The European Commission and the European Food Safety Authority

An infernal merry-go-round

By Daniel Guéguen (ETI*) | 19 June 2008

The Lisbon Treaty has been rejected by Irish citizens for many reasons, some big and some small: for example, a bureaucracy which has become excessive and paralysing for citizens and even for the biggest businesses. The authorisation of phytosanitary substances is a prime example.

A very complex process

The authorisation of active substances is a competence of the European Commission. Only active substances listed in Annex I of Directive 91/44/EC – also known as the 'positive list' – can be used in final phytosanitary products.

To submit an active substance for inclusion in Annex I, a company must provide a scientific dossier detailing chemical analyses and toxicological and ecotoxicological impact assessments. The dossier is then submitted, according to a pre-determined order, to a member state which becomes the 'rapporteur member state' (RMS) for this substance.

After a detailed analysis, the RMS submits the dossier – or DAR (draft assessment report) – to the independent experts of EFSA (European Food Safety Authority) who study it themselves, asking for clarifications if necessary. The DAR is then submitted to the other 26 member states who comment, ask questions, and request additional information: this is known as 'peer review'.

When a common opinion is reached between the rapporteur member state, the other member states and the EFSA, the dossier is transmitted to the European Commission (DG SANCO and DG ENVI), which examine it and formulate a proposal for a decision.

The final decision is taken by the Commission, after an opinion from the Standing Committee on the Food Chain and Animal Health, a committee composed of experts from the 27 member states. Following this decision, either the active substance is included in the positive list for a renewable ten-year period, or its inclusion is refused and all corresponding authorisations are removed.

New difficulties

The authorisation process for phytosanitary products was introduced in 1992. In principle, it should have lasted ten years. In 2000, the delays in examining the dossiers led the Commission to move the deadline back from 2002 to July 2008.

But in 2007, confronted by new difficulties with meeting this deadline, the Commission adopted a new regulation (EC 1095/2007) stipulating that no new information submitted after the DAR can be accepted for the peer review. In other words, a company having submitted its dossier several years earlier is forbidden from providing new scientific information, except for occasional clarifications.

A ping pong game

Despite its 300 permanent officials and numerous expert groups, the EFSA (whose role is to provide the Commission and the member states with independent opinions) does not have sufficient resources to carry out a true scientific analysis of all its dossiers. As such, the EFSA position and those of the other member states often follow that of the rapporteur member state.

Moreover, the EFSA, whose role is also to guide business and civil society through the complex authorisation procedures, usually acts in opacity:

- the calendar of EFSA expert group meetings is not accessible

- obtaining the names of the experts is often a mission impossible

- effective participation of these experts at the meetings is random

- the minutes of these meetings are published on the EFSA website, but sometimes with a delay of over two months

- the opinions are indeed available on the website, but these documents are difficult to understand without a scientific background and they are only published when the process is completed

- as much as it is understandable that contacts with the scientific experts of EFSA would not be appropriate, it is astonishing that its administrative officials often refuse to give any practical information whatsoever

- all this creates an infernal merry-go-round where information requests sent to EFSA meet with the response “speak to DG SANCO” and the subsequent call to DG SANCO is answered by “go and ask EFSA”.

This leads to a real trauma for the company that has submitted an authorisation request, which can sometimes be vitally important, as the dossier is totally inaccessible. The company finds it impossible to provide new scientific information based on technological advances. Moreover, they don’t know who is dealing with the dossier, when, and on what timeline.

In these uncertain conditions, how can one manage a serious industrial project? Is this really what the legislator wants? Is this what producers, distributors and consumers expect? It is this kind of 'success story' that swells the ranks of the Eurosceptics.

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