

**Response of GeneWatch UK to questionnaire for Member States on the
implementation of Regulation (EC) 1829/2003 of the European Parliament and of the
Council on genetically modified food and feed.**
(February 2005)

GeneWatch only feels able, at this time, to answer one question fully. This is because most of the questions are of a factual nature and/or are better answered directly by the UK Competent Authority.

Q 1.4 Have any issues on Article 29 (public access) and 30 (confidentiality) arisen for you? If so, please provide the details.

Our main points are;

- **Public access to the full dossiers has been appalling. The EFSA has not been ready to fulfil such requests and is thus, well exceeding the time limits set down in Regulation (EC) 1049/2001.**
- **The EFSA has not been provided reasons for CBI claims over certain sections of the dossiers.**
- **GeneWatch does not understand how many sections of the dossiers are covered by CBI claims.**
- **The failure to provide the full dossiers and the lack of reasoning over CBI claims will only fuel distrust in the EFSA and in the GMOs the public are being asked to accept.**

On 3rd of November 2004 GeneWatch UK asked the EFSA for 5 dossiers of applications for authorisation under Regulation (EC)1829/2003. None of the dossiers were given to us within the 15 days laid down in Regulation (EC) 1049/2001. GeneWatch has now received access to 3 of the dossiers but, 2 are still outstanding despite making confirmatory applications and that the 15 day response period has again been exceeded. On 1st of February 2005, GeneWatch requested access to a further 5 dossiers. The 15 day response period ends today (23rd February 2005) and we have, as yet, heard nothing on these dossiers.

In addition to asking for the dossiers, GeneWatch asked for information regarding applicant claims for the CBI sections of the dossiers and have asked for confirmation that the EFSA is in agreement with these claims. In their correspondence with GeneWatch the EFSA has never answered these questions. Furthermore, only in one instance has the EFSA indicated that the Commission is still in dialogue with the applicant over the CBI sections of a dossier.

The debate over GM crops and food has been characterised by a distrust in the risk assessment procedure carried out by applicants and how Competent Authorities view these assessments. GeneWatch believes that full access to these dossiers is crucial in maintaining informed debate from all sides of the argument. Without informed debate the public can only be sceptical at the secrecy surrounding the safety assessments of foods they are being asked to eat.

When GeneWatch has been given access to the dossiers it appears to have been easy for the EFSA to give limited access to their intranet. GeneWatch believes this demonstrates that the dossiers could easily be made available to anyone wishing to see them. The EFSA website should therefore provide clear information on how to view the full dossiers.

On the issue of confidentiality, GeneWatch believes that very little if any of the dossier should be confidential. These GMOs are about to be commercialised. It is necessary for the applicants to provide full molecular details of the modification to enable identification of those specific transformation events. It is also usual for the transformation events and techniques used to be protected by patents. Therefore, GeneWatch believes there can be very little real CBI information in the dossiers. GeneWatch finds it particularly difficult to understand how the protocols and results of feeding trials can be confidential. Again the secrecy surrounding such results only leads to public distrust of the applicants and the regulatory process.