

## Scientific arguments for an import ban of herbicide tolerant oilseed rape GT73 (Notification C/NL/98/11)

The statement is based on the previous statements of Austria during the notification procedure of herbicide tolerant OSR GT73 (notification C/NL/98/11) and takes into account the responses of the notifier to the statements of the Member States as well as the opinion of the EFSA GMO panel.

### 1. Flaws in the toxicological and allergological risk assessment

Regarding the **allergological risk assessment** the approach chosen by the notifier for the product in question is considered to be unsatisfactory. A recently published opinion paper based on scientific expertise (SPÖK et al. 2005) seriously questions the current approaches for assessing the allergological risks of genetically modified organisms. This is also relevant for GT73 oilseed rape. The methods used can neither predict nor exclude with sufficient certainty allergenicity of a protein nor do they provide any information on the allergenic potential of a genetically modified plant as a whole. It is suggested to assess the whole genetically modified plant and not only the isolated proteins in order to include an assessment of possible pleiotropic effects which could be caused by the insertion of the foreign genes. Furthermore, it is suggested to test extracts from different tissues of the product in order to consider different exposure scenarios. Finally, experimental testing of the whole plant, i.e. serological testing for IgE reactivity with a representative number of sera from allergic patients is proposed (SPÖK et al. 2005).

The acute oral toxicity tests of the newly introduced proteins being the only toxicological testing regime within the **toxicological risk assessment** is considered to be insufficient. The statements that the introduced proteins can only act in an acute way and that they will be digested rapidly in the gastrointestinal tract are only supported by very poor scientific data. Acute toxicity testing has little relevance for substances or products which will be fed or consumed over a lifelong period. Also the question of the whole plant toxicity of GT73 oilseed rape is not dealt with adequately. The feed conversion studies provided by the notifier would only reveal very distinct toxic effects. Certain toxicological properties will only become evident in case of systematic testing. In order to assess the toxicological safety of GT73 oilseed rape a 90-day subchronic toxicity testing regime should be included and if necessary other relevant toxicity testing (SPÖK et al. 2004).

## **2. Flaws in the environmental risk assessment and monitoring plan**

### **a) Accidental spillage of GT73 oilseed rape**

Accidental spillage of herbicide tolerant oilseed rape GT73 is considered as a major risk and corresponding monitoring and emergency plans were required during the commenting phase of the notification of GT73 by several member states. Nevertheless accidental spillage of GT73 oilseed rape has not been considered as relevant by the notifier and neither an adequate proposal for monitoring of accidental spillage nor emergency measures were proposed in the monitoring plan.

Feral oilseed rape patches can arise from seed spillage at harvest, transport by farm machinery or trucks, seeds in excavated soil used for constructional and horticultural activities, from the soil seed bank, animal dispersal or other unknown origin. Because of its size and shape oilseed rape seeds are particularly prone to loss during harvest, transport and processing activities. Consequently, imported genetically modified oilseed rape GT73 may be introduced into the wild due to seed spillage during importation and transportation operations.

Accidental spillage of GT73 oilseed rape along roadsides, on field margins and in other disturbed habitats can be considered as highly likely. There is evidence that the main origin of feral oilseed rape patches along motorways is seed spillage from farm machinery and from lorries during transport to seed processing plants (CRAWLEY & BROWN 1995). Also more recent studies support the importance of incidental transport losses for feral oilseed rape populations growing on the verges of motorways. Feral oilseed rape densities were consistently and significantly higher over a ten year period on motorway verges leading to a processing plant than in the opposite way (CRAWLEY & BROWN 2004). Similar results were reported by PIVARD et al. (2005) who found that the frequency of feral populations of oilseed rape along roads directed towards a silo cannot be explained by past land use only thus indicating seed shedding during transport. They estimated that about one third of a feral oilseed rape population is due to annual seed immigration, both from transport losses and from neighbouring fields. More than one third is due to the soil seed bank and therefore seed persistence.

In conclusion it can be assumed that transport loss is a major factor for the establishment and persistence of feral oilseed rape populations.

### **b) Environmental consequences of accidental spillage**

Due to its primary colonizing nature oilseed rape has the potential to maintain ever-present populations in non-natural ecosystems including roadsides or industrial and waste sites (OECD 1997).

First evidence that feral oilseed rape populations can persist many years in self-sustaining populations via local recruitment or via seed banks even outside of cultivated fields was provided by PESSEL et al. (2001). Also recently published research results indicate the permanent character over longer time periods of some feral oilseed rape patches while other feral patches of oilseed rape

disappear rather quickly. The existence of patches of feral oilseed rape on verges of motorways which last longer than a single year or even show no decline over a time period of 10 years was shown by CRAWLEY & BROWN (2004). These results are supported by modelling studies which indicate that isolated patches of feral oilseed rape can persist for decades or even centuries despite other sites go extinct within five to ten years. Local extinction events can be compensated by few adjacent patches which remain more or less fixed in space and are likely to persist much longer than expected (up to 150 years, CLAESSEN et al. 2005b).

There are indications that feral oilseed rape populations are able to build up long persisting soil seed banks. In a recent investigation only three out of nine feral oilseed rape populations were closely related to commercial varieties which had been planted during the past five years (PASCHER et al. 2006). The genotype assessment showed that depending on the agricultural area the genetic composition of only few individuals of the feral populations was similar to that of the respective commercial varieties grown in the same area. This indicates that these feral populations mainly descended from the soil seed bank or from seed loss due to transport activities. Additionally, the feral populations had a higher allelic richness than the commercial varieties which had been cultivated in the respective areas possibly indicating hybridisation events, founding events or genetic drift in these populations. Feral oilseed rape populations which were located in close vicinity of agricultural oilseed rape fields were not related to these commercial varieties to a higher extent than spatially isolated feral populations thus also indicating that feral populations have a more permanent character than previously assumed.

Evidence that the distribution of feral oilseed rape populations is not restricted to the cultivation context and to sites where harvest losses are expected is given by BRECKLING & MENZEL (2004). The dispersal pattern of feral oilseed rape populations was not restricted to the vicinity of cultivation or transportation sites with seed loss as the main source of occurrence. Feral oilseed rape was found in urban areas such as the harbour area, adjacent industrial sites, and neighbouring traffic axes including rail tracks and housing areas. CRAWLEY & BROWN (2004) have shown that feral oilseed rape populations do not correlate with total agricultural oilseed rape production. These results indicate that fluctuations in feral oilseed rape populations do not necessarily reflect agricultural production fluctuations.

Also recent simulations of population extinction times show that even under low disturbance and therefore unfavourable conditions for feral oilseed rape the expected time for persistence is estimated to be six to ten years (CLAESSEN et al. 2005a). Considering higher disturbance and therefore more favourable conditions a feral oilseed rape patch may persist for several decades. Moreover, the same authors estimated that seed spills of oilseed rape of at least 10.000 seeds are likely to result in a feral oilseed rape patch with more than 100 plants. However, also half of the feral oilseed rape patches seeded by 1000 seeds persist for five years and a small fraction persists for 20 years. Spills of more than 10.000 seeds can persist at least 10 years and even longer (CLAESSEN et al. 2005a).

Research on persistence of seeds of oilseed rape in agricultural fields indicates extremely long time periods until these seeds disappear from a certain soil seed bank. The preliminary results of LUTMAN et al. (2005) have shown that in agricultural systems on average 7,6 years are necessary to achieve a seed loss of 95%. Low levels of seeds will persist for at least ten years and at maximum 19 years, depending on the cultivar and the site. Loss of 99% of seeds was predicted to take up to 49 years.

These results strongly indicate that feral populations of oilseed rape are not exclusively ephemeral but can establish stable and self-dispersing, cultivation-independent populations over several years in disturbed habitats outside cultivation or agricultural areas.

### **c) Relevance for Austria**

Austria imports approximately 100.000 tons of oilseed rape per year with the majority of imports coming from Hungary, followed by Slovakia (REINER 2005). Considerable amounts of oilseed rape are also imported from Germany, which itself imports large amounts of oilseed rape from Belgium and Holland where genetically modified oilseed rape GT73 will be landed from overseas. Some oilseed rape is directly imported to Austria from Canada and China (REINER 2005). Due to a decrease in oilseed rape production in Austria an increase in imports of oilseed rape is expected over the next years. Oil mills in Austria also use and process oilseed rape which is not cultivated in Austria, especially for the production of margarine and edible fats (REINER 2005). These oil mills are not directly located at points of entry and therefore the risk of accidental spillage has to be considered also for countries which depend on transports from oilseed rape importing countries in the European Union.

Latest research results strongly suggest that feral oilseed rape populations origin from transport losses, can build up persistent and self-sustaining populations outside agricultural areas and are not exclusively dependent on recruitment from agricultural fields every year. Feral oilseed rape can be frequently found in Austria along transport routes such as motorways, highways, railway tracks, roads or lanes (see PASCHER & DOLEZEL 2005 and references therein). In case of accidental spillage of GT73 oilseed rape it is assumed by the notifier that no selective advantage is conferred to GT73 oilseed rape as no selective pressure is exerted on the plants in the respective habitats. However, total herbicides such as Glyphosate are regularly applied at least once a year on railway tracks by the Austrian Railway Company with different intensities (SATTELBERGER 2001). Also on motorways and highways, especially near fences for game animals and parking areas, total herbicides are applied as illustrated by the use of considerable amounts of Glyphosate-containing herbicides on highways and motorways in Lower Austria in 1999 (SATTELBERGER 2001). Glyphosate is also used infrequently on industrial sites. Consequently, it can be concluded that it is likely that in case of accidental spillage in these habitats a selective advantage would be conferred to GT73 oilseed rape when Glyphosate is applied. Therefore the presence and establishment of GT73 oilseed rape due to seed spillage in these habitats should be subject to an intensive monitoring.

Additionally, presence of GT73 oilseed rape along transport routes near or in agricultural areas and consequently transfer of the herbicide tolerance trait to other cultivated oilseed rape plants or other *Brassica* species could also affect co-existence with conventional oilseed rape fields in the respective agricultural area. Feral oilseed rape as well as oilseed rape volunteers have the potential to cause impurities in oilseed rape crops (DEFRA 2003). GT73 oilseed rape is notified for import and processing only and not for cultivation within the European Union. Large scale spills of GT73 oilseed rape might therefore locally affect co-existence. A recent study has shown that for the seed production of oilseed rape in Austria co-existence is not feasible. Thus closed seed production areas will be necessary in order to minimize the risk of the presence of any source for contamination (AGES 2004), with which the presence of accidentally spilled and persistent GT73 oilseed rape could interfere.

No detailed monitoring plan has been provided by the notifier which foresees how the presence of GT73 oilseed rape in agricultural or non-agricultural areas will be monitored. Similarly, no emergency plan has been submitted in case accidental spillage is detected in order to minimize any environmental risk resulting from the presence of GT73.

### **3. Conclusion**

Both the toxicological and allergological risk assessments of GT73 oilseed rape are considered to be inadequate regarding the choice of methods. The data provided by the notifier do not give enough evidence that the use of GT73 oilseed rape is safe from a toxicological and allergological point of view.

Additionally, the monitoring plan does not take into consideration accidental spillage and its environmental consequences. Unprocessed oilseed rape is transported to Austria in considerable amounts, feral oilseed rape populations can be found along transport routes where Glyphosate is applied and oilseed rape seeds can establish and are likely to build up persistent populations. Therefore it can be considered as highly likely that imported GT73 oilseed rape will spread and persist in certain habitats in Austria. Due to the fact that GT73 oilseed rape is herbicide tolerant the application of Glyphosate in these habitats would confer a selective advantage to feral GT73 oilseed rape plants. For a complete risk assessment the knowledge of the frequency distribution of seed spills is therefore inevitable. Neither a monitoring plan nor an emergency plan was provided by the notifier in order to monitor the presence of GT73 oilseed rape in case of accidental spillage. Finally, co-existence issues of accidental seed spills of GT73 oilseed rape with conventional oilseed rape production are still unsolved.

## 4. Literature

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