

Greenpeace, September 2005

For the attention of EU Agriculture and Environment ministers

Unacceptable approvals by the Commission of GM maize MON863 and GM oilseed rape GT73

- The European Commission decided on 8 August 2005 to approve Monsanto's genetically modified (GM) maize MON863 for marketing in the EU. A simple majority of Member States had voted against this approval at the environment ministers Council on 24 June 2005.
- The Commission similarly approved Monsanto's GM oilseed rape GT73 on 22 June 2005¹. Two days later it withdrew the approval². On 31 August, the Commission re-approved GT73 - for import and marketing in the EU. A majority of Member States had voted against this at the Environment Council meeting on 20 December 2004.

With the authorisations for MON863 and GT73, the Commission has abused its powers and breached its agreement with the Council not to go against any predominant position in Council³.

The Commission has also gone beyond its mandate and now appears to be at odds with every one of the fundamental principles of Community policy governing GMOs. Both Moratorium declarations from June 1999⁴ (signed by 12 out of the then 15 member states) lay down the following six demands as a minimum requirement for any GMO to be considered for EU-wide approval :

- Risk assessment
- Use of precautionary principle
- Public access to information
- Monitoring
- Traceability, allowing to recall GMO
- Labelling, allowing consumers to avoid GMO

These demands have, since 1999, become the basis for EU common policy on GMOs and have been incorporated into the EU legislative framework. The primacy of these principles is recognised even in the Commission press releases⁵ announcing the approval of GT73 and

¹ <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32005D0465:EN:HTML>

² [http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32005D0465R\(01\):EN:HTML](http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:32005D0465R(01):EN:HTML)

³ Declarations 1999/C 203/01 on Declarations on Council Decision 1999/468/EC: to "*act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure*", 28 June 1999, laying down the procedures for the exercise of implementing powers conferred on the Commission

Link: http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/c_203/c_20319990717en00010001.pdf

⁴ Cf <http://register.consilium.eu.int/pdf/en/99/st09/09433-r1en9.pdf>

See also : <http://register.consilium.eu.int/pdf/en/01/st07/07191en1.pdf>

And : <http://register.consilium.eu.int/pdf/en/01/st07/07191en1.pdf>

⁵ *GMOs: Commission authorises import of GM-oilseed rape for use in animal feed*, IP/05/1077 :

<http://www.europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1077&format=HTML&aged=0&language=en&guiLanguage=en>

MON863. In both documents, the Commission pays lip service to all six agreed principles – but these are hollow claims.

“Risk assessment” and “Precautionary principle”

The Commission claims that MON863 and GT73 have been “*subject to a rigorous pre-market risk assessment*”. The reality suggests otherwise. Short term feeding trials with rats for both MON863 and GT73 resulted in several statistically significant abnormalities in body weights, blood parameters and vital organs of the test animals. Rather than investigating these variations and conducting further studies, Monsanto and the EFSA used dubious scientific arguments to justify ignoring the adverse results. Disregarding the observed abnormalities and the requirement that GMOs must undergo strict risk assessment based on the precautionary principle, no further studies were conducted for either application as part of the EFSA risk assessment. This procedure is clearly not functioning as intended and the precautionary principle is being ignored. The EFSA goes as far as to dismiss the use of the precautionary principle in the risk assessment, claiming that “*The precautionary principle as addressed in Regulation 178/2002 is a risk management tool*”⁶. This statement is in clear contradiction with EU policy, wherein the precautionary principle is deemed relevant at both risk assessment and risk management levels.

“Public access to information”

The Commission claims in its press releases that the application procedure for both MON863 and GT73 has been clear and transparent. On the contrary, for both GMOs, unfavourable results in feeding trials were kept illegally confidential, preventing NGOs and independent scientists from contributing to the risk assessment. Directive 2001/18/EC prohibits any material concerned with the risk assessment being kept confidential.

In June 2005, a German court ordered Monsanto to release the data on MON863 feeding trials to Greenpeace. A decision on whether the feeding trial data for GT73 must be released is awaited from Regeringsrätten’s, the highest administrative court in Sweden. Despite Commission claims to the contrary, public access to information is far from secured.

“Monitoring”

The Commission further claims that it has assured “robust post-marketing rules” that will ensure monitoring of the GMOs. However, in its decision of 31 August 2005 to approve GT73, the Commission has sought to deal with post-market monitoring and accidental spilling of the GM rape with a simple Recommendation containing guidelines to Monsanto. The strict framework called for by Member States is reduced to a voluntary suggestion, which Monsanto is not legally bound to follow. In an earlier example, a majority of Member States at the Environmental Council on 10 March protested against the Commission’s lack of implementation of monitoring plan obligations for another Monsanto GM maize (MON810). In September 2004, the previous Commission had assured Member States that the required monitoring plans were in place for MON810, when in fact no monitoring plans had been made in accordance with the current legal standards.

“Traceability system – ability to later recall harmful GMOs”

GMOs: Commission authorises the import of GM maize MON 863 for use in animal feed, IP/05/1046 : <http://www.europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/1046&format=HTML&aged=0&language=EN&guiLanguage=en>

⁶ “Response by the Chair of the Management Board of EFSA to the letter sent from Friends of the Earth (FoE), an environmental organisation”, 19 January 2005, link : <http://www.efsa.eu.int/mboard/correspondance/786/foe-reply1.pdf>

The Commission maintains that the traceability system established in April 2004 ensures that authorities can recall GMOs which are found to pose a risk to health or the environment after marketing. The proper functioning of this system is a precondition for considering approving any GMO. Yet the failures of the system were made clear with the Bt10 scandal in March 2005. A year after the traceability system came into force, the company Syngenta admitted that it had mistakenly released to US farmers the untested, unapproved, GM maize Bt10, which contains a gene conferring antibiotic resistance, instead of the approved Bt11. Bt10 had been arriving in the EU in shipments of Bt11 corn gluten for over a year without the traceability system discovering the fact. The system failed again when, after the EU was informed of the mistake, it was unable to locate batches of Bt11 gluten that had arrived in the EU and needed to be tested for Bt10 contamination. This shows that the ability of national or European authorities to recall GMOs such as Bt10, or MON863 and GT73 if needed, is not guaranteed. The current system leaves national authorities powerless in the event of a harmful or unapproved GMO needing to be recalled. In addition, the lack of a coherent EU policy on the contamination of non-GM farming raises further questions about the EU's ability to withdraw GMOs from the market.

“Labelling – consumer choice”

The Commission claims that it has provided consumers with the information necessary for them to avoid GMOs if they so choose. The EU imports GMOs principally as animal feed. Yet all animal products are exempt from GMO labelling laws. So claims that the labelling regime provide “*consumers with the information they need to decide whether to buy the product or not*” are misleading. For consumers to make an informed decision, the millions of tonnes of GMOs imported and used in the EU and currently exempted from end-user-labelling should be included in the labelling regulation.

Conclusion

The Commission states in its press release IP/05/1077 from 31st August that “*Requests for authorisations which do not fulfil all criteria have been and will continue to be rejected*”. Since, as has been shown above, neither MON863 nor GT73 fulfils any of the fundamental criteria, both should have been rejected, as more than half of the Member States expressed in Council.

Greenpeace urges Member States to:

- enact safeguard clauses against the import and processing of GM oilseed rape GT73 and GM maize MON863;
- remind the Commission that it cannot go against a predominant position on such a sensitive issue and insist that it honours the 1999 agreement and immediately cancel the MON863 and GT73 approvals;
- remind the Commission of the six central requirements that since 1999 have been the basis for a common EU GMO policy;
- take necessary steps to ensure that the Commission agrees not to put forward any further applications before the agreed principles are enacted and properly implemented,
- demand that the work of the EFSA GMO Panel be assessed and re-organised, and that the EFSA respect its legal obligation to take into account national scientific authorities,
- demand that comitology procedures are not used to approve GMOs.