

Position Paper
on
Draft Commission Directive amending Council
Directives 66/400/EEC, 66/401/EEC, 66/403/EEC,
69/208/EEC, 70/458/EEC and Decision 95/232/EEC
as regards the adventitious or technically
unavoidable presence of genetically modified
seeds in seeds of non-genetically modified plant
varieties and the labelling of seeds of genetically
modified plant varieties
[SANCO/1542/02 – January 2002]

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ESA welcomes the opportunity to comment on the draft Commission Directive setting our requirements as regards the adventitious or technically unavoidable presence of genetically modified seed in seed of non-gm plant varieties. ESA already in 1999 made the EU Commission aware of the imminent fact of adventitious presence of GM seed in conventional seed and requested practical, science-based regulations to allow for the undisrupted trade in seeds and to assure the legal certainty for plant breeders, seed production and marketing and for farmers.

This need for legal certainty has become even more evident after presentation of the so-called Interim Action Plan. Today, only a minority of Member States is applying the provisions as laid down in the Interim Action Plan whereas a majority implemented unworkable national administrative measures, sometimes even differing between regions within one Member State.

ESA has contributed in delivering positions to the earlier working paper of SANCO (1542/01 of 25.05.2001) and pointed out on that occasion that the approach taken by the Commission did not address the practical issues confronting the European seed industry.

ESA welcomes the significant change in the regulatory approach in providing for labelling provisions for compliance with thresholds and moving away from sales restrictions.

ESA also welcomes the fact that the Commission addresses the issue of adventitious presence in its explanatory memorandum as well as in the recitals to the draft Directive. However, ESA is extremely concerned that the scope of the proposal is too limited by being restricted to adventitious presence resulting from events authorised for placing on the market. Furthermore, no improvements are seen by ESA on a number of other important points:

1. The thresholds of 0.3%, 0.5% and 0.7% as proposed are not realistic as was already stated by the Scientific Committee's opinion of March 2001 and "will only be achieved under ideal production conditions...and with increasing difficulty as GM

crop production increases”.

Any threshold must take account of the biology of each particular crop species together with the practices of seed production of each crop. In addition, when determining threshold levels, the Commission must consider whether these thresholds will be sustainable in the future once GM crops are widely used. Based on these considerations, ESA is convinced that thresholds need to be set at least at 1% and at even higher levels for some crops (e.g. oilseed rape) according to their biology.

2. The scope of the proposal is limited only to events authorised for the placing on the market. It should also address and include the following events:
 - a. events cleared for deliberate release into the environment under Directive 2001/18 (90/220) with conditions covering the possible consequences of pollen dispersion (e.g. part B approved releases),
 - b. events which have not been approved under EU legislation but have been approved under comparable legislation in third countries, e.g. in OECD countries and in other third countries with similar approval procedures in place,
 - c. events which have received a positive opinion of a Scientific Committee or of the European Food Safety Agency.
3. ESA agrees with the EU Commission that validated testing protocols must be in place when implementing the Directive – however it must be stated that controls should focus on production lots, thus ensuring traceability.
4. ESA disagrees with the need to set out any additional restrictions to seed production. Once labelling thresholds are set, it is within the competence and responsibility of the seed industry to meet these thresholds.

In any case, the provisions especially as to previous cropping and isolation distances for seed production cannot be met as they do not take the current EU seed production situation into account. For example, the increase of isolation distances to 5000m for rapeseed is totally unrealistic in view of the current production situation; this would mean an exclusion zone of 7850 ha of any *brassica* production around a seed production field.
5. In view of the position stated in 4. (i.e. as to previous cropping, isolation distances etc.), ESA also opposes the current Commission’s proposal to provide for exemptions from the examinations of the satisfaction of those conditions in areas where no gm plants are grown. In any case, the mechanisms

proposed lack the practical provisions, control mechanisms and requirements as regards the declaration of so-called 'non-gm' areas and in particular as to decision making powers at EU and local level.

6. ESA notes the intention of the EU Commission to adapt the existing seed equivalence decisions to comply with the provisions of this Directive and thus to submit production from third countries to the same provisions as EU production.

Conclusion:

The Commission's draft proposals for amending the seed marketing Directives in view of adventitious presence of GMOs in seed of conventional plant varieties are too limited in their scope by focussing exclusively on events authorised for placing on the market, unrealistic in view of the levels of proposed thresholds, inherently illogical and unworkable under EU agricultural and seed production reality as regards the proposed additional requirements for isolation distances and incomplete concerning the provisions for definition and related requirements of areas where no GM plant varieties are grown.

ESA urges the Commission to reconsider its draft in the light of the comments made and to consult with the EU seed industry prior to publication of the next draft proposal in order to arrive at workable and realistic legislative measures which do not put a whole industry at risk.

In this respect, ESA reminds the Commission of the overall political goals as set out by the European Parliament in its recent report on the future of biotechnology in Europe, by the European Council's declaration of Stockholm as well as of its own declaration as set out in its Action Plan for Biotechnology published on 23. January 2002.

The draft proposal is incompatible with these overall aims and goals. It seriously endangers the future of research in and application of biotechnology in the EU and unnecessarily puts economic growth and employment in this sector at risk.

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