



Vår ref:2017/RX\_004  
Deres ref: 2017/11005

Miljødirektoratet  
Postboks 5672 Sluppen  
7485 Trondheim  
Dato: 23.01.17

Vedlagt er innspill fra GenØk – Senter for Biosikkerhet på høringen av fornyessøknad **EFSA/GMO/RX/004**, for genmodifiserte rapslinjer MS8, RF3, MS8xRF3 som gjelder mat, fôr, import og prosessering fra Bayer CropScience GmbH.

Vennligst ta kontakt hvis det er noen spørsmål.

Med vennlig hilsen,

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Vår ref:2017/RX\_004  
Deres ref: 2017/11005

**Vurdering av fornyelsessøknad EFSA/GMO/RX/004 under EU-  
forordning 1829/2003/EC som gjelder mat, fôr, import og  
prosessering av genmodifiserte rapslinjer MS8, RF3 og MS8xRF3.**

**Sendt til**

**Miljødirektoratet**

**av**

**GenØk-Senter for Biosikkerhet  
Januar 2017**



Vår ref:2017/RX\_004  
Deres ref: 2017/11005

**Assessment of the application for renewal of MS8, RF3 and MS8xRF3 oilseed rape.**

**Sent to**

**Norwegian Environment Agency**

**by**

**GenØk- Centre for Biosafety  
January 2017**

## OPPSUMMERING

GenØk–Senter for Biosikkerhet, viser til høring av søknad om fornyelse av EFSA/GMO/RX/004 gjeldende for **MS8, RF3 og MS8xRF3** rapslinjer som omfatter bruksområdet import og prosessering og til bruk i fôr og mat eller inneholdende ingredienser produsert fra **MS8, RF3 og MS8xRF3** raps.

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

- Ingen av rapslinjene er godkjent for noen bruksområder i Norge.
- Matilsynet har kommentert at rapslinjene MS8, RF3 og MS8xRF3 er like trygge som ikke genmodifisert raps til bruk i fôr og næringsmidler (1).
- Bioteknologirådet kommenterte i 2013 at søknad om bruk av rapslinjer MS8, RF3 og MS8xRF3 til mat, fôr import og prosessering skulle avslås pga at disse ikke bidrar til bærekraftig utvikling eller samfunnsnytte. I tillegg kunne de ikke «etisk forsvares» (2).
- VKM kommenterte i Mars 2014 via sin miljørisikovurdering at frøspill fra transport, lagring og håndtering av rapslinjer MS8, RF3 og MS8xRF3 potensielt kan gi utkrysning og potensial for spredning til konvensjonelle og ville rapssorter i Norge. I tillegg ble det kommentert at det var lite sannsynlig at det vil endre risiko for miljø og landbruk sammenlignet med annen raps i Norge med den bruken det var omsøkt for (3).
- I sin rapport av 2014 kalt «Genmodifisert oljeraps MS8, RF3, MS8xRF3» konkluderer Miljødirektoratet at det foreligger miljørisiko ved spill av spiredyktige raps frø fra linjene MS8, RF3, MS8xRF3 og at det har slektninger i norsk natur som medfører fare for overføring av transgener til disse. Miljødirektoratet kommenterer i tillegg at disse rapslinjene ikke har egenskaper som er ønsket i Norge eller løser samfunnsproblemer blant forbrukere her. Disse rapslinjene vurderes i tillegg til å ha både positive og negative økonomiske konsekvenser der disse dyrkes men som ikke gjøres avgjørende iht spørsmålet om bærekraft. Fremstilling og bruk av disse kan imidlertid gi spredning av resistens genet for glufosinat ammonium og ha negative effekt på biodiversitet og økosystem som dermed ikke fremmer bærekraftig utvikling. Den samlede anbefaling fra Miljødirektoratet er at det legges ned forbud med bakgrunn i faktorer som omhandler risiko for spredning av transgener, redusert samfunnsnytte, ikke-bærekraftig og ikke etisk forsvarlig (4).
- Glufosinate- ammonium – har helse-og-miljø fare ved bruk.

## SUMMARY

We have assessed the documents available, and highlights in particular the following points for the current application for renewal of MS8, RF3 and MS8xRF3 oilseed rape:

- None of the oilseed rape events are approved for any of the applications in Norway.

- The Norwegian Food Safety Authority has commented that the oilseed rape events MS8, RF3 and MS8xRF3 are as safe as non-modified oilseed rape for use in feed and foodstuffs (1).
- The Biotechnology Advisory Board recommended in July 2013 that the application on oilseed rape events MS8, RF3 and MS8xRF3 for food, feed import and processing should be declined due to “not contributing to sustainable development or social utility”. In addition, they commented it was “not ethically justified” (2).
- The Norwegian Scientific Committee for Food Safety commented in 2014 through their environmental risk assessment of seed dispersal from transport, storage and handling of oilseed rape events MS8, RF3 and MS8xRF3, that there is a potential for outcrossing and spread to conventional and wild oilseed rape species in Norway. They also commented that there was a low likelihood for a change in the risk for environment and agriculture as compared to other oilseed rape species in Norway with the intended use (3).
- In the report from 2014 on the evaluation on gene modified oilseed rape events MS8, RF3 and MS8xRF3, the Norwegian Environment Agency recommend to lay down prohibitions against these oilseed rape events based on the following (4):
  - There is an environmental risk from spills of viable oilseed rape seed from these events as they have wild relatives that transgenes can be transferred to.
  - The oilseed rape events do not have traits that are wanted or solves any societal problems among consumers in Norway.
  - These oilseed rape events are considered to have both negative and positive economical consequences for the producers but this is not decisive on the question on sustainability.
  - Production and use of these oilseed rape events can lead to spread of the gene encoding glufosinate ammonium resistance. This can have a negative effect on biodiversity and ecosystems and does not promote sustainability.
  - In addition, these oilseed rape events are not considered to be ethically justifiable.
- Glufosinate ammonium – has health and environmental dangers upon use.



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## **ASSESSMENT OF THE APPLICATION FOR RENEWAL OF AUTHORISATION RELATED TO EFSA/GMO/RX/004**

GenØk, as a National Competence Center for Biosafety, aims at providing independent, holistic and useful analysis of technical and scientific information/reasoning in order to assist authorities in the safety evaluation of biotechnologies proposed for use in the public sphere.

The information in this assessment is respectfully submitted for consideration in the evaluation of product safety and corresponding impact assessment of events **MS8, RF3 and MS8xRF3** oilseed rape, setting out the risk of adverse effects on the environment and health, including other consequences of proposed release under the pertinent Norwegian regulations.

## **MAIN SUMMARY:**

As the summary of the application for renewal is not available, our assessment is based on previous applications and assessments on oilseed rape events MS8, RF3 and MS8xRF3. We find that data provided on social utility and sustainability is lacking in the previous applications on these events and support the evaluation by the Norwegian Environment Agency on this issue in the report from 2015 (4). There is also a need for further investigation of whether the gene for glufosinate ammonium is able to spread in Norway due to the potential of hybridization with wild relatives and survival of oilseed rape seed.

We therefore comment that the applicant has not provided the information required to perform an assessment of social utility and sustainability as required by the Norwegian Gene Technology Act (NGTA, Appendix 4) (5).

## ASSESSMENT OF APPLICATION FOR RENEWAL OF AUTHORISATION OF EFSA/GMO/RX/004

### Background

GenØk has previously assessed stacked events with oilseed rape events MS8, RF3 and MS8xRF3 in the following:

- EFSA/GMO/NL/2013/119: Stacked event MS8xMON88302xRF3
- EFSA/GMO/NL/2009/75: Stacked event MS8x RF3x GT73
- EFSA/GMO/BE/2011/81: Events MS8, RF3, MS8xRF3

Oilseed rape, *Brassica napus*, (also referred 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 (6) and are potential hybridisation 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 (6).

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 (7). 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 (8). 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 (9).”*

Another important issue is that glufosinate ammonium is banned in Norway and the Norwegian Environment Agency has commented that a spread of genes for resistance towards this herbicide is not wanted in Norway (4).

### Situation in EU

In the EU, MS8, RF3 and MS8xRF3 have been approved for import, processing and feed since 2007. This approval is not for cultivation of these oilseed rape events.

The EU commission has decided that:

*“The opinion adopted in September 2005 by the European Food Safety Authority, concluded that the genetically modified oilseed rape products (*Brassica napus* L., events Ms8, Rf3 and Ms8xRf3) are as safe as conventional oilseed rape for humans and animals, and in the context of the intended uses, for the environment. The European Food Safety Authority also concluded*

that the monitoring plan provided in the notification was acceptable in view of the intended uses”(10).

In 2012, EFSA came with a scientific opinion concluding that it is unlikely that these events pose any negative effects for human and animal health or environment in EU (11).

### **About the event**

The gene modified oilseed rape events MS8, RF3 and MS8xRF3 were developed as a hybrid development system with tolerance to the herbicide glufosinate-ammonium (called SeedLink).

MS8xRF3 is obtained by conventional crossing of MS8 and RF3.

- MS8 encodes a gene called *barnase* (a RNase), making the male plant sterile,
- RF3 encodes a *barstar* gene (inhibitor of RNase), restoring fertility of the oilseed rape plants.
- Both MS8 and RF3 encodes in addition a gene called *bar* providing tolerance to glufosinate ammonium.

### **ASSESSMENT FINDINGS**

These oilseed rape events have been thoroughly investigated by The Norwegian Biotechnology Advisory Board, the Norwegian Environment Agency and the Norwegian Scientific Food Authority, with their major points summarized on page 4-5.

In addition, we have the following comments to the renewal of application for MS8, RF3 and MS8xRF3:

#### **Oilseed rape – in general**

Oilseed rape seed 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 thoroughly described by the Norwegian Biotechnology Advisory Board in their report of 2013 (2) 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.

#### **Herbicide tolerance (HT) and use on GM plants**

Oilseed rape events M8, RF3 and MS8xRF3 contains the *bar* gene providing tolerance to the herbicide glufosinate-ammonium. Herbicide tolerant plants are sprayed with the actual herbicide aiming at weeds to die, whereas the plant, having the inserted transgenes for tolerance, will survive. However, the accumulation of herbicides inside plants is often not tested as part of the risk assessment of the HT plants. It is not clear from the data available if this has been tested.

Bøhn et al. (12) have 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 (13, 14). As we lack access to the summary of the renewal of the application, we can not evaluate to what extent the potential accumulation of glufosinate ammonium has been considered for oilseed rape in food and feed.

Glufosinate-ammonium belongs to a class of herbicides that is banned in Norway and has limited use in EU (limited use on apples) due to both acute and chronic effects on mammals including humans. Studies have shown that glufosinate-ammonium is harmful by inhalation, ingestion and skin contact and that serious health risks may result from exposure over time. Observations of patients poisoned by glufosinate-ammonium have found that acute exposure causes convulsions, circulatory and respiratory problems, amnesia and damages to the central nervous system (CNS) (15). Chronic exposure in mice has been shown to cause spatial memory loss, changes to certain brain regions, and autism-like traits in offspring (16, 17).

### **Toxicology**

In our previous assessment of MS8, RF3 and Ms8xRF3 (18) we commented that the toxicology data should be new/updated. As we do not have access to the summary of the renewal of application, we can not evaluate this issue or see if new data is present.

#### *Summary:*

- Oilseed rape events MS8, RF3 and MS8xRF3 are tolerant to glufosinate ammonium. This herbicide is damaging to health and environment.
- Potential of accumulation of glufosinate ammonium should be considered for GM plants used in food and feed.
- The potential for spread of transgenes with pollen through wind and insects is present.
- Toxicity data can not be evaluated due to lack of access to the summary of the renewal of application.

### **Social utility and sustainability aspect**

In addition to the EU regulatory framework for GMO assessment, an impact assessment in Norway follows the Norwegian Gene Technology Act (NGTA) (5). In accordance with the aim of the NGTA, production and use of the GMO shall take place in an ethically and socially justifiable way, under the principle of 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*”. These issues are further elaborated in the regulations relating to impact assessment pursuant to the NGTA, section 17 and its annex 4. Recent developments within European legislation on GMOs allows 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 there has been an increase in attention within academic as well as policy spheres to include broader aspects in the assessment of new and emerging (bio)technologies that reach beyond human and environmental health, such as sustainability, benefit for society and ethical considerations (19-24).

In the data available for the renewal of application, no relevant information is provided that allows an evaluation of the issues laid down in the aim of the Act regarding ethical justification, social utility or the contribution to sustainable development of the GMO. Given this lack of necessary information for such an evaluation, the Applicant has not demonstrated a benefit to the community and a contribution to sustainable development from the use of transgenic Rapeseed MS8, RF3 and MS8xRF3.

In the following, we identify areas that are relevant to consider in order to assess the criteria of social utility, ethical justifiability and the contribution to sustainability and highlight information that is missing from the Applicant.

#### *Impacts in producer countries*

As already stated, the Applicant does not provide data relevant for an environmental risk assessment of Rapeseed MS8, RF3 and MS8xRF3, 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. Importantly, 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 sustainability is lacking, and sufficient information relevant for the ERA and socio economic impacts assessment in these agricultural contexts 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.

#### *Assessment of alternatives*

It is also important to evaluate whether alternative options may achieve the same outcomes in a safer and ethically justified way. 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 to anticipate impacts and reflect on underlying values, assumptions, norms and beliefs within research and policy of science and innovation (22, 25) 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. Indeed, in order to evaluate whether transgenic Rapeseed MS8, RF3 and MS8xRF3 contributes to social utility, it is important to consider current and future demand for this product in Norway and if there are alternative sources that could be cultivated in Norway that may satisfy this demand.

#### *Ethical considerations*

Transgenic Rapeseed MS8, RF3 and MS8xRF3 are meant to be resistant to glufosinate-ammonium, a herbicide that is banned in Norway due to the risk to human health and the environment.

While it is understood that the Applicant has not applied for cultivation of transgenic Rapeseed MS8, RF3 and MS8xRF3 in Norway, the acceptance of import would continue the use of a

harmful herbicide not allowed in Norway, in other countries, while considering the herbicide as too harmful to be used in Norway. This problematic issue has also been noticed previously in earlier applications of MS8, RF3 and MS8xRF3 (18, 26), though no uptake to include any information on this has been documented by the applicant. Furthermore, the aim within the NGTA to assess the ethical justifiability, social utility and contribution to sustainable development is not limited to Norway, but a significant emphasis is placed on consideration of the impacts and consequences for producing countries from which Norway imports food and feed as well. Specifically, this issue is relevant in the revised guidelines for impact assessment pursuant to the Act of 2005 Section 17: “*Other consequences of the production and use of genetically modified organisms*” points 2 and 3, “*ethical considerations that may arise in connection with the use of the genetically modified organism(s)*», and “*any favorable or unfavorable social consequences that may arise from the use of the genetically modified organism(s)*”, respectively. Therefore, we do not consider transgenic Rapeseed MS8, RF3 and MS8xRF3 as contributing to sustainability, nor being ethically justifiable.

### **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 social utility of Rapeseed MS8, RF3 and MS8xRF3 and its contribution to sustainable development. 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 pesticide use, development of pest resistance in target populations, impacts on non-target organisms, potential for gene flow and possible impacts among poor and/or small-scale farmers in producing countries and share of the benefits among sectors of the society. Furthermore, Rapeseed MS8, RF3 and MS8xRF3 is tolerant to glufosinate-ammonium which is banned for use in Norway. Banning the use of glufosinate-ammonium based herbicides domestically due to health and environmental concerns, while supporting its use in other countries would be ethically ambiguous. Moreover, the applicant does not attempt to identify socio-economic implications, nor demonstrate a benefit to the community and a contribution to sustainable development from the use of Rapeseed MS8, RF3 and MS8xRF3 and does therefore not provide sufficient information as required by the NGTA.

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