European Food Safety Authority

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SCIENTIFIC OPINION

Request from the European Commission related to the safeguard clause invoked by Austria on oilseed rape MS8, RF3 and MS8xRF3 according to Article 23 of Directive 2001/18/EC[1]

Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2008-743)

Adopted on 15 June 2009

PANEL MEMBERS[*]

Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Patrick du Jardin, Lieve Herman, Niels Hendriksen, Sirpa Kärenlampi, Jozsef Kiss, Gijs Kleter, Ilona Kryspin-Sørensen, Harry Kuiper, Ingolf Nes, Nickolas Panopoulos, Joe Perry, Annette Pöting, Joachim Schiemann, Willem Seinen, Jeremy Sweet and Jean-Michel Wal.

SUMMARY

On 15 July 2008, Austria invoked Article 23 of Directive 2001/18/EC (safeguard clause) to provisionally prohibit the marketing of genetically modified oilseed rape MS8, RF3 and MS8xRF3 on its territory. Austria provided detailed reasons listed in supporting documents.

On 31 July 2008, the European Food Safety Authority (EFSA) has been requested by the European Commission to provide a scientific opinion on the statement and documents submitted by Austria in the context of a safeguard clause invoked under Article 23 of Directive 2001/18/EC.

In light of the information package provided by Austria in support of its safeguard clause and, having considered all relevant scientific publications, the Scientific Panel on Genetically Modified Organisms (GMO Panel) of EFSA concludes that, in terms of risk to human and animal health and the environment, no new scientific evidence was presented that would invalidate the previous risk assessment of oilseed rape MS8, RF3 and MS8xRF3. The EFSA GMO Panel also concludes that no new scientific data or information was provided in support of adverse effects of oilseed rape MS8, RF3 and MS8xRF3 on the environment and on human

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[*] (minority opinion) This opinion is not shared by 0 members of the Panel. / (conflict of interest) 0 members of the Panel did not participate in (part of) the discussion on the subject referred to above because of possible conflicts of interest.

and animal health in Austria. Therefore, no specific scientific evidence, in terms of risk to human and animal health and the environment, were provided that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC.

Key words: **GMOs, oilseed rape (*Brassica napus*), MS8, RF3, MS8xRF3, Austria, safeguard clause, human and animal health, environment, Directive 2001/18/EC**

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BACKGROUND

On 15 July 2008, Austria notified to the European Commission a national safeguard clause on genetically modified (GM) oilseed rape events MS8, RF3 and MS8xRF3 under Article 23 of Directive 2001/18/EC. The notification was accompanied by the scientific document entitled "*Scientific arguments for an import ban of herbicide tolerant oilseed rape Ms8, Rf3 and Ms8xRf3 (notification C/BE/96/01) in Austria*".

On 31 July 2008, the European Food Safety Authority (EFSA) has received a request from the European Commission to provide a scientific opinion from its Scientific Panel on Genetically Modified Organisms (GMO Panel) on the statement and documents submitted by Austria in the context of its invoked safeguard clause.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA was requested, under Article 29(1) and in accordance with Article 22(5) of Regulation (EC) No 178/2002, to provide a scientific opinion as to "*whether, in accordance with Article 23 of Directive 2001/18/EC, the statement and documents submitted by the Austrian authorities comprise new or additional information affecting the environmental risk assessment, such that detailed grounds exist to consider that the above authorised GMO, for the uses laid down in the corresponding consent, constitute a risk to human health or the environment*".

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

Directive 2001/18/EC provides the possibility for Member States to invoke safeguards on specific genetically modified organisms in the case where new or additional information, made available since the date of the consent, would affect the risk assessment of an authorised GMO. Provisions foreseen by Austria seek to provisionally prohibit the marketing of oilseed rape MS8, RF3 and MS8xRF3 for its intended uses on the Austrian territory.

The EFSA GMO Panel examined the set of supporting documents submitted by Austria. In this respect, the EFSA GMO Panel assessed whether the submitted documents comprise new scientific information that would change the outcome of previously performed risk assessments, and if detailed grounds exist to consider that the authorised oilseed rape MS8, RF3 and MS8xRF3, for its intended uses, constitute a risk to human and animal health or the environment.

The EFSA GMO Panel looked for evidence for GMO-specific risks – including long-term effects (e.g., BEETLE report, 2009) – taking into consideration the EFSA GMO Panel guidance document for the risk assessment of GM plants and derived food and feed (EFSA, 2006a) as well as any related risk assessments carried out in the past. In addition, the EFSA GMO Panel considered the relevance of raised concerns in light of the most recent scientific data and relevant peer-reviewed publications.

2. Assessment of documents provided by Austria

A set of supporting documents, accompanying the mandate of the European Commission (see *Terms of Reference as provided by the European Commission*), was forwarded to EFSA on 31 July 2008.

Austria provided the following set of documents in support of its safeguard clause:

- Austrian letter on new supplementary scientific evaluation (10 July 2008);
- Verbot des Inverkehrbringens von gentechnisch verändertem Raps aus den Ölrapslinien MS8, RF3 and MS8xRF3 in Österreich;
- Scientific arguments for an import ban of herbicide tolerant oilseed rape MS8, RF3 and MS8xRF3 (Notification C/BE/96/01) in Austria.

Based on the supporting documents, several issues were identified and therefore considered by the EFSA GMO Panel in the following two main areas: (1) the toxicological and allergenicity risk assessment, and (2) the environmental risk assessment and post-market environmental monitoring plan relating to the accidental spillage of oilseed rape MS8, RF3 and MS8xRF3 seeds.

Issues related to the coexistence of oilseed rape cropping systems and the adventitious presence of authorised GM material in non-GM products were not considered, as they fall outside the remit of the EFSA GMO Panel. In addition, the EFSA GMO Panel notes that it

only gives its opinion on the scientific quality of the post-market environmental monitoring activities proposed by applicants, whilst the final endorsement thereof is done by risk managers.

During its assessment, the EFSA GMO Panel identified issues raised by the Austrian authorities that would require further clarifications. To present and clarify the provided set of documents, an informal meeting between the Austrian delegation, several experts of the EFSA GMO Panel and EFSA staff was held on 23 April 2009. A representative of the European Commission attended the meeting as observer.

2.1. Food and feed safety issues

2.1.1. Toxicological and allergenicity assessment

The EFSA GMO Panel observes that these two publications related to toxicological and allergenicity aspects of the risk assessment quoted by Austria (Spök et al., 2004, 2005) do not provide new data specific on the safety of oilseed rape MS8, RF3 and MS8xRF3: current approaches for assessing toxicological and allergenicity risks of genetically modified organisms are questioned in generic terms. The EFSA GMO Panel emphasises that the approach taken by the Panel in order to assess the potential toxicological and/or allergenicity risks of GM plants is in accordance with internationally developed guidelines (e.g., Codex Alimentarius, 2003).

Specific issues raised by Austria pertain to what they perceive as insufficient, inappropriate, or lacking data in the dossier. Moreover, Austria points to the observed differences in glucosinolate levels. The EFSA GMO Panel notes, however, that it has already taken the issues raised by Austria into account in its opinion on MS8xRF3, including the acute toxicity of phosphinothricin acetyltransferase (PAT), the safety of PAT if it would sustain food /feed processing, and variability in glucosinolate levels. The rabbit and chicken studies mentioned and considered inappropriate by Austria have not been included into the safety assessment of MS8xRF3 as summarized in the EFSA GMO Panel's opinion. Again, no new data indicating potential adverse effects of MS8xRF3 have thus been provided by Austria, whilst the data provided do not lead the EFSA GMO Panel to diverge from its previous opinion on the potential toxicity and allergenicity of MS8xRF3 (EFSA, 2005).

2.2. Environmental safety issues and post-market environmental monitoring

2.2.1. Environmental risk assessment

In line with its previous scientific opinions on herbicide tolerant oilseed rape GT73 (EFSA, 2004), MS8xRF3 (EFSA, 2005) and T45 (EFSA, 2008), the EFSA GMO Panel confirms that in regions where oilseed rape is grown and/or where oilseed rape seeds are imported and transported, feral oilseed rape populations are likely to occur in non-natural disturbed ecosystems (such as ports, processing facilities, margins of agricultural fields, roadside verges, railway lines, and wastelands) (Bagavathiannen and Van Acker, 2008). It is well-known that human activity contributes to the dispersal of plants (Wichmann et al., 2009), especially the transport of seeds by vehicles (Zwaenepoel et al., 2006; von der Lippe and Kowarik, 2007a,b; Garnier et al., 2008).

In the scientific literature, the occurrence of feral oilseed rape populations has been reported not only in Austria (Pascher et al., 2006), but also in Canada (Simard et al., 2002; Yoshimura et al., 2006; Knispel et al., 2008), France (Pessel et al., 2001; Garnier et al., 2008; Pivard et al., 2008a,b), Germany (Menzel, 2006; Reuter et al., 2008; Neuffer, 2009), Japan (Saji et al., 2005; Aono et al., 2006; Kawata et al., 2008; Nishizawa et al., 2009) and the United Kingdom (Crawley and Brown, 1995, 2004; Wilkinson et al., 1995; Charters et al., 1999; Norris and Sweet, 2002). These populations can be large and show significant variation in size from one year to the next (Crawley and Brown, 1995).

Due to its early germination potential and capacity to capture resources rapidly, oilseed rape can take advantage of disturbed land (Blackshaw et al., 2003, 2004). However, successful recruitment of oilseed rape from seed spillage from passing traffic mainly depends upon its ability to compete for space with primary colonizers, particularly perennial grasses. In most non-agricultural areas, oilseed rape lacks the ability to establish stable populations due to the absence of competition-free gaps (Crawley et al., 1993; Warwick et al., 1999; Hails et al., 2006). Once established, oilseed rape populations often become extinct after 2 to 4 years (Crawley and Brown, 1995; Crawley et al., 2001; Norris and Sweet, 2002). If habitats are disturbed on a regular basis (e.g., by mowing, herbicide application, soil disturbance) and replenished with seed from seed spillage or recruitment from seeds produced by residents or from seeds from the seedbank, then feral oilseed rape populations can persist for longer periods (8-10 years) (Pessel et al., 2001; Pivard et al., 2008a,b). Using genetic analyses and farmer surveys, Pessel et al. (2001) revealed that some members of feral oilseed rape populations in road verges in France originated from varieties that had not been marketed for at least 8 years.

Oilseed rape is generally regarded as an opportunistic species, and not as an environmentally hazardous colonizing species (Warwick et al., 1999). Several field studies and model predictions reported that the presence of herbicide tolerance in oilseed rape does not confer a fitness advantage, unless the respective herbicide is applied (Crawley et al., 1993, 2001; Fredshavn et al., 1995; Warwick et al., 1999, 2004; Norris and Sweet, 2002; Claessen et al., 2005a,b; Simard et al., 2005; Garnier and Lecomte, 2006; Garnier et al., 2006). In the absence of glufosinate-ammonium-containing herbicide applications, oilseed rape MS8, RF3 and MS8xRF3 is neither more likely to survive, nor more invasive or persistent than its conventional counterpart. Moreover, there is no evidence that tolerance to glufosinate-ammonium enhances seed dormancy, and hence the persistence of feral oilseed rape populations (Crawley et al., 1993, 2001; Claessen et al., 2005a,b; Sweet et al., 2004; Lutman et al., 2005; Messéan et al., 2007). Because glufosinate-ammonium-containing herbicides are not widely used in ruderal ecosystems in the European Union (EU), feral oilseed rape plants ensuing from spilled seeds of oilseed rape MS8, RF3 and MS8xRF3 would not show any enhanced fitness and would thus behave as conventional plants. Only where and when glufosinate-ammonium-containing herbicides are applied, is oilseed rape MS8, RF3 and MS8xRF3 expected to have a fitness advantage. Likewise, there are no indications that the *barstar*/*barnase* gene complex would alter seed survival characteristics and confer a selective advantage (Fredshavn et al., 1995; Sweet et al., 2004; Lutman et al., 2008). The scientific information provided in the Austrian safeguard clause notification does not give any new information regarding increased likelihood of establishment or survival of feral oilseed rape plants in case of accidental release into the environment of oilseed rape MS8, RF3 and MS8xRF3 seeds during transportation and processing.

The EFSA GMO Panel is aware that if feral oilseed rape plants derived from spilled seeds remain uncontrolled and reproduce, they may survive, outcross and eventually disperse genes to cross-compatible plants such as *Brassica rapa* and *Raphanus raphanistrum* (Scheffler and Dale, 1994; Eastham and Sweet, 2002; Chèvre et al., 2004; Warwick et al., 2003, 2004, 2008; Claessen et al., 2005b; Jørgensen, 2007; BEETLE report, 2009; Devos et al., 2009; Jørgensen et al., 2009). Scientific evidence suggests that feral oilseed rape populations may serve as a reservoir that could hold and return (trans)genes to cultivated populations of oilseed rape in a different place and time, and act as a genetic bridge delivering the (trans)genes to sympatric cross-compatible plants (Saji et al., 2005; Aono et al., 2006; Pascher et al., 2006; Yoshimura et al., 2006; Knispel et al., 2008; Nishizawa et al., 2009). In Canadian regions where GM oilseed rape is frequently grown (e.g., Beckie et al., 2006), feral oilseed rape populations were shown to actively outcross with cultivated populations of GM oilseed rape and to accumulate transgenes (Knispel et al., 2008). However, compared to cultivated oilseed rape populations, the contribution of feral oilseed rape plants in vertical gene flow is expected to be limited: feral oilseed rape populations are small compared to cultivated populations and contribute little to the pollen load in the environment (Colbach et al., 2001a,b, 2005; Devaux et al., 2005, 2007, 2008; Gruber and Claupein, 2006; Knispel et al., 2008; Colbach, 2009). Moreover, there are no compelling data to suggest that the presence of an herbicide tolerance trait in a wild relative changes the behaviour of the wild relative so far (e.g., Warwick et al., 2008). In the absence of glufosinate-ammonium-containing herbicides, hybrids or wild relatives containing the herbicide tolerance trait do not show any enhanced fitness and behave as conventional plants. Thus escaped plants and genes dispersed to other cross-compatible plants would not create additional environmental impacts. If needed, feral oilseed rape MS8xRF3 and hybridised/introgressed relatives can be managed by the use of other herbicides and/or adequate mechanical practices (Beckie et al., 2004; Devos et al., 2004; Warwick et al., 2004; Légère, 2005; Simard et al., 2005; Gruber et al., 2008; Lutman et al., 2008).

The environmental exposure due to GM oilseed rape grain imports is anticipated to be low, as the amounts of viable oilseed rape seeds imported in the EU are limited with most seeds being imported by boat and crushed in or near the ports of entry. Some of the oilseed rape seeds imported into the EU are likely to be transported inland to Austria by boat. Moreover, some oilseed rape seeds entering Austria are transported by road or rail to processing plants in Austria. As indicated above, survival and outcrossing from plants derived from seed spillage will be at very low frequencies and have no hazardous environmental consequences compared to current feral oilseed rape populations.

In conclusion, the EFSA GMO Panel confirms that feral oilseed rape plants are likely to occur wherever oilseed rape is cultivated and/or transported and that transgenic oilseed rape is no exception (e.g., Saji et al., 2005; Aono et al., 2006; Yoshimura et al., 2006; Bagavathiannen and Van Acker, 2008; Kawata et al., 2008; Knispel et al., 2008; Nishizawa et al., 2009). However, there is no evidence that the herbicide tolerance trait introduced by genetic engineering results in increased invasiveness of oilseed rape MS8, RF3 and MS8xRF3, except when glufosinate-ammonium-containing herbicides are applied. As such, escaped plants and genes dispersed to other cross-compatible plants would not create additional agronomic or environmental impacts. This – together with the assessment that oilseed rape MS8, RF3 and MS8xRF3 and hybridising relatives have no enhanced fitness or invasiveness characteristics (except in the presence of glufosinate-ammonium-containing herbicides) – confirms earlier conclusions of the EFSA GMO Panel.

2.2.2. Post-market environmental monitoring plan

The EFSA GMO Panel maintains its position that the scope of the post-market environmental monitoring plan provided by the applicant complies with (1) the intended uses of oilseed rape MS8, RF3 and MS8xRF3, which excludes cultivation, (2) the requirements of the EFSA GMO Panel guidance document for the risk assessment of GM plants and food and feed products (EFSA, 2006a), and (3) the EFSA GMO Panel scientific opinion on post-market environmental monitoring (EFSA, 2006b).

European operators importing, handling and processing viable oilseed rape commodities have recently joined with the European Association of Bioindustries (EuropaBio) in developing monitoring systems for GM oilseed rape imported through main points of entry and processing facilities (Lecoq et al., 2007; Windels et al., 2008). These monitoring systems are based on Hazard Analysis and Critical Control Points (HACCP) principles. Therefore, it is anticipated that risk managers will opt for post-market environmental monitoring of imported oilseed rape MS8, RF3 and MS8xRF3 seeds in accordance with these arrangements.

2.2.3. Conclusion

The EFSA GMO Panel confirms its opinion that the likelihood of unintended environmental effects as a consequence of spread of (trans)genes from oilseed rape MS8, RF3 and MS8xRF3 will not differ from that of conventional oilseed rape varieties in the context of its intended uses. The EFSA GMO Panel agrees with the monitoring plan submitted by the applicant, especially now that comprehensive arrangements have been made by applicants and operators for monitoring at major points of import and processing in the EU. However, the EFSA GMO Panel continues to recommend that appropriate management systems should be in place to minimise accidental loss and spillage of transgenic oilseed rape seeds during transportation, storage and handling in the environment, and processing into derived products. These conclusions are in line with previous scientific opinions of the EFSA GMO Panel on the import and processing of herbicide-tolerant oilseed rape GT73 (EFSA, 2004), MS8xRF3 (EFSA, 2005) and T45 (EFSA, 2008).

OVERALL CONCLUSIONS AND RECOMMENDATIONS

The EFSA GMO Panel has investigated the claims and documents submitted in support of the Austrian safeguard clause and presented at the informal meeting between the Austrian delegation, several experts of the EFSA GMO Panel and EFSA staff on 23 April 2009. In these documents, the EFSA GMO Panel did not identify any new data subject to scientific scrutiny or scientific information that would change previous risk assessments conducted on oilseed rape MS8, RF3 and MS8xRF3 which currently has marketing consent in the EU. Furthermore, the Austrian submission did not supply scientific evidence, that the environment or ecology of Austria was different from other regions of the EU, sufficient to merit separate risk assessments from those conducted for other regions in the EU.

Having considered the overall information package submitted by Austria as well as a broad range of relevant scientific literature, the EFSA GMO Panel is of the opinion that there is no specific scientific evidence, in terms of risk to human and animal health and the environment, that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC for the marketing of oilseed rape MS8, RF3 and MS8xRF3 for its intended uses in Austria. In conclusion, the EFSA GMO Panel finds that the scientific evidence currently

available does not sustain the arguments provided by Austria, and therefore the EFSA GMO Panel reiterates its previous scientific opinion on oilseed rape MS8, RF3 and MS8xRF3.

DOCUMENTATION PROVIDED TO EFSA

1. Letter, dated 31 July 2008, with supporting documents from Jos Delbeke, Acting Director-General Environment EC, to Catherine Geslain-Lanéelle, Executive Director EFSA (ref ENV/B3/AA/lh ARES(2008) 18278), requesting for a scientific opinion on the safeguard notification submitted by Austria under Article 23 of Directive 2001/18/EC for oilseed rape MS8, RF3 and MS8xRF3 and comprising the following supporting documents:
   - Scientific arguments for an import ban of herbicide tolerant oilseed rape MS8, RF3 and MS8xRF3 (notification C/BE/96/01) in Austria.

2. Letter, dated 15 October 2008, from Catherine Geslain-Lanéelle, Executive Director EFSA to Jos Delbeke, Director-General Environment EC (ref CGL/RM/PB/SM/shv (2008) 3369831), acknowledging the receipt of the mandate accompanied with the supporting documents.

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