WISSENSCHAFTLICHE BEGRÜNDUNG FÜR EIN IMPORTVERBOT VON GENTECHNISCH VERÄNDERTEM RAPS Ms8, Rf3 und Ms8xRf3 DER FIRMA BAYER CROP SCIENCE (NOTIFICATION C/BE/96/01) IN ÖSTERREICH

ZUSAMMENFASSUNG

Die Zulassung von gentechnisch verändertem Raps Ms8xRf3 wurde ursprünglich gemäß Richtlinie 90/220/EWG beantragt. Der Antrag wurde später aktualisiert, um den Anforderungen der Richtlinie 2001/18/EG gerecht zu werden. Ursprünglich umfasste die Notifikation Import und Verarbeitung sowie den Anbau von gentechnisch verändertem Raps Ms8xRf3. Aufgrund von Bedenken bezüglich der Sicherheit für die Umwelt dieses Produktes wurde der Antrag auf Anbau über Betreiben der belgischen Leitbehörde im Laufe des Zulassungsverfahrens zurückgenommen. Der Genehmigung, welche auch die weibliche (Ms8) und die männliche (Rf3) Linie umfasst, sind als Managementmaßnahme technische Richtlinien beigefügt, die ein unbeabsichtigtes Verschütten von diesem gentechnisch veränderten Raps verhindern sollen.

Als Verwendungszweck von Raps Ms8xRf3 ist vorrangig die Anwendung von Rapsschrot als Tierfutter vorgesehen. Demzufolge sollte somit auch die Futtermittelsicherheit im Vordergrund der Risikoabschätzung dieses Produktes stehen. Insbesondere die toxikologische Risikoabschätzung muss allerdings als unzureichend eingestuft werden, da die vom Antragsteller vorgelegten toxikologischen Studien von limitierter Relevanz für die Futtermittelsicherheit sind. Die in diesen Studien gewählten Testorganismen, die verfütterten Testmaterialien, die Art und Weise der Verabreichung der Testmaterialien, sowie die begrenzte Prüfdauer der vorgelegten Fütterungsstudien sind nicht geeignet, um die toxikologische Sicherheit für den vorgesehenen Verwendungszweck dieses Produktes zu garantieren. Dies gilt analog für die durchgeführte Risikobewertung der potenziellen Allergenität.

Weiters wurde das Risiko einer unbeabsichtigten Verschüttung von diesem gentechnisch veränderten Raps sowie deren Konsequenzen für die Umwelt durch den Antragsteller nicht ausreichend berücksichtigt. Das Ausmaß der unbeabsichtigten Ausbringung oder Verstreuung von Rapssamen, der Verbreitung und Verwilderung von transgenem Raps allein aufgrund von Rapsimporten wurde bereits in anderen Ländern nachgewiesen und ist daher auch unter österreichischen Bedingungen vorhersehbar, da die Zulassung den Import von lebens- und vermehrungsfähigen Rapssamen umfasst.

Im Hinblick auf das eingesetzte barnase/barstar-System kann überdies kritisch angemerkt werden, dass es sich hier um einen Eingriff in das Reproduktionssystem von Raps handelt, dessen Ausmaß an potenziellen negativen Auswirkungen auf die Umwelt derzeit nicht abschätzbar ist.

Die im Dossier gemachten Angaben, dass sich der Import dieses gentechnisch veränderten Rapses im wesentlichen auf wenige Häfen in Belgien und in den Niederlanden sowie entlang des Rheins beschränken und auch dort an Ort und Stelle die sofortige Verarbeitung („crushing") zu nicht lebensfähigem Material erfolgen soll, werden durch das Aufzeigen der internationalen Transportwege von Raps in die EU, innerhalb der EU sowie nach Österreich im Rahmen dieser Stellungnahme ernsthaft in Frage gestellt.

Auch wurden unter experimentellen Bedingungen Introgression sowie stabile Expression der eingebrachten Merkmale von Raps Ms8xRf3 in Hybriden von Raps und bestimmten wilden Verwandten nachgewiesen und diese sind daher auch unter natürlichen Bedingungen zu erwarten. Dies kann ökologische Konsequenzen für Regionen haben, in denen zur Einkreuzung geeignete wilde Verwandte von Raps vorkommen. Darüber hinaus könnte es auch zu einer Beeinträchtigung der konventionellen Rapsproduktion kommen. Vom Eintreten beider Szenarien ist in Österreich mit hoher Wahrscheinlichkeit auszugehen.

Die vorgeschlagenen Managementmaßnahmen sind deshalb zu unspezifisch, um unbeabsichtigtes Verschütten zu verhindern oder verwilderten transgenen Raps nachweisen und vernichten zu können. Zudem inkludiert auch der vom Antragsteller vorgelegte allgemeine Überwachungsplan keine spezifischen Vorschläge zur Überprüfung von nicht vorhersehbaren nachteiligen Effekten dieses Produktes, wie etwa mögliche nachteilige Effekte auf die Tiergesundheit, die der Fokus der Überwachungsstrategie bei diesem Produkt sein sollten.

Österreich hat sich deshalb - gemeinsam mit einer Reihe von anderen Mitgliedstaaten - bereits im Rahmen des Zulassungsverfahrens wiederholt gegen das Inverkehrbringen dieses Produkts ausgesprochen. Im Regelungsausschuss vom 5. Dezember 2005 sowie im Umweltrat vom 18. September 2006 stimmte in der Folge eine große Mehrheit (151 bzw. 156 Gegenstimmen) gegen die Marktzulassung. Nachdem die EK dennoch mit 26. März 2007 dieses Produkt EU-weit zugelassen hat, und Österreich nach wie vor die Meinung vertritt, dass dieses Produkt eine Gefahr für die Tiergesundheit und die Umwelt darstellt und dies auch anhand neuer bzw. zusätzlicher wissenschaftlicher Erkenntnisse in der gegenständlichen wissenschaftlichen Stellungnahme belegen kann, hat Österreich in Anwendung der Schutzklausel gemäss Art. 23 der Richtlinie 2001/18/EG das Inverkehrbringen dieses Produktes in Österreich bis 1. Oktober 2010 verboten. Dieser Zeitraum soll auch zum wissenschaftlichen Diskurs über dieses Produkt genutzt werden.

SCIENTIFIC ARGUMENTS FOR AN IMPORT BAN OF GENETICALLY MODIFIED OILSEED RAPE Ms8, Rf3 AND Ms8xRf3 (NOTIFICATION C/BE/96/01) IN AUSTRIA

SUMMARY

Genetically modified oilseed rape Ms8xRf3 was initially submitted under Directive 90/220/EEC. Later the notification was updated in order to comply with the provisions of Directive 2001/18/EC. Originally the notification comprised import, processing and cultivation but due to several concerns on the environmental safety of this product cultivation was excluded at a later stage of the notification procedure. Technical guidelines as a management measure were attached to the consent, which covers also the female (Ms8) and male (Rf3) lines, in order to prevent accidental spillage of this transgenic oilseed rape.

As the main use of oilseed rape Ms8xRf3 will be feed use of oilseed rape meal, the focus of the risk assessment must be on the feed safety of this product. However, the toxicological risk assessment of oilseed rape Ms8xRf3 is flawed with respect to the limited relevance of the toxicological studies provided by the notifier for the assessment of feed safety. The test organisms, the choice of test materials fed to these animals, the route of administration of the test material and the limited testing period are not adequate in order to assess the toxicological safety for the intended use of this product.

Additionally, potential unforeseen adverse effects on animal health were not specifically addressed in the general surveillance plan submitted. As long as the toxicological safety of this product is not clarified, risks from the genetically modified oilseed rape Ms8xRf3 to animal health cannot be excluded. Therefore the toxicological safety of genetically modified oilseed rape Ms8xRf3 has not been sufficiently proven by the notifier.

With regard to the evaluation of allergological risks it has to be mentioned that a comprehensive risk assessment, taking into account also potential secondary effects resulting from the genetic modification are missing and should be studied in depth.

With regard to the barnase/barstar-system it can be stated that this genetic modification implies interference in the reproductive system of *Brassica napus* and could affect as a consequence also other related wild *Brassicaceae*. The RNA destroying gene, "protected" by the barstar inhibitor could propagate in volunteer oilseed rape (OSR) thus the consequences on the reproduction of feral OSR or wild relatives can currently not be estimated. Therefore the spread of the transgenes in feral oilseed rape populations and its environmental and economic consequences are currently unpredictable.

Furthermore, the risk of accidental spillage of oilseed rape Ms8xRf3 (including the female and male lines) and its consequence on the environment have not been considered sufficiently by the notifier. The foreseen provisions regarding the management of accidental spillage are not specific enough and therefore insuffient: They do not ensure the prevention or, in case of accidental spillage, detection and eradication of feral transgenic oilseed rape when whole oilseed rape seeds are imported. As has been shown, dissemination, establishment and persistence of feral transgenic oilseed rape Ms8xRf3 is likely as well as introgression of the respective

traits into wild relatives. The presence of feral genetically modified oilseed rape Ms8xRf3 in the environment may exhibit adverse effects on wild relatives in the long term. In addition, feral transgenic oilseed rape will be an additional main factor for co-existence problems with respect to conventional oilseed rape production because feral oilseed rape can also function as transgene donor.
Accidental spillage, dissemination and establishment of transgenic oilseed rape from oilseed rape imports have been confirmed already in other countries and are expected to happen also under Austrian conditions as imports of whole (viable) oilseed rape seeds are likely.

The statement in the dossier, that the import of this transgenic oilseed rape is limited more or less to a few ports in Belgium, the Netherlands and Rhine river, where all grains are treated in crushing facilities within the service areas of these ports, can not be regarded as appropriate. It has to be stated that oilseed rape is a world commodity and the most imported oilseed plant in Austria: Oilseed rape from Canada could reach Europe mainly via the ports of Amsterdam, Rotterdam and Antwerp (ARA-ports). For example, seed is shipped up the Rhine River to oil mills along the Rhine or can be brought via the Rhine-Main-Danube Canal and down the Danube to Austria. Oilseed rape can also be shipped from the Black Sea and from Eastern European countries up the Danube to Austria. The European inland waterway network consists of a dense system of rivers and canals throughout the continent and allows shipping and transport of goods along various routes in all directions.

As the oilseed crushing industry has undergone a concentration process in the last decades, it is a common practice that one company owns numerous oil mills in different EU-member states and will therefore operate them at full capacity. Additionally, the different international transport routes of oilseed rape in the EU as well as within the EU underline the Austrian position that accidental spillage of this transgenic OSR could take place in Austria, due to its geographic location and transit routes.

As introgression and stable expression of the respective traits of oilseed rape Ms8xRf3 in hybrids of oilseed rape and certain wild relatives have been shown under experimental conditions, they are expected to occur also under natural conditions. This may have ecological consequences in areas where relevant wild relatives of oilseed rape occur as well as affect conventional oilseed rape production. Both scenarios are very likely in all Austrian oilseed rape cultivation areas.

In regard of these scenarions, the proposed risk management measures are too unspecific and will not prevent accidental spillage or detect and eliminate feral transgenic oilseed rape. Finally, the general surveillance plan submitted by the notifier does not include specific proposals for the detection of unforeseen adverse effects of this product, specifically potential effects on animal health which should be the focus of the surveillance strategy of this transgenic oilseed rape.

As a consequence, Austria has – in line with a lot of other member states – voted against the placing on the market of this product during the Regulatory Committee acc. to Directive 2001/18/EC on 5th December 2005 and the Environmental Council on 18th September 2006, where a representative - though not qualified - majority could be reached (151 respectively 156 votes against the placing on the market).

Nevertheless, the EC decided on 26th March 2007 in favour of this product, which got approval for placing on the market.

Austria still holds the opinion that the risks of this product on the animal health and the environment were not assessed properly by the notifier and underlines this argumentation also with new, additional scientific arguments. For these reasons Austria has made use of the safeguard clause according to Art. 23 of Directive 2001/18/EC and prohibited the marketing of this product in Austria up to 1st October 2010. This timeframe should also be used for a scientific discussion on this transgenic oilseed rape.

BACKGROUND AND DOCUMENTS CONSIDERED

The notification of genetically modified oilseed rape Ms8xRf3 was originally submitted by Plant Genetics System (PGS) in 1996 under the provisions of Directive 90/220/EEC. The introduced traits of genetically modified oilseed rape line Ms8 are male sterility (*barnase* gene) and herbicide resistance to glufosinate ammonium (*bar* gene). The introduced traits of oilseed rape line Rf3 are restoration of the male fertility (*barstar* gene) and herbicide resistance to glufosinate ammonium (*bar* gene). The hybrid oilseed rape Ms8xRf3 is fully fertile and glufosinate tolerant.

The scope of the initial notification by PGS comprised import and processing as well as cultivation. In 1998 an annex was supplied by the notifier containing additional information on the genetically modified product. The Scientific Committee on Plants published its opinion on genetically modified oilseed rape Ms8xRf3 in May 1998 (SCP 1998). In 2003 an updated notification according to Article 35 of Directive 2001/18/EC was submitted by the new notifier, Bayer Crop Science (BCS).

Following the risk assessment report and the statement by the lead member state (Belgium) in 2004 recommending the exclusion of cultivation from the scope of the notification as well as several objections of member states during the 60 day assessment procedure, the notifier took note that an approval for cultivation could not be granted at that time. Consequently, the notifier prepared answers to the comments of member states and provided additional information in October 2004 but did not pursue consent for cultivation.

As several member states maintained objections, the European Food Safety Authority (EFSA) was consulted in 2005. Its opinion of 14th September 2005 (EFSA 2005) relates to import and processing for feed and industrial uses only but excludes cultivation and food use. EFSA concluded that the genetically modified oilseed rape Ms8xRf3 is as safe as conventional oilseed rape for humans and animals and, in the context of the proposed uses, for the environment. However, EFSA advised that appropriate management systems should be in place to minimize accidental loss and spillage during transportation, storage, handling in the environment and processing into products (EFSA 2005).

The decision for the placing on the market by the European Commission comprises grains from the individual female and male lines Ms8 and Rf3, respectively, as well as grains from crossing of the individual lines (Ms8xRf3) and grains derived from crosses of these lines with any traditionally bred oilseed rape (EC 2007). As laid down in the decision, the scope of the consent comprises the same use as any other oilseed rape with the exception of cultivation and use as or in food (EC 2007).

The following argumentation is based on the documents provided by the notifier in the original application, the additional information, the updated notification according to Directive 2001/18/EC as well as on previous statements of Austria during the notification procedure of oilseed rape Ms8xRf3. Additionally, it takes into account the responses of the notifier to the statements of the member states as well as the opinion of the Belgium competent authority, the Scientific Committee of Plants and the European Food Safety Authority.

ARGUMENTATION

1. Flaws in the toxicological risk assessment/possible adverse effects to animal health

For the assessment of the toxicological safety of genetically modified oilseed rape Ms8xRf3 the notifier refers to a whole food feeding study with rabbits and a male broiler chicken feeding study. The rabbit feeding study originally cited in the updated risk assessment of 1999 and again in the update of 2003 (but contained in the annex provided already in 1998) did not use the respective genetically modified oilseed rape lines Ms8xRf3 but instead used a genetically modified oilseed rape line derived from other plasmids (pTTM8RE and pTVE74RE, respectively, see update 1998: Annex 2, part 2, Annex III.5.). This clearly contradicts the case-to-case approach of the environmental risk assessment principles of Directive 2001/18/EC. Additionally, the rabbits were fed the leaves of the genetically modified oilseed rape, which is not representative of the plant organs usually fed to livestock.

The male broiler chicken feeding study cited in the update of the risk assessment in September 2003 was not attached to the notification or any of its updates and can therefore not be considered as relevant for the toxicological assessment of genetically modified oilseed rape Ms8xRf3.

The acute toxicity study provided by the notifier administered the PAT protein isolated from *E. coli* intravenously to mice (provided as additional information in 2004). This acute toxicity study, using the isolated protein only, is insufficient in order to assess the potential and long-term toxicological risks for animal health of Ms8xRf3 oilseed rape. The method of administration of the protein via intravenous injection rather than exposure via feeding does not represent the relevant exposure pathway when genetically modified oilseed rape Ms8xRf3 is used as livestock feed. Oral toxicity studies with newly expressed proteins are explicitly required according to genetically modified food and feed regulation (EFSA 2006). Additionally, acute toxicity tests with isolated proteins have poor relevance for a lifelong feeding of the genetically modified product to animals.

In most cases meal of the genetically modified oilseed rape derived from the oil extraction procedure will be fed to livestock. As shown in the environmental risk assessment there are indications, that the PAT protein is heat stable at least to a certain extent (see Appendices 3 and 4 of the additional information provided by the notifier in 2004) and e.g. barnase undergoes a highly “cooperative thermal transition” with a melting temperature of about 50°C over a broad pH range (5,0-8,5), indicating a thermal stability of the enzyme. Furthermore, the barnase/barstar complex is very stable and has a dissociation constant of about 10^{-14} M, indicating that once it forms it rarely dissociates (HARTLEY 1989, MARIANI et al 1992). This indicates that the proteins may not be fully destroyed during the processing to meal used as a feed.

An assessment of the expected herbicidal treatment of genetically modified oilseed rape on both, the stability of the plant produced protein and the glucosinolate levels, is considered crucial.

In view of the above mentioned considerations and the life long exposure of animals to this genetically modified product when used as feed, a 90-day sub-chronic toxicity test using relevant plant organs and assessing relevant toxicological endpoints is a minimum requirement in order to assess the toxicological safety of this product (see also SPÖK et al. 2005).

2. Flaws in the allergological risk assessment

The assessment of any potential allergenic effects is reduced to the assessment of the allergenicity of the isolated proteins produced from the newly inserted genes. This is done primarily through literature review and research into databases (e.g. BLAST Sequence Similiarity Search) for comparison of the introduced sequence with known allergens. No experimental tests with the GMO itself are conducted. From the absence of amino acid sequence similarities it is concluded that no adverse effects are to be expected. The risk of an unintended enhancement of allergenic potential is therefore not thoroughly evaluated. Secondary effects resulting from the event of insertion, which might lead to new/unexpected allergenic qualities, should be studied in depth.

As a consequence a comprehensive risk assessment as described in SPÖK et. al. (2005) should be carried out. The proposed tests should be performed by the notifier and the resulting data provided in order to guarantee a high level of safety and public confidence in the approach taken.

3. Environmental consequences of the barstar/barnase-System

Transgenic hybrid plants having traits with a direct impact on the reproduction system of the plant can have a long term influence on the population genetics and the evolution of crops and wild relatives. For the *Brassicaceae* family this is of special relevance because of the high number of closely related species.

A recent study has shown stable transgene expression and unchanged fitness of hybrids between genetically modified oilseed rape containing the barnase/barstar gene complex and the wild relative *Brassica rapa* (AMMITZBOLL et al. 2005). Consequently, the dissemination of the respective transgenes when introgressed into wild relatives is highly likely and a selective disadvantage in such hybrids must be questioned.

Additionally, it has to be remarked that the consent for placing on the market of genetically modified oilseed rape Ms8xRf3 is not restricted to the hybrid itself but also extends to the individual lines Ms8 and Rf3; therefore it has to be examined whether the presence of the RNAse (barnase) without the barstar inhibitor might have consequences for the reproductive potential of feral oilseed rape populations or wild relatives.

The system barnase/barstar can only be regarded as safe being part of the microorganism *Bacillus amyloliquefaciens*. Brought into a higher crop plant with a pollen specific promotor, the reproductive systems of the crop *Brassica napus,* of many vegetable Brassicas (like cabbage, turnip and others) and many wild growing relatives could be influenced in an unintended way.

The barnase/barstar system introduces a gene into oilseed rape which is specialized to destroy RNA. As mentioned before, in transgenic oilseed rape the protein barnase forms a stable complex with barstar and the plant has a normal reproduction system, even in spilled oilseed rape or feral populations. Based on the description of the functionality of barnase and barstar the use in plants should be questioned – especially with regard to the inheritance of these genes via e.g. crossing of Ms8xRf3 with wild relatives where most of the progeny (F2) is expected to inherit transgenic traits and a part of these even carry both genes – the dominant trait for male sterility and for restoring fertility; as a consequence both transgenic traits could be passed on to following generations.

It has also to be stressed that the transformed proteins (barstar and barnase) are of prokaryotic origin, in particular of *Bacillus amyloliquefaciens,* and barnase has an extracellular function for this prokaryotic species to degrade and digest RNA in the environment of the microoganism for further nutritional use. It is not an intracellular RNA-processing enzyme and therefore the cell has to protect itself from its lethal effects by production of barstar. Application of this microbial system in higher plants and extrapolating microbial safety concepts up to eukaryotes including the plant kingdom cannot be regarded as state of the art.

With regard to oilseed rape Ms8, carrying male sterility, potential negative effects on the environment caused by the absence of barstar-inhibition have to be considered. In this case it could happen that feral oilseed rape, related crop species or wild relatives, become male sterile genotypes and phenotypes. In general, the maintenance of line Ms8 is achieved via crossing with conventional *B. napus*, where 50% are carrying the desired trait.

4. Accidental spillage and risk management measures

In the notification update of 2003 the notifier did not propose any case specific monitoring. The notifier states that in the risk assessment, considering the restricted scope of import and processing only, the receiving environment is described as the unmanaged environment only where no risk was identified and consequently no case specific monitoring was necessary (BCS response to member state comments, 18th October 2004). However, in managed and semi-managed environments the notifier identified the establishment of transgenic herbicide tolerance through genetically modified oilseed rape volunteers or through transfer of the herbicide tolerance gene to wild *Brassica* relatives as a potential adverse effect (Annex 8, additional information delivered by the notifier in October 2004). It is unclear why the notifier considered only unmanaged environments as the receiving environment in case of import of genetically modified oilseed rape seeds as spillage usually occurs in managed and/or disturbed environments (see below).

The import volume of oilseed rape to Austria was more than 200,000 tons in the year 2007 (Statistik Austria 2008). Major source countries for oilseed rape imports are Hungary, Slovakia and Czech Republic. There is also import from Germany, Slovenia, Croatia, Italy and the Netherlands and even small amounts from Canada, China and Australia. Import of whole seeds of genetically modified oilseed rape Ms8xRf3 and processing in Austrian oil mills will be highly likely due to the connection of Atlantic and Black Sea ports via major transport routes along the Danube and the Rhine-Main-Danube-Canal (RMD-canal).

The following ports are of high relevance for the import of oilseed rape from overseas production:

- ports at the North & Baltic Sea (Hamburg)
- ARA-ports on the Rhine (Amsterdam, Rotterdam, Antwerp)
- French ports (St. Nazaire)
- Mediterranean Sea-ports (Genova, Ravenna, Triest)
- Black Sea-ports (Constantza, Galati)
- Ports along the Danube River

The European inland waterway network consists of a dense system of rivers and canals throughout the continent and allows shipping and transport of goods along various routes in all directions. Especially the northern region of Germany, France, Belgium and the Netherlands are connected via a dense canal system. The Rhine-Main-Danube-Canal connects the canal system in the north via Rhine and Main with the Danube River. All these routes allow the transport of oilseed rape e.g. from France or from the Black Sea to Austria. The international seaports of Constantza and Galati, are gaining increasing importance. This is of relevance due to the fact that in the surrounding of the port of Galati the Ukrainian ports of Remi and Ismail are situated with a modern railway connection to the rural areas where oilseed rape is cultivated. Therefore, also the import of GM oilseed rape from Eastern Europe is possible. Additionally, these ports could receive oilseed rape from Russia and via the Bosporus and Suez Canal even from India, China or Australia (REINER 2007).

So the import of transgenic oilseed rape to Austria is not only possible from Belgium and the Netherlands, but also via a vast canal system from the northern part of France and the northern part of Germany. Agri-commodities are shipped in bulk to many countries in Europe. There are examples that cereals from France go down the Mosel River, enter the Rhine, go up the Rhine to the RMD-canal and go down to Serbia. The limiting section is not the RMD-canal but the section between Vilshofen and Straubing in Bavaria. Ships have to be unloaded and reloaded to fit the depth of this section of the Danube River - which also implies the possibility of accidental spillage (REINER 2007).

In Austria the supply of oilseed rape is not covered by domestic cultivation and tends to increase in the near future due to new intended uses of agrofuels such as biodiesel. This implies that the import of oilseed rape from Hungary, Slovakia and other states in Eastern Europe is increasing (Comparing the import data of oilseed rape from 2004 with those of 2007 a duplication is evident (STATISTIK AUSTRIA 2008).

Additionally, along European inland waterway network new oilmills have been built or scaled up - often from international operating companies - to process seeds from the big growing areas in Romania, Bulgaria and Hungary and even from Ukraine and Russia. Oilseed rape is also transported up the Danube River, as acknowledged by port operating companies along the Danube, in order to ensure the full usage rate of the facilities. In Austria also a lot of new decentralised oilmills have been built in the recent past, which implies the transport from the ports of Vienna-Albern, Krems, Linz, Enns and Aschach via railway and lorry throughout the country (Web: via-donau, REINER 2007). Also ships have to be cleaned up in the ports and new commodities are loaded. Therefore, the possibility of accidental spillage and mingling GM seed with conventional seed exists.

Furthermore the main cultivation areas of oilseed rape in Austria are situated in the areas where potential negative impacts due to the import of GM oilseed rape (PASCHER et al. 2000) could happen. These decentralized mills process regional cultivated oilseed rape but due to the huge supply and for economic reasons it is expected that also imported (GM) oilseed rape is used.

Before giving approval for the placing on the market for import, also all aspects and transport routes as well as all related aspects like accidental spillage have to be taken into consideration.

Also the increasing cultivation of oilseed rape in Belarus, Ukraine and Russia means that in the near future the import of oilseed rape in the EU will augment. These aspects are not considered in the actual dossier.

Accidental spillage and transport loss of Ms8xRf3 oilseed rape seeds in Austria are considered as a major risk when genetically modified grains are imported in the EU from non-EU production areas. This spillage risk of genetically modified oilseed rape has also been reflected in the request of many member states for specific measures to minimize the loss and spread of genetically modified oilseed rape seeds. The notifier argues that spillage of genetically modified oilseed rape will be avoided or minimized by routine procedures.

But it has been shown that feral oilseed rape patches along motorways and roads are mainly derived from seed spillage during transport to seed processing plants or silos (CRAWLEY & BROWN 1995, CRAWLEY & BROWN 2004, PIVARD et al. 2005, 2007). Also studies conducted in Austria have shown the presence of feral oilseed rape along transport routes such as roads, lanes, highways or railway tracks (PASCHER et al. 2000, DOLEZEL et al. 2002 and PASCHER & DOLEZEL 2005). The occurrence of transgenic, herbicide resistant oilseed rape in Japanese ports and major roads originating from these ports has been reported and their origin was attributed to seed spillages from oilseed rape imports as transgenic oilseed rape has not been commercially cultivated in Japan (SAJI et al. 2005). Later AONO et al. (2006) found multiple herbicide resistance traits in these feral oilseed rape populations suggesting intraspecific gene flow of these transgenes. Once oilseed rape occupies appropriate habitats it is able to establish stable and self-dispersing populations outside cultivated fields (PESSEL et al. 2001). Individual patches of feral oilseed rape along motorways have been shown to persist for a time period of up to 10 years (CRAWLEY & BROWN 2004, CLAESSEN et al. 2005a) and persistence for even longer time periods has been suggested (CLAESSEN et al. 2005a, CLAESSEN et al. 2005b). Also outside the agricultural context there is evidence that feral oilseed rape can establish, such as in urban areas, harbour areas or industrial sites (BRECKLING & MENZEL 2004). Indications for a permanent character of feral oilseed rape populations in Austria have recently been suggested by PASCHER et al. (2006).

In a recent study (D'HERTEFELDT et al. 2008) evidence of long-term GM seed persistence in conventional agriculture is provided. Ten years after a trial with GM herbicide-tolerant oilseed rape, emergent seedlings were collected and tested for herbicide tolerance. Seedlings that survived the glufosinate herbicide (15 out of 38 volunteers) tested positive for at least one GM insert.

Additionally the argument of the notifier (MacDONALD & KUNTZ 2000) that these plants would not likely produce viable seed before the first killing frost may apply to some regions of Canada but not to European conditions.

Consequently, it must be assumed that in case of accidental spillage of genetically modified oilseed rape Ms8xRf3 the build up of feral populations of genetically modified oilseed rape which are able to establish permanently is considered highly likely.

Several species of wild relatives of oilseed rape occur at ruderal sites and overlap in flowering with feral oilseed rape populations (PASCHER et al 2000). Introgression of the introduced traits of feral genetically modified oilseed rape Ms8xRf3 to certain wild relatives has already been confirmed in Canada (YOSHIMURA et al. 2006) and can therefore not be excluded also under Austrian conditions. In the longer term a possible selective advantage or disadvantage of the herbicide tolerant trait conferred to feral transgenic oilseed rape or when introduced into wild relatives can currently not be estimated, the use of the respective non-selective herbicide in the relevant habitats (e. g. railway tracks, road sides) where genetically modified oilseed rape may establish cannot be excluded. Glufosinate-ammonium is registered for the use in a non-agricultural context in several plant protection products in Austria (SATTELBERGER 2001).

Due to the pannonian climate and the early harvest period compared to Germany, Austria has not only a processing industry, but also a seed producing sector. Apart from environmental risks, accidental spillage of genetically modified oilseed rape must be viewed in the context of conventional oilseed rape production as well as seed production and multiplication (which is of great importance and relevance) in Austria and has its center in Lower and Upper Austria (AGES website). Adventitious presence of the respective genetically modified traits in conventional oilseed rape seed is considered as a fundamental co-existence problem and might lead to contamination of conventional crops. As has been shown, co-existence of genetically modified and conventional oilseed rape is not feasible under Austrian seed production conditions (AGES 2004, PASCHER & DOLEZEL 2005). In this context also oilseed rape volunteers and feral oilseed rape will be an additional impeding factor in the realisation of coexistence (PASCHER & DOLEZEL 2005). The implications for breeding and seed production, especially in those countries where agriculture is based on open-pollinating oilseed rape cultivars and conventional hybrid systems, are currently unpredictable (REINER 2007). Oilseed rape is itself a hybrid and is closely related to a wide range of many other Brassica vegetable crops, herbs and green manure plants, like cabbage, turnip rape and others.

The risk of accidental spillage of GM oilseed rape Ms8xRf3 has also been recognised by EFSA (2005) demanding respective management measures. Consequently, an annex containing technical guidelines was attached to the consent (EC 2007). However, these measures are too general in order to prevent accidental spillage of genetically modified oilseed rape when imported into the European Union. The proposed measures which are only based on providing information by the notifier to operators of oilseed rape are not considered sufficient as they leave open defined responsibilities in case of accidental spillage. It remains unclear who is in charge of carrying out regular checks in and around points of entry of genetically modified oilseed rape in order to detect transgenic volunteer oilseed rape plants. As detection and identification of genetically modified volunteers cannot be based on phenotypic traits this task must be assigned to beforehand in order to identify such volunteers in a timely manner. Furthermore, detailed procedures are not part of the technical guidelines which should contain specifications with respect to the locations, the methodology of detection and eradication of transgenic oilseed rape as well as the frequency of these checks.

In conclusion, the proposed management measures considering accidental spillage of genetically modified oilseed rape Ms8xRf3 are not sufficient in order to prevent spillage and establishment of genetically modified oilseed rape in relevant habitats.

General surveillance of unforeseen and long-term effects

The general surveillance plan proposed by the notifier is too general and unspecific to allow the detection of potential adverse effects upon import and processing of genetically modified oilseed rape Ms8xRf3. The monitoring plan contains examples of potential surveillance networks to be used in general surveillance, but lacks contact details of specific organizations in the respective member states.

It remains unclear, how the relevant networks will be included in the monitoring activities, what frequency of monitoring will be applied and which methods will be used in order to detect possible adverse effects. The methodology provided by the notifier, namely providing information to European operators and collecting information through unspecified “key external networks” and “other sources” such as media and Internet is not appropriate in order to assess potential adverse effects.

In view of the fact that most of the imported genetically modified oilseed rape seeds will be used as animal feed, a robust monitoring plan in order to ensure safety of this product for animal health is particularly important, especially with regard to the lack of a thorough allergological and toxicological testing (see above).
The notifier states that examples of networks to be included in the general surveillance will be provided at the time of the first import of grain based on the outcome of the ongoing discussion between industry and authorities (BCS response to member states objections, 18th October 2004). This cannot be viewed as a satisfying proposal for a general surveillance plan. Details on networks involved, methodology used, location and frequency of monitoring activities must be provided before placing on the market of a genetically modified product.

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