



Commission presents scientific criteria to identify endocrine disruptors in the pesticides and biocides areas

Brussels, 15 June 2016

Today the European Commission presents criteria to identify endocrine disruptors in the field of plant protection products and biocides.

The Commission proposes to the Council and the European Parliament to adopt a strong science-based approach to the identification of endocrine disruptors and to endorse the WHO definition.

Endocrine disruptors are substances, both natural and chemical, that can alter the functions of the hormonal system and consequently cause adverse effects on people or animals. Today, the European Commission presents two draft legal acts with scientific criteria that will allow for a more accurate identification of chemical substances which are endocrine disruptors, in the plant protection products and biocides areas.

Today's package includes:

- A **Communication** providing an overview of the scientific and regulatory context;
- an **Impact Assessment Report** which presents the state of science regarding different criteria to identify endocrine disruptors, and provides information on possible consequences;
- and **two draft legal acts – one under the Biocidal Products legislation, the other under the Plant Protection Products** legislation – which set the criteria to identify endocrine disruptors.

The President of the European Commission **Jean-Claude Juncker** said: "*Endocrine disruptors can have serious health and environmental impacts and even if many substances containing them are already banned as a result of existing legislation on pesticides and biocides, we have to remain vigilant. The Commission is committed to ensuring the highest level of protection of both human health and the environment, which is why we are today putting forward strict criteria for endocrine disruptors – based on science – making the EU regulatory system the first worldwide to define such scientific criteria in legislation.*"

The Vice-President for Jobs, Growth, Investment and Competitiveness **Jyrki Katainen** declared: "*The scientific criteria for endocrine disruptors presented today will contribute to the objectives of minimising exposure to endocrine disruptors and to bringing legal certainty. Today's Communication outlines the issues we have considered in this process, it defines the scope of what is relevant to determining the scientific criteria, and sets out the implications of setting these criteria – for the two pieces of legislation directly concerned and for other parts of the EU regulatory framework and actions.*"

Commissioner for Health and Food Safety, **Vytenis Andriukaitis**, said: "*The scientific criteria that the Commission is presenting today guarantee that the high level of protection of human health and of the environment set in our legislation on plant protection and biocidal products is maintained. The plant protection products and biocides' legislation are among the strictest in the world because of their prior approval system, their extensive data requirements, and their hazard approach for decision making. The Commission reinforces today its commitment to protect health of people in European Union.*"

The scientific criteria endorsed by the Commission today are based on the World Health Organisation's (WHO) definition of an endocrine disruptor, for which there is a wide consensus.

The WHO defines an endocrine disruptor as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations". (*)

The criteria endorsed today also specify how the identification of an endocrine disruptor should be carried out:

- by making use of all relevant scientific evidence;
- using a weight of an evidence-based approach;

- and applying a robust systematic review.

The Commission Communication which accompanies the two acts provides an overview of the complex scientific and regulatory context around endocrine disruptors and describes how a scientific consensus on the definition has grown over the last years, all of which has been taken into account by the Commission in arriving at its decision. Looking beyond the criteria, the Communication sets out a number of actions where the Commission will increase its efforts to minimise exposure to endocrine disruptors, in the short-term (research and international cooperation), mid-term (test methods) and long-term (regulatory).

To ensure that swift action is taken, today the Commission is also asking the European Food Safety Authority and the European Chemicals Agency to begin looking at whether approved individual substances that show indications of being endocrine disruptors can be identified as endocrine disruptors according to the criteria in the draft texts presented today. This will also help to ensure that the two regulatory Agencies are ready to apply the criteria as presented today by the Commission, and in accordance with the applicable regulatory procedures, once the criteria enter into force.

The two draft legal acts containing the criteria now need to be adopted by the Commission under the relevant procedures. In the context of the Plant Protection Products Regulation, the draft legal text specifying the criteria will be voted by Member States. In the context of the Biocidal Products Regulation, the draft measure will be discussed in a group of experts of Member States prior to adoption by the Commission.

Both measures involve the European Parliament and the Council. In order to ensure coherence between the two acts, the Commission will present both texts simultaneously to the European Parliament and the Council for them to exercise their functions.

The Commission is also proposing to adjust the ground for possible derogations under the plant protection products legislation in order to take into account the latest scientific knowledge. The 'hazard-based' approach of the Pesticides Regulation will be maintained, meaning that substances are banned on the basis of hazard without taking account of the exposure. However, the grounds for possible derogations have been adjusted so they are based on scientific knowledge and make the best use of available scientific evidence including information related to exposure and risk.

Background

Endocrine-disrupting chemical substances are substances that alter the functions of the hormonal system and consequently cause adverse effects to human health. As scientific awareness of endocrine disruptors grew, the Commission responded with a "Strategy for endocrine disruptors" in 1999.

Under EU legislation on chemicals endocrine disruption is often considered specifically (Plant Protection Products, Biocidal Products, REACH, water quality legislation), or addressed through general risk assessment methodology, thus insuring a high level of protection for consumers and the environment.

Many chemicals used in plant protection products or biocidal products have already been banned because of their adverse effects. This testifies to the EU's commitment to protect citizens from risks resulting from unsafe chemical substances.

For more information

[Frequently Asked Questions: Endocrine disruptors](#)

(*) Definition of an endocrine disruptor made in 2002 by the International Programme on Chemical Safety, a joint programme of various UN Agencies, including the World Health Organisation.

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