

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>EUROPEAN COMMUNITY</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: European Commission Agency or authority designated to handle comments regarding the notification can be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Products containing or consisting of genetically modified organisms (GMOs).
5.	Title, number of pages and language(s) of the notified document: Commission Directive 97/35/EC of 18 June 1997 Adapting to Technical Progress for the Second Time Council Directive 90/220/EEC on the Deliberate Release into the Environment of Genetically Modified Organisms (2 pages)
6.	Description of content: The Directive extends the information requirements of Annex III so that notifiers will in the future include in their dossiers:  (a) specific label for the GMOs they intend to place on the market as well as  (b) molecular data in a form which can be included in a potential register.
7.	Objective and rationale: The Commission Directive amends Annex III to Directive 90/220/EEC in order to facilitate the risk assessment of products containing or consisting of GMOs.  The <u>rational</u> is the following:  Products cleared under Directive 90/220/EEC are assessed for their safety to human health and the environment. Once approved, they can circulate freely within the Community thus becoming part of the environment.

7.	<p>Objective and rationale: (cont'd)</p> <p>Any risk assessment for a given GMO to be placed on the market has to take into account potential interactions of the GMO in question with other organisms in the environment, including other GMOs already approved for placing on the market. It is to be expected that as the number of authorized GMO products increases, so will the complexity of the risk assessment for the placing on the market of further GMOs. Thus, a register/database on molecular information concerning modifications already introduced in organisms will certainly become necessary for carrying out environmental risk assessment in the future.</p> <p>Furthermore, any data generated during post-release observation of GMOs will greatly facilitate the risk assessment task. In turn, the generation of such data will be greatly facilitated by specific labelling of GMOs already cleared for placing on the market under the Directive.</p>
8.	<p>Relevant documents: Official Journal of the European Communities No. L 169, 27 June 1997, p.72.</p>
9.	<p>Proposed date of adoption: 18 June 1997 Proposed date of entry into force: 28 June 1997</p>
10.	<p>Final date for comments: 30 September 1997</p>
11.	<p>Texts available from: National enquiry point [X] or address and telefax number of other body: DG III-A-1</p>