

Position

The Need of the European Seed Industry

for

Practicable and Sustainable Provisions

in view of

**Traceability and Labelling of GMOs
[Proposal for a Regulation of the
European Parliament and the Council
COM/2001/0182]**

and

**Labelling of GM food and GM feed
[Proposal for a Regulation of the
European Parliament and the Council
COM/2001/0425]**

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The legislative proposals on Traceability and Labelling of GMOs and on labelling of GM food and GM feed currently under discussion in the Council and already debated and amended in the European Parliament in its 1st reading of 03.07.2002 are of vital importance for the EU based seed industry - for plant breeders, seed producers and seed traders alike.

The final Regulations will determine if the development and practical use of plant biotechnology in the European Union will be possible or not – no more, no less is at stake.

ESA, the head organisation of the European seed industry is urgently requesting representatives of EU Member States in the Council and in the Council Working Groups as well as the representatives of the European Commission to amend the legislative proposals in order to make the introduction and use of GM technology in plant breeding and crop production in the EU a real possibility and to assure the practical, sustainable and non-discriminatory co-existence of all possible forms of plant breeding, seed production, agriculture and of food production in the EU.

I. The need for a uniform definition of GMOs and a uniform scope of Directive 2001/18/EC and Regulations on traceability and labelling of GMOs and labelling of GM food and GM feed

Genetically Modified Organisms are defined in Directive (2001/18/EC). In addition, this Directive also defines what technologies (in general as well as in plant breeding) do not fall within the scope of the Directive, i.e. what technologies do not constitute a genetic modification that would require authorisation procedures as laid down in the Directive.

Both, the definition of GMOs as well as the definition of this scope should be uniform in different pieces of legislation.

Commission proposals and amendments by the EP:

The **Commission's** proposals are unclear and misleading in this respect. They do contain references to the definition of GMOs as in Directive 2001/18/EC but lack the same clear reference as to the definition of the scope of the same Directive.

The **European Parliament** in both Committees and plenary did put forward respective amendments and in respect of the Regulation on the labelling of GM food and feed did adopt an amendment that introduces a clear reference to both the definition of GMOs as well as the scope of Directive 2001/18/EC.

ESA Position:

The European seed industry insists on the need to lay down clear and consistent legislative provisions in this area and urges Council and European Parliament to amend both Commission proposals in such a way that the definition of GMOs as well as the scope of Directive 2001/18/EC are taken over in similar provisions for the Regulation on traceability and labelling of GMOs and the Regulation on labelling of GM food and GM feed.

ESA recommends the following texts to be introduced in the Regulations:

ESA recommendations for amendments securing a consistent definition of GMOs and a harmonised scope of respective EU Legislation:

**Regulation concerning Traceability and Labelling of GMOs
COM (2001) 182fin
Article 2, 3 (NEW)**

Commission proposal	ESA Position
	<p>...</p> <p>(3) This Regulation shall not apply to organisms obtained through techniques of genetic modification listed in Annex I B of Directive 2001/18/EC which shall be exempt from the scope of this Regulation.</p>

**Regulation on GMO Food and GM Feed
COM (2001) 425fin
Article 2, 2 bis (NEW)**

Commission proposal	ESA Position
	<p>...</p> <p>(3) This Regulation shall not apply to organisms obtained through techniques of genetic modification listed in Annex I B of Directive 2001/18/EC which shall be exempt from the scope of this Regulation.</p>

II. The need for an overall regulation of Adventitious Presence AP of GMOs in all products and specifically in conventional seed

It is of vital importance to pass legislation within the EU that will regulate all possible sources of adventitious and technically unavoidable presence of GMOs in all products, regardless of the origin of such presence and taking full account of the international development of the use of GMO technology in plant breeding and crop production around the world.

The desired high level of consumer and environmental protection can be achieved without disrupting international trade and without discouraging further investment and employment in EU based GMO technology and use.

For this, it is indispensable to put forward a consistent and sufficient amendment to Directive 2001/18/EC and to lay down rules for the adventitious and technically unavoidable presence of GMOs. These rules must be based on the nature and biology of seed and crop production. This implies the possibility of adventitious presence of GMOs irrespective of their EU legal status, i.e irrespective of their approval for placing on the market. Therefore, these rules must cover all events that have either been authorised under part B or part C of Directives 90/220/EC resp. 2001/18/EC or that have been authorised in third countries with comparative legislation and authorisation procedures.

Commission proposals and amendments by the EP:

The **Commission** has put forward an amendment to Directive 2001/18/EC in order to take account of the fact of adventitious and technically unavoidable presence of GMOs (v. Proposal for a Regulation on Labelling of GM food and GM feed, Art 42).

This amendment limits the acknowledgement of the fact of adventitious and technically unavoidable presence of GMOs in conventional products to such GMOs that have subject to a scientific risk assessment according to the provisions of Directives 90/220/EC (2001/18/EC) and/or have obtained the authorisation for placing on the market according to part C of Directive 90/220/EC (2001/18/EC). Furthermore the scope is limited to the direct use of the products as food, feed or for processing.

These limitations are contrary to the very concept of adventitious and technically unavoidable presence. The presence is not only unintentional but also can not be avoided - even when taking all possible identity preservation, company internal quality management and precautionary measures.

The **European Parliament** in its 1st reading has deleted all proposed amendments to Directive 2001/18/EC. It must however be noted that in both the Agricultural Committee as well as the Environment Committee and also for the plenary a number of amendments to this Directive and in view of a more general provision for AP were tabled - and some adopted in Committees.

ESA Position:

The European seed industry is convinced that an overall solution to the biological reality and practical fact of adventitious and technically unavoidable presence of GMOs in conventional products in general and specifically in seed must be introduced in European legislation. In view of the horizontal character of the proposed Regulation on traceability and labelling of GMOs, ESA recommends to transfer this acknowledgement of biological and production reality from the GM food and feed proposal (Art. 42) into the proposal on traceability and labelling under Art. 7 as follows:

Article 7
Amendment to Directive 2001/18/EC

III. The need for a threshold of 1% for the labelling of adventitious and technically unavoidable presence of GMOs in conventional products

The threshold triggering labelling and traceability requirements for food and feed in which GMOs are adventitiously or technically unavoidably present according to the Commission proposals is uniformly set at 1%. This level must not be lowered to levels of 0.5% or even below as such levels would result in unnecessary economic and trade disruptions without creating any consumer or environmental benefits. As there is neither scientific evidence nor practical knowledge that suggests an increase of adventitious or technically unavoidable presence of GMOs along the production chain, the threshold for seed should be set at the same level as the thresholds for food and feed.

Commission proposals and amendments by the EP:

The **Commission's** proposals putting forward a threshold level of 1% that would trigger the various traceability and labelling requirements are in line with the existing EU legislation in this area. This level also takes some account of production and economic cost realities.

The **European Parliament** supported by a small majority a threshold of 0.5% for the adventitious presence of EU authorised GMOs (according to part C of Directive 90/220 resp. 2001/18) in non-GM food and feed that would trigger labelling and traceability requirements. This level is practically unsustainable with the increasing production and trade in GMOs all over the world.

Furthermore, the limitation of the scope to EU authorised events does not take account of international research and production of GMOs (e.g. in plant breeding and seed production) or trade with bulk commodities in which GMOs may adventitiously be present at minute trace levels.

ESA Position:

In line with the recommendations and findings of the Scientific Committee (March 2001) and the Joint Research Centre JRC (2002), ESA insists on a minimum threshold of 1% that may have to be reviewed in line with the overall development of GMO production and use in both the EU and third countries.

A threshold must not be set in line with technical detection technology and its possibilities but must allow for a practical and economically viable separation policy by plant breeders, seed producers, farmers, traders, retailers and feed and food industry in an international environment. Therefore again, this threshold must include events authorised under EU legislation as well as events authorised in third countries (v. also 1. above) in order to reflect economic and biological reality.

Brussels, 16th July 2002