April 2004

NO OLD GMOs in NEW EUROPE!

Why reassessment is needed in accession countries

I.

With the enlargement of the European Union a lot of things will change, but one will remain the same: the EU-wide permission for the 18 GMOs currently authorized within the EU. However, the area for which they are permitted will enlarge by ten more countries. Most of them do not have these GMOs permitted on their markets, nor assessed their impacts on local environments. One of extreme examples is Slovakia which has only one GMO permitted for food, feed and technical use (not planting) – MON 810. After 1st May they will have all 18 – without additional assessment.

Most of the acceding governments seem to be reluctant to take any steps in dealing with this unresolved problem. Part of this attitude can be explained by the fear that they would provoke the anger of the Commission if they go against the free movement of goods.

This paper is to help governments and relevant authorities of accession countries to formulate their standing on the issue of reassessment and let them know about the legal arguments which enable them to ask on the basis of Art 22 and 23 of Dir. 2001/18/EC for a temporary ban of the three EU-approved GMOs for cultivation until adequate environmental risk assessment has been carried out for their ecosystems.

Since no European GMO-related provisions exist on how to deal with new Member States joining the single market, the question on the status of GMOs after accession could only have been adequately addressed within the Accession Treaties. However, the question of automatical acceptance of already approved GMOs for commercial releases has not been addressed.

Given the special nature of GMOs, the "commitology procedures" under which they are authorised and the "precautionary principle", it is clear that the **GMOs authorized for deliberate release must not be accepted in new Member States simply by default**.[1]

II.

Existing European legislation, general principles of EU law, and Annex II of the Treaty of Accession support the argument that reassessment is needed before EU-approved GMOs could be released into the environments of accession countries.

[1] Report by *ANPED and Friends of the Earth:* T. Schweiger, „EU Enlargement – The introduction of GMO's by the Backdoor of EU Accession?", updated version, May 2003, pg. 27

A. **The use of a temporary ban**[2] until adequate reassessment has been carried out in new Member States **is in line with the aims and obligations set out in Directive 2001/18/EC.**

Member States are not allowed to „prohibit, restrict or impede the placing on the market of GMOs" under the condition that they comply with the requirements of the Directive (Art. 22). However, these requirements are not met – and thus new Member States have the right „to prohibit, restrict or impede" already approved GMOs – for the reasons stated below.

Not only does Art. 22 indicate that prohibiting, restricting or impeding the placing on the market of GMOs is justified in case of non-compliance with the requirements of the Directive, but also Art. 23 allows Member States to use a „safeguard clause" and to enact temporary bans on EU-approved GMOs. Since the original authorisation of the three GMOs already approved fro cultivation in 1996 and 1997, a new circumstance has developed which affects „the environmental risk assessment or reassessment of existing information", and that is the inclusion of a new ecosystem with different environmental features within the boundaries of the Community. This raises serious doubts as to the validity of the existing risk assessment done for the biodiversity of existing Member States. The scientific acknowledgement of the new ecosystem constitutes a legal ground for provisionally restricting or prohibiting the use of the three GMOs in the territory of accession states.

1. i. No environmental risk assessment carried out for accession countries

GMOs approved within the EU need to undergo an application process under the EU's "commitology procedures", whereby authorisation is only granted after all Member States and the Commission have had the chance to evaluate all aspects of the application, including different ecosystems within Europe.

GMOs with EU-wide approval for commercial releases **have not undergone an environmental risk assessment for the ecosystems of the new Member States**. The specific nature of accession countries' ecosystems was not taken into account when conducting the assessment. Neither did notifications include information that took into account „the diversity of sites of use of GMOs" in accession countries, as required by Art. 13 (2)(a). The preamble (19) of the Directive also requires a **case-by-case environmental risk assessment**, which should be carried out prior to release. Automatical acceptance of EU-approved GMOs for commercial release would infringe this obligation.

Another important element must be taken into account when looking at the **already approved GMOs in EU**. Those authorisations were all based on the „old" Directive 90/220/EC and **granted without the improved risk assessment** procedure that extends to cumulative, long-term effects on human health and the environment, including biological diversity and non-agricultural eco-systems, as required by Annex II of Dir. 2001/18. (Accordingly, Slovenia already implemented Art. 23 by providing for a safeguard clause, which gives the possibility not to automatically authorise GMOs already approved in the EU.[3])

ii. Different environmental features in accession countries

The **distinct environmental settings are acknowledged in Annex II of the Treaty of Accession**, which replaces a point in the Annex to Council Decision of 3 October 2002[4] establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of GMOs for purposes other than for placing on the market. The inserted text into Part 1 Section B of the Annex to Council Decision requires the notifier to indicate the

[2] If a Member State invokes Art. 23 of Dir. 2001/18, the GMO is banned in its territory and a renewed "commitology procedure" is initiated, during which all other Member States and the Commission review the new scientific evidence. According to the law, this process should be completed within 3 months.
[3] Art. 62(4) of Slovenia's 2002 GMO law
[4] Page 6, http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_280/l_28020021018en00370061.pdf

type of ecosystem in which the organism is found. Among them**, the *Pannonian* ecosystem** is mentioned, **not anywhere found within EU countries before**.

The bio-geographical regions take into account the variability of biodiversity features within Europe, depending on climatic and geographical conditions, which do not follow national borders. The EU-15 bio-geographical regions map, including six regions (Boreal, Atlantic, Continental, Alpine, Mediterranean, Macaronesian) was initially developed in October 1995 by the Commission DG Environment.[5] Compared to this, Annex II of the Treaty of Accession adds a new ecosystem, called Pannonian, covering all Hungary, parts of Slovakia, Slovenia and the Czech Republic[6]. Also, new habitat types 'Pannonia' and 'Pannonic' were accepted to be added to Annex I of the Habitats Directive (92/43/EEC), which has to be applied to a much larger territory after accession.[7]

Moreover, the Carpathian Basin is an even wider area with numerous different habitat types, which are home to a high number of native species. Beside the diversity of species, a diversity of geological, geo-morphological and other values is also typical for this area. The **Framework Convention on the Protection and Sustainable Development of the Carpathians,** of which members include the Czech Republic, Hungary, Poland, and Slovakia, aims at the preservation of the region's unique biological heritage for the long term.
Acknowledging that with accession new types of ecosystems will appear within the new EU borders, environmental risk assessment is of crucial importance for the conservation of these unique, fragile regions taking into account the negative effects that GMO releases could entail.

2. Not only has risk assessment has not been carried out in accession countries, but also the status of the 18 GMOs within the EU is rather unclear. Five different member States have **imposed national bans on eight of these GMOs** (under Art. 16 of Dir. 90/220/EEC, now Art. 23 of 2001/18/EC), among them on all GMOs approved for cultivation. The use of this safeguard clause has not been overturned so far.

3. Accession countries were not **consulted and did not have the opportunity to ask for information, present observations or reasoned objections** to the competent national authorities when notifications were submitted to them in accordance with Art. 6(5), 11(2) and 15(1) of 2001/18/EC.

4. Accession countries have **not yet given the public the opportunity to express an opinion** on whether to automatically accept EU approved GMOs for deliberate release or not. Thus, they did not yet comply with Art. 9 of Directive 2001/18/EC. As the article points out, states must „lay down arrangements (…), including a reasonable time-period", so as to consult the public.

5. Also, the **public was not even given the opportunity to comment on the assessment report** and invoke its right of participation in the approval procedure in accordance with Art. 24 of the Directive. Depriving the citizens of accession countries of their right to participate in the decision-making process of such important issues affecting their environment and agricultural traditions would be to jeopardize their fundamental human rights enshrined in the general principles of Community law.

   Moreover, it is also recommended by the Secretariat of the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters [8] that **public participation should be provided in the decision-making procedures** for as appropriate **when first time deliberate release takes place** into the environment of GMOs in any new location.

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[5] http://reports.eea.eu.int/topic_report_2002_3/en/Topic_3_2002.pdf
[6] See the Pannonian Region at: http://dataservice.eea.eu.int/atlas/viewdata/viewpub.asp?id=221, also at http://europa.eu.int/comm/environment/nature/enlargement.htm
[7] Interpretation Manual of European Union Habitats - EUR25 , at http://europa.eu.int/comm/environment/nature/habitats_im_en.pdf
[8] MP.PP/2003/3 KIEV.CONF/2003/INF/7 5 May 2003, at http://www.unece.org/env/pp/documents/gmoguidelinesenglish.pdf

B. The use of Art. 23 is crucial in order to comply with the aims and obligations of Directive 2001/18, but it is also **necessary for the following reasons:**

i. The European legislation still have some gaps, e.g. it **does not provide for a liability regime** addressing damage caused through GM contamination. Until such measures are not been worked out, there is a high risk of the contamination taking place with no way of insuring that farmers could avoid damages. No GMO should be authorised for cultivation in accession countries before clear rules have been established on liability, co-existence and seed contamination.

ii. The approval of the three GMOs now authorized in the EU for cultivation will run out on 17th October 2006 as Article 17 stipulates. It would be unwise for any accession country to release these GMOs in the coming growing seasons, as there is a high chance that there will be no reapplication for these GMOs, or they would be rejected in two years time. They were approved under a completely different legislation that did not require the same level of environmental and health risk assessment. Thus, an Art. 23 ban should be introduced, since **the applications are set to expire after one or two cultivation seasons**, after which accession countries will have to face the problem of getting rid of these GMOs again.

iii. Last, but not least, the automatical acceptance of old GMOs should be rejected due to the **non-implementation of the Regulations** on Labelling and Traceability (1830/2003) and GM Food and Feed (1829/2003) becoming applicable right upon accession. Until this legislation is translated and published in all the accession states (which has not happened so far), and implemented, no GMOs should be authorised for commercialisation in any of the accession countries, otherwise acession countries might infringe the obligations set out in these Regulations.

III.

Since EU-wide approval is only given if the GMO is considered safe in all perceivable circumstances, it must be argued that EU approval must not automatically include new Members States.[9] **Since risk assessments for the deliberate release of GMOs in accession countries were not conducted, the public did not have the right to participate and since competent authorities did not have the right to raise objections, EU authorisations cannot be extended to the territories of new Member States. A new approval procedure must be initiated for GMOs** (with special emphasis given to the new Member States) before any of the GMOs approved within the EU for commercial release can also be authorized in the new Member State. **Until such reassessment is completed, a temporary ban should be put in place** fully in line with the purpose and obligations of Directive 2001/18/EC.

[9] Report by *ANPED and Friends of the Earth:* T. Schweiger, „EU Enlargement – The introduction of GMO's by the Backdoor of EU Accession?", updated version, May 2003, pg. 25.