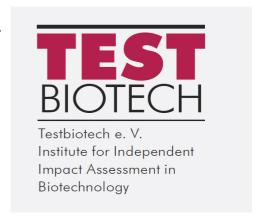
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Working towards more safety for consumers and the environment – the right way to implement precaution in the context of food safety

Summary

The purpose of this discussion paper is to consider the EU Commission REFIT program process currently being applied to re-evaluate the content of the basic food Regulation 178/2002. Clearly, it is not the text of the Regulation that should be changed, but rather its implementation to achieve the high level of protection for the environment and human health that it foresees.

It appears that a lack of adequate balance in political strategies is to blame for major deficiencies in the current implementation of the Regulation. While the EU Commission has put much emphasis on supporting technology, competition and innovation, it has never pushed in a similar way for a coherent and effective approach to improve food safety.

Recommendations are the

- development of an integrated participative approach in the process of risk analysis,
- broader scientific expertise involved in risk assessment,
- systematic promotion of independent risk research and
- taking more account of the uncertainties and limits of knowledge.

Introduction

Currently Regulation 178/2002, which is perceived as one the most basic regulations on food safety, is undergoing scrutiny by the EU Commission REFIT program¹ to evaluate its content and overall effectiveness. This regulation is fundamental to the European Food Safety Authority (EFSA).

In Article 5 ("*General objectives*") of Directive 178/2002 it is stated:

Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

However, the current process of risk analysis (which includes risk assessment and risk management) is not as strong and reliable as it should be according to Regulation 178/2002. Moreover, there is a perception of a permanent, substantial and systemic bias driven by vested economic interests. The reason for this is a lack of adequate balance in political strategies: While the EU Commission places much emphasis on supporting technology, competition and innovation, it has never tried to develop a coherent and effective approach to improve food safety and to implement the requirements of Regulation 178/2002. Many NGOs have identified the resulting problems and even the European Food Safety Authority (EFSA) has complained about a lack of sufficiently qualified experts with no links to industry. Consequently, risk research, risk assessment and risk management in the EU lacks sufficient credibility and reliability.

Some deficiencies which need to be addressed

While there is a highly efficient EU policy already in place to foster competition, technology and innovation, there is no coherent political strategy when it comes to improving the protection of the environment and human health. A new strategy is urgently needed: The purpose of Regulation 178/2002 to safeguard a high level of protection can only be implemented if

 the science underlying decisions is produced by independent scientists, including peerreview

¹ http://ec.europa.eu/smart-regulation/refit/index_en.htm

- the overall process of risk analysis (including risk assessment and risk management) is improved substantially,
- the guidelines for risk analysis are developed by involving independent scientists and not just by an EU agency or body,
- the availability of expertise and research from researchers independent of industry is established systematically,
- the limits of knowledge and the uncertainties are given sufficient consideration before new products and technologies can enter the market.

Some demands for moving forward

The right way to tackle the problems is not to change the text of the current Regulation 178/2002, but to enforce its implementation. This can be substantially promoted by:

- Developing an integrated participative approach in the process of risk analysis
- Broadening scientific expertise involved in risk assessment
- Systematically promoting independent risk research
- Taking more account of uncertainties and the limits of knowledge

• Developing an integrated participative approach in the process of risk analysis

Civil society organisations such as NGOs active in the fields of consumer protection, consumer interests, public health, environmental issues, animal welfare and agriculture should be integrated in the overall process of risk analysis. For example, relevant civil society organisations could be involved in selecting the experts and in safeguarding the standards of independence of EU agencies. This would help to strengthen the reliability of EU risk analysis. At the same time, there should be stricter avoidance of influence from industry or affiliated institutions with direct or indirect vested economic interests in the outcome of risk analysis.

• Broadening scientific expertise

Heterogeneity of the relevant committees and the panels should be a priority in selecting the experts. In many cases, scientific truth is not a matter of the expertise of single experts but the result of a proper and even controversial debate amongst experts. This is especially true when it comes to identifying the limits of knowledge and uncertainties. There should be a requirement for the integration of a 'second opinion', independent from the current authorities such as EFSA. These 'second opinions' should have a specific focus on the precautionary principle, be reliable and not

driven by vested economic interests in the outcome of risk analysis. For example, the European Environment Agency should have a decisive role in the field of environmental risk.

• Systematically promoting independent risk research

There should be more scope for the EU institutions to commit to independent scientific investigations and safety tests carried out by independent laboratories. Funding needs to be organised to support scientists and institutions that are not working for industry to make sure the risks of new products and new technologies are investigated in the light of the precautionary principle. Industry should be involved in raising new funds for independent research. Civil society organisations active in relevant fields should be involved in the allocation of funds, whilst at the same time there should be a strict avoidance of any influence exerted by vested economic interest.

• Taking more account of uncertainties and the limits of knowledge

Strengthening the protection of human health and the environment requires concerted action. This includes the aforementioned broadening of expertise and public debate. Others are enhanced standards for risk assessment such as requiring strict scientific standards for the preparation of dossiers by industry. Attempts to assess risks and potential hazards only if relevant evidence is already available, should be rejected as should statistical methods (such as TTC), allowing a certain level of harm. A much more specific requirement should be established to identify the limits of knowledge and the true range of uncertainties within each risk analysis. A referee panel of experts strictly independent of industry should be established to deal with the case by case quality of publications that are taken into account or are dismissed by the expert panels.

Conclusions:

Given the severe gaps in the current implementation of Regulation 178/ 2002, it is clearly not the text of the Regulation which has to be changed. Rather, the EU Commission should start a coherent and targeted process to implement a high level of protection as requested by the Regulation. Current EU politics place the interests of industry above those of consumers and the environment. Bearing in mind that Regulation 178/2002 was originally created in response to the major BSE food scandal and that its aim is to substantially enhance safety for human health, it is now time to make a new start to fulfill actual regulatory needs.