

Innspill til EFSA GMO Extranet

Søknad EFSA/GMO/NL/2010/87 – Oljeraps GT73

D.07.01

Comparative assessment

The Norwegian Panel on Genetically Modified Organisms would like to point to the fact that comparative assessment data as presented by the notifier do not meet EFSA Guidance standards for risk assessment of GM plants and derived food and feed (EFSA Journal 2011; 9(5):2150). In the Canadian studies (Nickson et al. 1994; Nickson & Taylor 1994) the plots were not replicated, and no non-GM reference varieties were included in the field trials. According to the EFSA Guidance (2011) the replication at each site should never be less than four. In addition, at each site there should be at least three appropriate non-GM reference varieties of the crop that have a known history of safe use. The reference ranges on each key nutrient and toxicant should have been provided to increase the transparency of the document.

Furthermore, detailed information about experimental design and statistical methods are not shown. Even if the experimentation has been already assessed during the previous authorization, the applicant should carry out a new computation of collected data in order to show them, as far as possible, in line with EFSA Guidelines.

According to OECD consensus document from 2001 (this document was available when the application was submitted) the constituent tannin is mentioned and should be considered in the evaluation of intended and unintended effects. It is also suggested to differentiate between the fiber fractions and give ADF and NDF. None of these suggestions have been considered in the application from Monsanto Company (EFSA/GMO/NL/2010/87).

D.07.04

Agronomic traits

For the comparative assessment of agronomic and phenotypic characteristics of oilseed rape GT73, the applicant has performed field trials in Canada (1992-1994), Belgium (1993, 1994), France (1994) and UK (1994). Observations were conducted on different parameters related to germination and emergence, vegetative and reproductive growth, volunteer/persistence and plant interactions with insect, disease and abiotic stressors. The applicant concluded that the introduced trait for herbicide tolerance has not altered the growth and development characteristics of GT73 in comparison to Westar and hence no changes in persistence or invasiveness would be expected.

The Norwegian Panel on Genetically Modified Organisms would, however, like to point out that limited agronomic data from these field trials are provided in the Technical Dossier (Appendix VI, VIII and IX) and that the description of the experimental design is minimal. An assessment of the study results is therefore not possible. The applicant is asked to provide updated agronomic studies in compliance with the EFSA Guidelines (EFSA 2011).

D.07.08

Toxicology

A general comment to the toxicological studies available is that they are too old and not according to OECD guidelines. New toxicological studies according to OECD guidelines should have been performed.

The Norwegian Panel on Genetically Modified Organisms points out that the acute toxicity studies were not performed according to OECD guidelines 420. The exposure should have been performed with a high enough toxic concentration and a proper length of observation period. The acute studies should also have been performed with a fixed dose of 2000 mg test substance/kg bw. Moreover, a

NOEL is determined based on these acute studies. According to the OECD guidelines it is not recommended to determine NOAEL based on acute oral toxicity studies since they are limited to a 14 days observation period. The acute study is designed for determination of LD₅₀. Moreover, a NOAEL should be determined based on the 90-day Guideline No. 408.

The applicant has performed three 28 days feeding studies on rats. These studies are of limited value. Instead of performing three 28 days feeding studies, the applicant should have performed 90-day sub-chronic study according to OECD guidelines 408. All animal studies in this assessment lack information whether the experiments are performed using rapeseed exposed to or unexposed to glyphosat. Such information should have been included in the animal experiments.

However, the applicant has included tests on many relevant species that would have been a great help for the assessment of the rapeseed as food and feed substance if the relevant animal studies had been made available. The Norwegian GMO Panel finds it difficult to conclude on this risk assessment due to the lack of information based on the available studies. The Norwegian GMO Panel request the applicant to perform appropriate feeding studies according to the OECD guidelines.

D. 10 Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

According to the notifier, the scope of the application EFSA/GMO/NL/2010/87 is for food containing and consisting of GT73 oilseed rape, and food produced from or containing ingredients produced from GT73 with the exception of refined oil and food additives. Furthermore, the applicant refer to that importation, storage, processing and industrial uses of GT73 previously have been assessed by EFSA (EFSA 2004) and are authorized by Commission Decision 2005/635/EC, and are not in the scope of the current application. The Norwegian Panel on Genetically Modified Organisms presumes, however, that the current application indirectly includes import of viable seeds.

Oilseed rape can establish feral populations outside cultivated areas (e.g. roadsides, railway ground, ports) and escaped populations of herbicide-tolerant oilseed rape have been reported along transportation routes, ports and close to processing plants in Japan, Canada and USA (Yoshimura et al. 2006; Knispel et al. 2008; Nishizawa et al. 2009; Schafer et al. 2011). Germination and establishment of volunteer GT73 plants may result in gene flow into cultivated and feral *Brassica napus* as well as into closely related wild relatives (Knispel et al. 2008; Schafer et al. 2011). In Norway glyphosate may be used for weed control in non-agricultural environments including traffic areas, and therefore spilled GT73 might have a selective advantage over conventional oilseed rape along some transport routes. The applicant should therefore be requested to provide an updated environmental risk assessment for GT73 covering accidental spillage of oilseed rape seeds during transport, handling and processing along transport routes and ports.

References

- Knispel AL, McLachlan SM, Van Acker RC, Friesen LF (2008) Gene Flow and Multiple Herbicide Resistance in Escaped Canola Populations. *Weed Science*, 56(1):72-80.
<http://www.bioone.org/doi/full/10.1614/WS-07-097.1>
- Nishizawa T, Nakajima N, Aono M, Tamaoki M, Kubo A, Saji H (2009) Monitoring the occurrence of genetically modified oilseed rape growing along a Japanese roadside: 3-year observations. *Environmental Biosafety Research* 8: 33-44.
- Schafer MG, Ross AA, Londo JP, Burdick CA, Lee EH, et al. (2011): The Establishment of Genetically Engineered Canola Populations in the U.S. *PLoS ONE* 6(10): e25736. doi:10.1371/journal.pone.0025736
- Yoshimura Y, Beckie HJ and K Matsuo (2006) Transgenic oilseed rape along transportation routes and port of Vancouver in western Canada. *Environmental Biosafety Research* 5: 67-75.

D. 12.02 Case-specific GM plant monitoring

Given the scope of the application (covering the use of food containing and consisting of oilseed rape GT73), accidental spillage and loss of viable seeds of GT73 during transport, storage, handling, processing and use cannot be precluded. The Norwegian Panel on genetically Modified Organisms is of the opinion that the applicant should be requested to provide a case-specific monitoring plan covering spillage or loss of GT73 oilseed rape during transport, storage and processing. If spillage of viable GT73 oilseed rape is confirmed, then spread and persistence of GT73 oilseed rape and out-crossing to cultivated and feral oilseed rape populations and wild relatives have to be monitored.