans"(44).

Summary:

- Oilseed rape event GT73 is tolerant to glyphosate. This herbicide has potential for damaging health and environment.
- Potential for accumulation of the herbicides should be considered in GM plants used in food and feed.

Allergenicity and toxicity issues

Toxicological assessment

Toxicological assessment on oilseed rape event GT73 were based on safety of donor organism, screening and similarity to other toxins with history of safe use, bioinformatic studies for similarity to other toxins and acute oral toxicity studies.

Most data referred to are old, and very few new are added.
The applicant is considering oilseed rape GT73 as not toxic, based on origin of inserted genes, history of safe use and data from previous acute toxicity studies.

Allergenicity

Allergenic assessment was based on the following: glycosylation pattern, lability to tryptic digestion, bioinformatics analysis and amount of proteins(s) as compared to total protein.
Also, oilseedrape is not a plant considered to contain any allergens.

Interestingly, almost all data referred to in the allergenic assessment from the applicant, is from 1975-1994. However, one of the references are from 2009 (p.136, Technical dossier, version 2011, Completeness check#2, 2011) commenting homologous proteins with common secondary structures etc. The amino acid sequence analysis is from 2011 and presents newer data. No homology to known allergens are found here.

The conclusion in the renewal of application for oilseed rape GT73 is based on mainly old data and some new data on aminoacid analysis.

Thus, oilseed rape GT73 is not considered to have allergenic potential.

Hazard identification
According to the applicant, it is unlikely that the proteins expressed from the gene modified oilseedrape GT73 will be hazardous to non-target organisms.

Main summary

Although oilseedrape GT73 is assessed to not have any risk towards animal and human health, it is tolerant to herbicides containing glyphosate that has distinct degrees of potential health and environmental dangers upon use, thus the issue on accumulation should be considered for GM plants to be used in food and feed.

Most data present for the renewal of application are old, and the applicant is not considering the potential for spread of oilseedrape together with the potential for hybridization with wild relatives as an important issue.

The applicant should provide data relevant for assessment of social utility and sustainable development according to the NGTA(11).

Thus, we can not see that new data has emerged that should change the current prohibition on import of oilseedrape GT73 as set down by the Norwegian authorities in 2012.

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