Avosetta Group of European Environmental Lawyers

Conclusions agreed on the basis of the meeting at the University of Siena, 29-30 September 2006

The group has studied the three authorisation regimes EC legislation provides for genetically modified organisms (GMOs), encompassing a basically national procedure for the deliberate release of GMOs based on Directive 2001/18 part B, a mixed national/EC procedure for the placing on the market of GMOs other than food and feed based on Directive 2001/18 part C, and a much europeanised procedure for GM food and feed based on Regulation 1829/1003.

The first (national) procedure reserves the competence of risk assessment, denial and approval to the MS of application, although possible comments of other MS must be invited and considered. The second (mixed) procedure as well reserves the competence of risk assessment, denial and approval to the MS of application, but due to the fact that the authorisation is binding on all MS approval is only possible after consent of the other MS or Commission decision overruling possible dissenting comments. The third (europeanised) procedure shifts the competence of risk assessment to the European Food and Safety Agency (EFSA) with the MS having the right of comment or the possibility of being invited to help with the risk assessment whilst the Commission is entrusted to take the decision based on the comitology procedure.

Analysing these procedures the group finds that with the increasing transfer of competences to the EC level it is important to ensure that both the quality and transparency of risk assessment and management are not impaired as a consequence. In particular the following concerns deserve attention:

(1) There is some confusion concerning the regime applicable to the placing on the market of genetically modified (GM) seeds. We are of the opinion that according to the clear definition by Regulation 1829/2003 of food and feed for GM seeds, including food and feed for cultivation, the second (mixed) rather than the third (fully Europeanised) procedure is applicable. We submit that the current practice which accepts GM seeds for authorisation under the third procedure is unlawful. Noting that legislation is planned to also europeanise the procedure for GM seeds we suggest that this should only be done if the procedure has substantially been improved (see (2) – (4)).

(2) GMOs that are used as food, feed or seed will at some point in their life cycle be introduced into the environment. The shift of competence for the risk assessment to EFSA raises concerns because EFSA is by its origin and organisational culture focussed on food issues. This has not adequately been made up by the recent practice to invite environmental expertise into the EFSA Committee on GMOs. We suggest that the European Environmental Agency (EEA) shall be entrusted with the environmental aspects of the risk assessment. Alternatively, EFSA must be developed to equally represent food and environmental concerns (and consequently be renamed as European Food and Environmental Safety Agency – EFESA). Care must also be taken to fully reflect agricultural concerns about feed issues.

(3) In contrast to Directive 2001/18, Regulation 1829/2003 does not mandate public authorities to elaborate an in-depth report evaluating the environmental risk assessment which must be submitted with the application. We consider this as a serious shortcoming. Either EFSA or, upon request by EFSA, national agencies should be under obligation to produce such report.

(4) Whilst Regulation 1829/2003 provides that the summary of the application dossier and the opinion of EFSA shall be made public and that the public may comment on the dossier, the information contained in the dossier and opinion is too general to allow for reasoned comment. We find although additional information can be asked for in accordance with general access to information legislation this will normally be too time- consuming to meet the 30 days deadline allowed for submitting comments.

(5) Membership in the scientific Committee on GMOs must reflect all relevant sciences including environmental ones. Given the controversial character of risk assessment on GMOs different scientific approaches must be reflected in the make-up of the committee. While the Committee should remain scientific, the nomination procedure for membership should provide for involvement by organisations representing civil society.

(6) As long as national administrative agencies are responsible for authorisations national law is called to provide for the participation of the public in procedures. The more the national agencies loose such competences and in effect become commentators on the European level the more national law should develop tools of integrating the preparation of comments into national public discourses. We recommend, for instance, that at the very least comments of national agencies on European risk assessment should be made public.

(7) We are concerned about the loss of legal protection which goes along with the Europeanisation of the authorisation. MS with liberal standing rules grant standing to sue to associations with regard to product related authorisations issued by national administrative agencies. Given the narrow interpretation of Art. 230 para 4 EC and its upholding by the recently adopted Regulation 1367/2006 on access to European Courts the increasing shift of the competence to authorise GM products to the Commission frustrates such possibilities to invoke the courts. The same will be true of other economic interests, such as organic farmers, who may feel aggrieved by an authorization decision.

(8) We appreciate that both Directive 2001/18 and Regulation 1829/2003 demand an environmenmtal risk assessment that covers all types of environment and geographical zones in which the GMO shall be released. However, practice shows that this is far from exhaustive – and can by no means ever be truly exhaustive. The authorisation granted under European law for the placing on the market of a GMO must therefore be restricted to certain uses in certain types of environment and geographical zones, and go no further than the risks addressed in the risk assessment. The current practice of granting permission to use the GMO without restriction other than monitoring requirements is misleading and unlawful and may run counter to other EC policies, such as species protection under the Habitats Directive.

(9) Authorising a GMO on the market under the European legislation, even though it attests that the GMO is generally safe for human health and the environment, should not inhibit further decisions as to usage by Member States. We do not consider that the Directive and Regulation is exhaustive in this sense that any further action by Member State is legally prohibited under Community law. Member States may still exercise site related prevention of the release, especially in order to ensure the co-existence of conventional and organic agriculture and the preservation of sensitive habitats. Guidance should be elaborated in cooperation with civil society to identify the scope of such measures.

(10) In order to ensure co-existence of conventional and organic agriculture MS should not only introduce the measures provided in the Commission Recommendation on

Co-existence. Displacing the fundamental conflict of GM and non-GM concerns to the level of individual farmers allows states and the Community to evade their responsibility. In order to alleviate the burden on local conflict resolution land-use planning should be employed to allow for proper separation between GM and non-GM agriculture. We find, for instance, that the establishment of an agricultural zone free of a specific GMO or even of GMOs in general is not precluded by an authorisation to place a GM seed on the market. Such measures appear to us to be in line with what is meant by Art. 26a Directive 2001/18.

(11) In order to ensure the preservation of valuable habitats a site specific impact assessment can be required. This is not precluded by the authorisation of the placing on the market of the GMO. As for Natura 2000 habitats, Directive 92/43 requires the carrying out of specific environmental assessments of any projects, and this would include the deliberate release and placing of the market of GMOs. But MS may introduce more such impact studies for other sensitive nature protection sites since existing EC nature protection legislation has not carried out a complete harmonisation of MS rules on this matter. Therefore, MS are competent to designate other areas apart from those already enshrined in the Wild Birds and Habitats Directive. Moreover, we submit that zones free of specific GMOs or of GMOs in general can be declared by MS if they find it reasonable to preserve areas for genuine "natural" evolution, or, so to speak, to ensure co-existence of different natural sites including zones free of GMOs. It should also be noted that Article 175(2)(b) (first and third indents) EC-Treaty requires a unanimous decision by the MS for the enactment of measures 'affecting' town and country planning and land use. This means that MS retain basic competences in those two fields and that EC GMO legislation may not necessarily prevail over those considerations.

(12) We find that the establishment of GM-free zones aiming at co-existence or nature protection is not excluded by the Commission decision and the ECFI judgement in the Oberösterreich case. The only question addressed by the court was whether the Austrian measure was allowed under Art. 95 para 5 EC. Neither the Commission nor the Court discussed the question of knowing to what extent the authorisation of placing a GMO on the market is exhaustive or leaves a margin of MS discretion for use related measures.

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