

## **Comments from the public : T45 Oilseed rape**

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**Organisation: Individual**

**Country: Finland**

**Type: Individual**

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**a. Assessment:**

**b. Food Safety Assessment:**

**Toxicology**

Finland does not protect citizens from animal products produced with genetically modified crops. The freedom of food choice is guaranteed, but consumers, especially school children, do not have any choice, because public schools do not offer meals prepared from gm and gm-free raw materials separately. Additionally animal products produced with gm-crops are not labelled. Reasonable risk assessment requires at least 10-50 years (> 2 generations) observation before the impact on both animal and consumer's health is evident. The opinion of the GMO Panel is based rather on believe than on scientific research. The consumer is not concerned about the knowledge of the members of the GMO panel in respect of the applicant's crop but rather about what they do not know and therefore assume.

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**Allergenicity**

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**Nutritional assessment**

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### **Others**

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### **3. Environmental risk assessment**

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### **4. Conclusions and recommendations**

Rejection of the application

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### **5. Others**

All animal products produced from animals fed with the applicants product should be labelled as "produced with genetically modified crops"

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**Organisation: Individual**  
**Country: United Kingdom**  
**Type: Individual**

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**a. Assessment:**

**3. Environmental risk assessment**

Experiences in Canada, where T45 oilseed rape is grown, are showing that 'super-weeds' are already emerging. A study by English Nature (Gene Stacking in Herbicide Tolerant Oilseed Rape; Lessons from the North American Experience - English Nature Research Report No 443) revealed the widespread emergence of multiple herbicide resistant volunteer oilseed rape plants following the growing of GE oilseed rape in the Canadian prairies. As a result, known toxic chemicals are being used to control the new weeds. The use of GE crops is also leading to the genetic contamination of seed production by GE varieties. Therefore we should not be encouraging further damage in Canada by allowing the placing on the EU market of food, feed and other products containing, consisting of or produced from genetically modified oilseed rape T45. For that reason I wish to lodge an objection to this application.

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**Organisation: None**  
**Country: United Kingdom**  
**Type: Individual**

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**a. Assessment:**

**Others**

It is not clear that it is guaranteed that by a GM process that no other proteins or other chemicals will be formed in the organism that are not naturally present in a GM alternative. From experience of long term effects of even very small amounts of unnatural chemicals in the environment (for instance pesticide residues) it seems exceedingly unwise to release organisms that potentially have this effect and due to spread of pollen to non-GM plants may not be containable.

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**3. Environmental risk assessment**

Release of an organism that can become persistent in the environment through escape of seeds, pollen or remnants in the soil seems exceptionally unwise if there is the remotest chance that this will have any adverse impact on the people or animals that consume it, or on the environment as a whole. Unknown genetic stability across many generations, or the effect of natural mutations on the GM modifications both increase the risks.

It does not seem that any GM modification has benefits that as yet outweigh these risks.

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#### **4. Conclusions and recommendations**

Do not allow the marketing of any GM products for food or animal feed in the EU.

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**Organisation: Individual**

**Country: Sweden**

**Type: Individual**

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**a. Assessment:**

**b. Food Safety Assessment:**

**Toxicology**

I dont want any genetically modified oilseed rape T45 at all in my food, not direct or via animals. The GMO process stinks.

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#### **4. Conclusions and recommendations**

Stop all GMO handling! The whole world is hurt by it!

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**Organisation: University of Helsinki**

**Country: Finland**

**Type: Individual**

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**a. Assessment:**

**3. Environmental risk assessment**

The spreading of pollen cannot be prevented. Pollen can sometimes even travel 1000 km to areas where there are no GM plants.

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#### **4. Conclusions and recommendations**

Oil seed rape should not be allowed in Europe.

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**Organisation: Consiglio dei diritti genetici**

**Country: Italy**

**Type: Non Profit Organisation**

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##### **a. Assessment:**

###### **Molecular characterisation**

The informations on SNIF refer to analysis conducted by applicant and not disposable for the public. This means that we can't draw conclusions on human and animal safety of the product. We think that explanations regarding the integrity and the equivalence of the insert are needed, with respect to the sequences of the plasmid used for the transformation. Furthermore the expression of bar gene in the plant tissues, regarding both protein and RNA, should be analyzed. Finally it would be better if we could verify the unattended potential effects on the expression of other plant genes, due to the transformation technique, comparing the profile expression of the mRNA and of the protein synthesis of GM plants with the isogenic counterparts.

Le informazioni riportate nello SNIF (Summary Notification Information Format) si riferiscono ad analisi condotte dal notificante e non disponibili al pubblico. Questo non consente di trarre delle conclusioni sulla sicurezza per la salute umana e animale del prodotto. Riteniamo necessari chiarimenti sull'integrità ed equivalenza dell'inserto rispetto alle sequenze del plasmide utilizzato per la trasformazione; inoltre andrebbe analizzata l'espressione del gene bar nei tessuti della pianta, a livello sia di proteina sia di RNA. Infine, sarebbe opportuno verificare i potenziali effetti indesiderati sull'espressione di altri geni della pianta, dovuti alla tecnica di trasformazione, confrontando i profili di espressione di mRNA e di sintesi proteica delle piante GM con i corrispettivi isogenici.

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###### **Comparative analysis (for compositional analysis and agronomic traits and GM phenotype)**

The compositional analysis shows several statistically significant differences between oilseed rape T45 and the non-transgenic counterpart. Particularly the linolenic acid levels are 22% higher in T45 oilseed rape and significantly increased levels of the anti-nutrients indole glucosinolates and total glucosinolates are found. These results show that the biochemical pathway of the GM oilseed rape has been changed. Therefore a deeper evaluation of the characteristics of this product seems necessary, to verify the compositional equivalence with traditional oilseed rape.

Per quanto riguarda la composizione, la colza T45 presenta una serie di differenze statisticamente significative rispetto al controllo; la più rilevante riguarda il contenuto di acido linolenico, che è del 22% più elevato nel prodotto GM. Inoltre aumentano i livelli di glucosinolati, composti potenzialmente tossici.

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## **b. Food Safety Assessment: Toxicology**

Despite the absence of a compositional equivalence between T45 and non-transgenic counterpart, the 90-days toxicological study on rodents was not carried out. We remember that this study is requested by EFSA when GM product and traditional counterpart have significant differences.

Nonostante l'assenza di equivalenza compositiva tra T45 e controparte non transgenica, il notificante non ha effettuato lo studio di alimentazione di 90 giorni con i roditori, che invece è richiesto dall'EFSA quando prodotto GM e controparte tradizionale manifestano significative differenze.

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## **Allergenicity**

The allergenicity of the GM oilseed rape T45 has not been evaluated with experimental analysis and the conclusions of safety are based only on deductions. There is not substantial equivalence between traditional oilseed rape and GM oilseed rape, thus analysis should be conducted to check the possibility of allergological risk of the GM plant.

Le proprietà allergeniche della colza T45 non sono state valutate sperimentalmente e la loro assenza è dichiarata unicamente in base a prove indirette. Però, poiché non c'è sostanziale equivalenza tra T45 e controllo, appare necessario verificare la possibilità di rischio allergenico della colza GM.

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## **3. Environmental risk assessment**

In this application the authorisation for cultivation of T45 oilseed rape it is not requested in Europe. But volunteer plants of GM type could grow from lost seeds too, during the transportation, storing, processing and use by farmer. These seeds could persist in the ground and produce volunteer plants for several years after their release. In agricultural environment, where glufosinate-ammonium is used, these volunteer plants would have a great selective advantage. Oilseed rape has a high percentage of cross fertilization and can spread a great amount of pollen on long distances both through the wind and, above all, bees and bumblebees. Furthermore the culture, also the T45 variety, is capable of forming vital and persistent hybrids with some wild plants species of the spontaneous European plant life. For these reasons we think that a case-specific monitoring plan is necessary, in order to control the potential gene flow deriving from the inevitable and accidental seed release and from the

growing of volunteer plants of oilseed rape T45. Finally, in the proposed hypothesis of general surveillance plan, the monitoring at the level of farm should have a greater weight.

Nella notifica non si richiede l'autorizzazione per la coltivazione della colza T45 in Europa, ma piante volontarie della coltura GM potrebbero svilupparsi anche da semi perduti durante le operazioni di trasporto, stoccaggio, trasformazione e uso a livello di fattoria. Tali semi potrebbero persistere nel terreno e generare piante volontarie per diversi anni successivi al rilascio. Negli ambienti agricoli in cui viene usato il glufosinato d'ammonio queste piante volontarie avrebbero un considerevole vantaggio selettivo. La colza è una coltura con alta percentuale di fecondazione incrociata e può diffondere considerevoli quantità di polline su lunghe distanze sia tramite il vento sia, soprattutto, tramite api e bombi. Inoltre, la coltura, compresa la varietà T45, è capace di formare ibridi vitali e persistenti con alcune specie di piante selvatiche presenti nella flora spontanea europea. Per questi motivi riteniamo necessario un piano di monitoraggio caso-specifico, predisposto per controllare l'eventuale flusso genico derivante dall'inevitabile rilascio accidentale di semi e dallo sviluppo di piante volontarie di colza T45. Infine, nell'ipotesi di piano proposta per la sorveglianza generale dovrebbe avere un peso maggiore il monitoraggio a livello di azienda agricola.