

BEUC

The European Consumers' Organisation

Bureau Européen des Unions de Consommateurs

Avenue de Tervueren, 36/4

B - 1040 Bruxelles

Tel: (32 2) 743.15.90

Fax: (32 2) 740.28.02

consumers@beuc.org

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Subject: Adventitious or unavoidable presence of GM seeds in seed lots of non- genetically modified plant varieties

BEUC, the European Consumer Organisation, representing 33 independent consumer organisations from 23 European countries, welcomes the opportunity to comment on the Commission working document : P: bn/doc2001/va/1542-jan2002

COMMISSION DIRECTIVE .../EC of [...]amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC and 70/458/EEC on the marketing of beet seed, fodder plant seed, cereal seed, seed-potatoes, seed of oil and fibre plants and vegetable seed and Decision 95/232/EC on the organisation of a temporary experiment in order to establish conditions to be satisfied by the seed of hybrids and varietal associations of swede rape and turnip rape

BEUC and its member organisations have carefully analysed the working document.

We wish to comment on the explanatory notes, which we believe should be recorded in the regulatory text:

General Comments

We consider this working document the basis for further discussion on the traceability and labelling of GMO food and feed. It is consequently an important step to realise honest label claims of final food products.

Therefore we think it is important to consider seed, legislation on traceability and GMO food and food authorisation and labelling in one unity as it all contributes to the consumer right to exercise free choice of food based on honest labelling information.

Individual comments on the explanatory notes

Scope

It is mentioned that the scope of the draft Commission Directive is limited to the plant species for which genetically modified varieties have currently been obtained and which are cultivated in the EU irrespective whether the seed was produced or harvested in the EU or in a third country.

The legislative text applies to: beet, maize, potato, swede rape, soya bean, cotton, chicory and tomato.

We understand that the Scientific Committee on Plants in its opinion of 7 March 2001 delivered figures for the GMO contamination of seeds to assure compliance with the requested threshold of 1 % in the final

food product.

Discussion in the European Parliament indicate that the level of 1 % for GMO food and feed is still subject of further consideration.

?? Consumers are clearly in favour of case by case decision for the fixing of thresholds for food products with the aim to achieve threshold levels at the lowest possible level, however never exceeding 1 % for adventitious contamination.

?? We are therefore concerned that the working document on accidental seed contamination exclusively considers one fixed threshold of 1 % for final food products, which might give raise to too high threshold of allowed seed contamination's, consequently influencing the correctness of the final food label claim. We refer to a speech given by Commissioner Fischler at the AGRIBEX Food Fair in Brussels on February 13. *"This Directive should increase a tolerance threshold for accidental contamination not exceeding the quantitative detection threshold (about 0.1%)., Franz Fischler, called for a policy which protects farmers who grow conventional or organic crops from accidental GMO-contamination"*

We understand that in the case of new releases of GMOs into the environment the annexes of the seed marketing directive will be adjusted accordingly later on.

?? Given the fact the adventitious contamination may occur any moment that GMOs are introduced into the environment we find it necessary to allow the release of new GMOs into the environment only if the thresholds for adventitious contamination in relation to the final food product are defined.

?? GMO crops might be grown for industrial purposes - non-food and non-feed –applications. We ask to consider a possible adventitious contamination and therefore suggest that industrial application must undergo an equally strict approval system as GMO food and feed.

?? Seed is the basis of food production and therefore the levels of contamination for non-GMO-seed with GMOs should be at the lowest level possible as they are determining any further contamination of food and feed.

?? We agree that we need a sound scientific basis for setting contamination levels in seeds. In the opinion concerning the adventitious presence of GM seeds in conventional seeds the Scientific Commission on Plants uses data from an unpublished source (ESTO). A check on the scientific value of the data is impossible. Moreover, the data represent 'mean values', which means that in practice higher values are possible.

We suggest therefore to follow a more cautious approach, starting from the most critical case like situations, consequently trying to consider possible ways to achieve non-contamination with GMOs.

?? We are concerned that this legislation is considered under the comitology procedure as we think that the adoption of the annexes of the seed marketing directive need to be seen in close connection with the aims of the traceability as well as GMO feed and feed legislation, which are considered under the co-decision procedure.

Recommendations:

It is necessary to:

?? consider the threshold of seed in relation to accepted adventitious contamination in food and feed, following the most cautious approach and therefore trying to set threshold at the lowest possible level, starting from a non-seed contamination with GMOs

?? consider also possible contamination of non-food and feed applications of GMO crops for industrial uses, providing they have undergone a proper risk assessment according to Regulation 2001/18.

?? look at any adoption of the annexes of the seed marketing directive in close relation to food and feed legislation in order to have realistic thresholds set for seeds.

Different requirements

Thresholds for authorised GM seed

The working document refers to the Commission Regulation (EC) n° 49/2000 fixing a maximum level of 1 % for the adventitious presence of genetically modified material in food and food ingredients and suggest that it is also covering 1 % threshold for beet, maize, potato, swede rape, soya bean, cotton chicory and tomato.

?? The Commission Regulation (EC) n° 49/2000 covers the threshold of 1 % for soya beans (glycine max L) or maize (Zea maize L), according to our understanding it is not covering other GMOs. Therefore, we have concerns that this assumption is correct and ask for clarification in this respect.

The working document refers the opinion of the Scientific Committee on Plants of 7 March 2001 and explains that the reproductive system of the plant as well as the probability of volunteers, as confirmed by the SF should be taken into account.

This opinion states the following thresholds:

- 0.3% in the case of cross-pollinating crops,
- 0.5% in the case of self-pollinating crops and vegetatively propagated crops.

?? The threshold of 0.7 % for soya bean, as a self pollinating crop was not considered by the Scientific Committee and we are therefore apprehensive that it might not be possible to match the threshold of 1 % for food and feed final products.

?? Given the influence of the contamination for food and feed we think the legislation on traceability and labelling as well as GMO food and feed should be carefully considered.

Recommendations

?? Threshold levels should always be set on a case by case basis, consequently the estimated threshold for seeds should take this into consideration.

?? Given that the opinion of the Scientific Committee on Plants considers a threshold of 0.5 % for cross pollinating plants. We understand that the data presented in the opinion of the Scientific Committee on Plants are "mean values" which means that in practice higher values are possible. The threshold of 0.7% for soya, we are afraid, could therefore possibly not meet the final food threshold of 1 % taking into consideration the reproductive system of plants.

?? Any establishment of seed thresholds for non-gmo seed with GMOs should strictly take into consideration the requirements resulting from the traceability and GMO food and feed legislation. We are therefore in favour of an integrated, seed, feed and food approach also with regard to legislative considerations.

Threshold for unauthorised GM seeds

Special attention is paid to the threshold for unauthorised crops.

We appreciate that the Commission has just presented a proposal of regulation aimed at transposing into Community law the provisions of the Cartagena Protocol on the prevention of biotechnological risks linked to cross-border movements of live genetically modified organisms (GMOs) likely to have harmful effects on biological diversity, aiming to complete the existing legislation on biotechnology.

Since we are very concerned about any contamination of seeds with non-authorized GMOs, we would like to stress that:

- ?? all appropriate steps are taken to avoid contamination;
- ?? the product has been the subject of positive risk assessment procedures under 2001/18/EC for live GMOs and under the relevant procedures dealing with GMO derived food and feed;
- ?? we need reassurance that the same care would be taken with regard to imports, for which it is not possible to check for adventitious contamination if the appropriate reference material is not available.

Regulation on sampling and testing

We suggest that appropriate sampling and testing is the basis to provide the conditions for good functioning of inspections systems which is so far considered one of the failures of the current system.

We therefore claim that:

- ?? validated testing and sampling methods are developed;
- ?? suitable reference material needs to be available to assist in the assessment(s).

Isolation distances and Good practice for seed production

Isolation distances have been considered in the opinion of the Scientific Committee on Plants of 7 March 2001.

- ?? No special attention has been paid to organic farming. We are therefore concerned that a threshold, being considered to meet the final food standard of 1 % adventitious contamination could not fulfil the special requirements for organic production.
- ?? For organic farming no contamination with GMOs is acceptable.

Recommendation

- ?? Special attention should be paid to requirements for organic production systems. Reference should be made when and where this question will be addressed. We think that organic production should be seen as a food production system having its role in the agricultural system.
- ?? Special attention should be paid to the best-possible avoidance of cross- pollination. (see annex 1— suggestions for considerations made by C&B, the biotechnology adviser of the Dutch Consumer Organisation Consumentenbond).

The nature and potential degree of contamination depends on the characteristics of the organism and the characteristics of the production chain (harvest-storage-transport-processing-packaging.¹ And therefore good practices for seed production are crucial and we think further guidance should be provided.

¹ INRA Study, presented on 19 November 2001 by Madame F Angevin at CNC (Conseil National de la Consommation)

Exemptions from the examination of the satisfaction of requirements

It is mentioned that the various requirements related to the seed lot, might not be carried out under given conditions, including the establishment and subsequent monitoring of areas for seed production for which it has officially been ensured that genetically modified plants of the same species or of a closely related species are not grown. Suitable arrangements should be taken at least by check inspection as regards compliance of the seed crop or seed lot with the requirements.

Reference to exemptions is made in every annex.

It is said;

“The examination of the satisfaction of these requirements need not be carried unless there is doubt whether the requirements have been satisfied, provided that suitable arrangements are taken at least by check testing as regards the compliance of the seed lot with the requirements”

?? We think this gives room for subjective interpretation and does not contribute to increase confidence in a system aimed at the avoidance of gmo contamination of non-gmo supply.

Recommendations

?? BEUC considers that further clarification is needed, in order to avoid misinterpretation and mistrust in regulations.

?? We find it important that also in the case of exemption the integrated approach of see, traceability, food and feed is considered with the aim to ensure honest and correct labelling of GMO feed and food.

Conclusion

1. BEUC thinks that it is important to follow an integrated seed - traceability and GMO food and feed approach to create the provisions for honest labelling claims of food products
2. Food and feed thresholds should be considered on a case by case basis, consequently seed thresholds should be established accordingly, but following the most cautious approach.
3. We think it is not sufficient to consider just cross- pollinating and self-pollinating with one individual threshold each, thresholds, if at all need to be considered in context with the production technology it is going to be used for, which means no contamination for organic farming and the lowest achievable threshold for conventional farming.
4. 0.7% tolerated contamination of soya with GMO is not in line with the Scientific Opinion for self pollinating crops of 7 March 2001 and we therefore have serious doubts whether it will be possible to comply with 1 % threshold for adventitious contamination in final food products.
5. When defining thresholds for adventitious contamination with GMO also seed for industrial use only, providing that it has undergone a rigorous approval procedure in compliance with Directive 2001/18, should also be looked at.
6. Good farming practice should be applied in order to reduce pollination to the absolute minimum. Appropriate means to achieve this aim should be further explored. This might be subject to seed manufacturing guidelines.
7. The special requirements for organic production need special attention. Action is needed to prevent

any contamination by GMO varieties .We are missing this consideration entirely in this working document.

8. Adventitious contamination with non-authorized GMOs is of specific consumer objection. Therefore imports from third countries should be treated with the same scrutiny as seeds produced in Europe.
9. We suggest putting in place the appropriate sampling system and the estimation of validated test methods.

The availability of reference material is hereby decisive for the application of testing methods and should be available prior to considerations of thresholds.

We think the Community should strengthen all its power in international agreements to establish a common "gene bank" for all existing GMOs in the world, with available reference material and corresponding analytical methods.

Annex 1

How to consider pollination – suggestions of Consumers and Biotechnology, Biotechnology Adviser of Consumentenbond in the Netherlands

Different possibilities for pollination should be considered, such as:

1. The characteristics of the organism or production chain do not lead to contamination. In that case no additional requirements are necessary.
2. The characteristics of the organism or production chain lead to controllable contamination, e.g. cross-pollination over relatively short distances or volunteers that do not survive the winter season. In these cases requirements concerning the contamination itself are necessary. For instance isolation distances, physical barriers around fields with GMO seed crops or a minimum latency in case of volunteers.
3. The characteristics of the organism or production chain lead to controllable contamination but it will be practically impossible to check the correct implementation the type of requirements meant previously. For instance in case of large-scale farm production it may become practically impossible to implement isolation distances. In that case additional requirements concerning the characteristics that cause the contamination problem are necessary. For instance, the requirement to disable the pollination potential of the organism by male sterility;
4. The characteristics of the organism or production chain lead to uncontrollable contamination, e.g. cross-pollination over long distances. In that case additional requirements concerning the characteristics that cause the contamination problem are necessary. For instance, the requirement to disable the pollination potential of the organism by male sterility;