SCIENTIFIC REPORT OF EFSA

Scientific report of the Endocrine Active Substances Task Force

European Food Safety Authority

European Food Safety Authority (EFSA), Parma, Italy

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SUMMARY

The issue of endocrine active substances touches upon the activities of several of the EFSA Units and Panels, recent examples being the risk assessment of bisphenol A, the hazard assessment of isoflavones and the implementation of the new regulation on plant protection products. Previous examples include contaminants like organotins, dioxins, PCBs, and hormone residues.

Discussions within the Scientific Committee and the Advisory Forum have called for the development of a common approach within EFSA towards endocrine active substances. A first step in this process was to appoint a task force to identify trends and developments in the assessment of the health risks and risk communication issues EFSA may have to address. The aim of this report by the task force is to clarify the state-of-play, and provide recommendations for the scientific and communication issues.

Current activities and developments within EFSA, European Commission, other European Union bodies, and Member States are reviewed. Both specific issues and new regulations make it necessary to follow up on recent developments within the EU bodies and Member States, in order to avoid diverging assessment approaches and the duplication of work. One such issue that now needs to be addressed is the development of specific criteria for determining endocrine disrupting properties. The proposed action for EFSA is to contribute to the work in progress under the auspices of DG Environment.

International consensus on testing strategies to determine the endocrine activities of substances that may be of significance to human health is needed for both hazard identification as well as for risk assessment. The harmonisation with regard to the testing of chemicals has been an ongoing activity of the OECD for more than 30 years. A core activity on endocrine disrupters was initiated in 1997 and under this umbrella both specific tests and a tiered assessment framework have been developed. The task force recommends that EFSA continues its participation in the ongoing OECD activities in the...
area of the testing of chemicals and evaluates how the tiered testing approach might be applied within EFSA’s work, not only to prioritise which substances in food and feed might require assessment for endocrine activity, but also to evaluate those substances which are prioritised.

The development of a generally accepted risk assessment methodology is an additional challenge due to the complexity of the issues involved. Multiple sources and routes of exposure exist for endocrine active substances, such as contaminants, residues or natural constituents of foods. From a toxicological point of view, the significance of the various adverse effects, gender and life stage must be assessed and different types of combined actions need to be considered. In addition, there is a need to have a better understanding of the significance of low-dose exposure, and an evaluation of the health risks and health benefits of certain naturally occurring substances, such as phytoestrogens.

The task force recommends that EFSA continues its activities aimed at developing harmonised methodologies for risk assessment of combined exposures to endocrine active substances in food. In order to ensure consistency between the approaches developed for risk assessment through other sources than food (non-dietary exposure), EFSA should continue to build a dialogue for developing a common strategy with the EC, other EU bodies, Member States’ Competent Authorities, international organisations and partners, as well as external experts and stakeholders on the before mentioned issues. In line with these recommendations, it is proposed that EFSA creates a working group of Panel experts and national experts to advise in prioritising the work on endocrine active substances.

From a risk communications perspective, it appears that the concept of “endocrine active substances” is not well known and that the public debate has been largely shaped by the negative connotations associated with the term “endocrine disrupters.” Further research on public perception is required in this area taking into account also perception regarding “natural” constituents of foods which have endocrine effects and which may be promoted for their health effects. It is recommended that EFSA work with the experts in its Advisory Group on Risk Communications in conjunction with the communication experts from Member States, and continues to monitor and analyse media and stakeholder developments, in order to define a strategy for communications addressing both the collective group and specific endocrine active substances.

**KEY WORDS**

Endocrine active substances, endocrine disrupters, hazard identification, risk assessment, method harmonisation, common strategy, risk communication