

QUESTIONNAIRE FOR STAKEHOLDERS ON THE IMPLEMENTATION OF REGULATION (EC) N°1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED

[Stakeholders to be consulted:

EuropaBIO (bioindustry), Amfep (enzyme producers), FEFANA (feed additive industry), Fediaf (pet food industry) ELC (food additives and enzymes industry), ESA (seed producers), COCERAL (grain trade), COPA/COGECA (farmers), FEFAC (feed industry), CIAA (agro-food industry), CELCAA (agro-food trade), EuroCoop (consumers co-operative), BEUC (consumers), EEB (environmental bureau), Friends of the Earth International (environmental NGO), Greenpeace (environmental NGO) = 16]

Your contact details:

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The questionnaire to stakeholders has the following objectives in view of the preparation of the report provided by Article 48(1) of Regulation (EC) N°1829/2003 on GM food and feed:

- to describe the experiences stakeholders had in implementing the Regulation,
- to identify any difficulties that have come up in implementing the Regulation,
- to make recommendations on how to strengthen the consistency and efficiency of the Regulation.

This questionnaire addresses various aspects of the implementation of Regulation 1829/2003. Please feel free to only answer the questions that you consider as relevant to your organisation.

Please return the questionnaire to Maria Gassavelis by 5 May 2005: maria.gassavelis-alcaide@cec.eu.int or fax: +32/2/295.17.35

If you have questions regarding the questionnaire, please contact Sébastien Goux, Tel: +32-2-292.15.55, e-mail: sebastien.goux@cec.eu.int

1. LEGISLATION AND PRACTICE

1. Have there been any problems with the interpretation of the Community legislation (Regulation (EC) N° 1829/2003, Regulation (EC) N° 641/2004)? If so, please give details.

There have been some problems with regards to the 0.9% threshold, in particular concerning:

- the lack of implementation of the requirement that the operator has to prove that the presence of GM material is adventitious or technically unavoidable. Some national authorities seem to consider that there is a general tolerance of 0.9% of GM content in all non GM products. It should be made clear that this is a wrong interpretation of Regulation 1829/2003. In addition, there has also been some misunderstanding on the “per ingredient” requirement.
- the fact that some national authorities use the 0.9% threshold as “baseline rule” in determining their national measures on the so-called “co-existence” policy. These authorities claim that Member States are not allowed to make national co-existence measures stricter than is necessary to meet the 0.9% threshold, thus risking to make genetic contamination a fait-accompli. According to the legal advice of Paul Lasok “*in relation to Coexistence, Traceability and Labelling*” (March 2005) this approach has no basis in Community legislation and is wrong in law. It concludes that the labelling thresholds (0.9%) are “legally irrelevant” to deciding how to implement co-existence measures and that, in this respect, the July 2003 Commission’s guidelines on “co-existence are “fundamentally flawed”.

2. What is your experience on the implementation of the labelling rules of Regulation (EC) N° 1829/2003? Do the new labelling rules have a positive effect in terms of facilitating informed choice and precluding potential misleading of consumers and farmers as regards methods of manufacture or production? Please provide details.

The new labelling rules – compared with the past situation – are facilitating a better informed consumer choice, even though labels are often small and well-hidden. However, the labelling rules need to be improved so as to close the major loophole in the regulation concerning the lack of mandatory labelling for animal products derived from animals fed with GM-feed.

Therefore the EEB calls for a revision of the regulation so as to allow a full informed consumer choice that would reward both farmers and food-producers. In fact, although farmers and producers know that consumers would reward the use of non-GM feed, they at present are deprived of this reward. It is also true for operators further down the production chain. By preventing consumers from rewarding and

punishing producers, the exclusion of animal products from the scope of the regulation constitutes a market failure where competitive pressure encourages the use of GM crops in feed.

3. How are the provisions on Article 47 of Regulation (EC) N° 1829/2003 and Regulation (EC) N° 641/2004 on the threshold of 0.5 % adventitious presence of GMO material been implemented? Please provide details.

There seems to be problems concerning whether or not approved GMOs – which are later banned – will qualify for the 0.5% threshold. It is likely that the authorisation of some GMOs approved under the previous legislation will not be renewed after October 2006. It will be three years after the regulation entered into force, so according to art. 47(5) no threshold should apply for these GMOs.

2. AUTHORISATION PROCEDURE

4. Have there been any practical problems with the preparation of the applications for authorisation? If so, please give details.

So far we can mostly comment on problems encountered on applications under the Novel Food Regulation (258/97) and under Directive 2001/18/EC. However these problems will be relevant in the context of Regulation 1829/2003. The practical problems are :

- A large part of the application dossier is usually kept secret, even though this information do not qualify for confidentiality, e.g. under article 25 of Directive 2001/18.
- The information we do get access to is most often only available in paper format, so the process is delayed, and the paper limit us from efficiently sharing the information between relevant experts. We strongly urge the Commission to demand that the applicants submit all application information in electronic format. This way it can be easily searchable, accessible on the web, and it will most likely allow more time to comment on the application. Therefore, because of difficulties in getting access to the application information coupled to such practical problems, we usually have too little time to analyse it. Sometimes the time available is reduced to just a couple of days.
- Many Member States have not yet established procedures so as to allow comments from citizens and NGOs. Where these procedures are in place there is usually no feedback nor indication on whether our comments have been taken into account or not, and for which reasons.

5. In your opinion, how is the new authorisation procedure according to Regulation 1829/2003 functioning? Does this procedure contribute to increase consumer confidence on GM products that are placed on the market of the EU? Please provide details.

We have serious concerns about the way the new authorisation procedure according to Regulation 1829/2003 is functioning and we do not believe that this procedure will contribute to increase consumer confidence on GM products that are placed on the EU market. Our concerns are mainly related to the quality of the assessment performed by the European Food Safety Authority (EFSA), to the centralised procedure itself, and to the lack of equivalence between requirements under Directive 2001/18/EC and Regulation 1829/2003, especially as far as the environmental risk assessment is concerned.

- The GMO panel of the European Food Safety Authority (EFSA) was set up to contribute to an improved risk assessment of GM crops in the EU. However, analysis of the assessments made so far by the EFSA shows that the EFSA has not contributed to a higher level of consumer and environmental protection from GM crops and foodstuffs. The criticisms made of the old regulatory framework are still valid. The data are often of poor quality and where differences and irregularities have been found, these have not been followed up sufficiently. There is no rigorous scientific consideration of high quality data where any departures from substantial equivalence are investigated thoroughly. The European Commission and Member States have the duty to take action in order to make sure that the requirements and standards for risk assessment in the European legislation are met by the EFSA and by national competent authorities. For now, the key role given to EFSA in the Regulation is a serious cause for concern.
- The centralised procedure involve a lesser degree of scrutiny of the applications by Member States, or by the public. Therefore relevant questions are not asked, and are thus not answered. We believe that this takes the risk assessment further away from the precautionary principle, which has to be implemented both at risk assessment and risk management levels.
- From a legal point of view, it appears that the requirements on risk assessment, risk management, monitoring, information to the public, and safeguard clauses, as provided by Regulation 1829/2003 and Regulation 178/2002, are not equivalent to the requirements provided by Directive 2001/18. We believe that there is here a serious legal problem that needs to be solved before any application can be processed through Regulation 1829/2003. This situation is worrying especially for applications to place on the market "a GMO or food containing or consisting of GMOs". Therefore it should be urgently clarified, through a legally binding legislation, how the EFSA has to apply the legal requirements on risk assessment and monitoring of GMOs, as they are provided in the relevant EU legislation and in particular Directive 2001/18.

6. Have there been any practical problems with the preparation of the applications for authorisation? If so, please give details.

7. In your opinion, how is the information to the public (articles 5(2)(b)(ii), 6(7), 17(2)(b)(ii) and 18(7)) on applications for authorisations functioning? Please provide details.

It is not functioning effectively and the EFSA only makes a summary available to the public. Information to the public should not be less than what article 25 of Directive 2001/18/EC provides for. Therefore information that has to do with the risk assessment must under no circumstances be confidential (article 25(4) in the above mentioned directive). Only information that constitutes harm to the applicant's competitive position can be treated as confidential. The applicant must offer verifiable justification of this harm to competitive position. At the moment the confidentiality provisions are abused and their application not justified to most of the application dossier. This information must be publicly available as soon as the application is lodged. Applications can often be several thousand pages, so 30 days to comment from the moment the entire dossier is made public must be an absolute minimum.

3. OTHER ISSUES

8. What is your opinion on the fermentation products (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using genetically modified micro-organisms (GMM) which are kept under contained conditions and are not present in the final product:

- *should a risk assessment be required? Yes*
- *should labelling be required? No*

If yes, please provide details on the kind of risk assessment required and a labelling proposal.

Risk assessment should be required for GMMOs, taking into account the existing EU legislation on additives. The exclusion from labelling is justified on the grounds that the GMMO is kept under contained conditions. It would be appropriate to have an environmental risk assessment of the conditions that guarantee that the GMMO is fully contained; and a health risk assessment for the product produced from or with the GMMO.

9. *If relevant for your sector, please provide statistics for the last three years on*

- GM plants cultivated (ha/year) in EU:
- GM food imported (tn/year) to EU:
- GM feed imported (tn/year) to EU:
- GM food produced (tn/year) in the EU:
- GM feed produced (tn/year) in the EU:

10. *Are you of the opinion that Regulation 1829/2003 has a positive or negative impact on innovation in biotechnology sector?*

Positive

Negative

No effect Yes

Please provide reasons for your answer.

The regulation relates primarily to the use of GM crops. The innovative and knowledge intensive segment of the biotechnology sector is not the crop and seed sector but the medicinal and contained use of biotechnology. GM food and feed crops are exclusively Bt and herbicide tolerant crops, the use of which if anything would result in a de-skilling of the European farming sector.

11. *Would you like to comment on any other aspects of Regulation (EC) N° 1829/2003 or on other related legislation that would improve the EU legislative framework for genetically modified food and feed? If so, please give your comments.*

- In order to safeguard consumer choice on the long term, to keep the possibility to implement emergency and recall measures provided for in the legislation

and for many other reasons (that we would be happy to provide on request), no threshold for the presence of GM seeds in non GM seeds should be set up higher than the reliable detection level (0.1%).

- As mentioned in our reply to question 1, the labelling threshold (0.9%) is legally irrelevant for the determination of a threshold in seeds and for the development of national or EU “co-existence” legislations.
- In order to safeguard consumer choice on the long term and the interests of organic and conventional farmers, it is necessary to establish an EU binding legislation on the issue of “co-existence”. Such a legislation should recognise the environmental aspects of “co-existence”, include a liability regime and recognise the right of regions and local communities to ban the release of GMOs in the environment.