

## Position Paper

on the Commission's Draft Working Document  
for a

**COMMISSION DIRECTIVE ..../EC**

**of [...]**

amending Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 66/403/EEC, 69/208/EEC, 70/458/EEC and Decision 95/232/EEC as regards additional conditions and requirements concerning the presence of genetically modified seed in seed lots of non-genetically modified varieties and the details of the information required for labelling in the case of seeds of genetically modified varieties

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## **1. General**

With reference to the proposals from the European Commission to establish labelling thresholds for adventitious or technically unavoidable traces of GMO impurities in conventional seed, ESA reiterates its position put forward on a number of occasions:

“Adventitious or technically unavoidable presence of an impurity - in this case a GMO - does not constitute a placing on the market of that impurity and therefore does not require an authorization under Part C of Directive 90/220.”

“Thresholds for adventitious presence of GMOs in conventional seed must take account of sustainable and economically viable seed production in Europe and therefore must not be set at levels lower than 1%.”

## **2. Specific**

- 2.1. Recognizing that there is both a practical and a political problem, ESA has examined the Commission's latest proposals and finds them both disproportionate and unsatisfactory.  
Disproportionate and unsatisfactory as the proposals introduce unsustainably low thresholds, event specific labelling requirements and the requirement of additional novel food authorizations for only a small and commercially insignificant number of GMO events which may be present in minute traces in conventional seed. It is unsatisfactory as well that even the commitment of the European Commission to regulate the issue of non-part C authorised events has been deleted from the recitals of the proposal.  
With that, neither legal certainty nor practicability are achieved and the impact on international seed trade will be significant.
- 2.2. Despite assurances received from the Commission, these proposals still fail to deal with the issues raised on many occasions by the seed industry, namely:
- 2.2.1 The proposals do not address the issue of adventitious presence in its totality - authorised events (as defined) represent only a small proportion of the events that may potentially be present in seeds at trace levels.
- The Commission attempts to distinguish without any justification those events which are tolerated because they have received authorisation under Directive 90/220 *for cultivation* from those events which have received authorisation *for placing on the market* under 90/220, and also fail to address events which have been approved *for deliberate release* under the same directive.
  - ESA does not accept that events which have been authorised for "placing on the market" or "deliberate release" are not to be considered as "authorised events" – particularly as these events have been authorised following an appropriate environmental risk assessment
- 2.2.2. As to the level of thresholds proposed, ESA maintains its position that a minimum threshold of 1% is needed. The thresholds proposed are far too stringent and can only be achieved under ideal seed production conditions. There needs to be flexibility built in to allow such thresholds to change should the circumstances warrant it, e.g. after wide scale introduction of GM production in the European Union.
- 2.2.3. As a result, and as a minimum, ESA recommends that the actual proposals should be amended to apply to all events approved for placing on the market pursuant to Directive 90/220 (Part C) and that a commitment be made to review the actual thresholds based upon experience following wide-scale production of GMO crops and based on the advice of the SCP. Otherwise, many seed companies would be placed in an impossible situation of having to discard significant seed

stocks - particularly in situations where there is no demonstrable risk to health or the environment.

Still, ESA is convinced that a practicable and sustainable regulation must include all possible sources of adventitious presence of GMOs in conventional seed (v. point 3.).

- 2.2.4. ESA considers the implementation of "good practice for seed production" as proposed in article (1)(a) of Annex I confusing and possibly giving rise to an unnecessary addition of non-harmonised rules for seed production in the individual Member States.

### **3. Regulatory action needed**

- 3.1. Even if the proposals were modified to accommodate industry's views as stated, there still remains the problem of addressing other GMO impurities that may be present in conventional seed.

The Commission has expressed the view that it cannot deal with adventitious or technically unavoidable traces of events not yet approved under Part C of Directive 90/220 or those events which have been approved for deliberate release under Part B of the same Directive, or those events which have been approved and commercialised in third countries and which have received positive review from the Scientific Committee.

However, the Commission has not put forward any proposals to address the issues raised by the technically unavoidable presence of these products.

We await as a matter of great urgency proposals in this regard.

- 3.2. In an effort to progress this matter, and to bring some certainty and guidance to the seed industry now, we set out below what we believe should be part of new legislation:
- The scope should establish maximum thresholds, by crop, for the technically unavoidable or adventitious presence of GMO impurities in plant varieties, both GM and conventional. These thresholds should be the same as those triggering labelling obligations for EU authorized events.  
Below those thresholds, adventitious presence would not trigger labelling requirements.
  - Events which are adventitiously present must have been authorized:
    - For Placing on the Market (Part C) under Directives 90/220 or 2001/18 or
    - For Deliberate Release (Part B) under Directives 90/220 or 2001/18; or
    - Having received a positive opinion from the Scientific Committee; or

- For commercial cultivation in a third country with comparable risk assessment procedures to those in the EU (the SCP shall prepare a list of crops and countries).

3.3. Pending the development of solutions along these lines, we believe that a statement at this point in time could be made to the extent that the Commission's services were reviewing this matter and that proposals to address this were being developed. This should include an appreciation and communication of the Commission and Members States ensuring growers that the presence of trace amounts of GMOs in a bag of seed does not convert the conventional variety in question into a genetically modified variety. Such statement would be extremely helpful in alleviate the confusion which currently prevails in the seed market and which is causing serious disruption to the business of European seed industry.