

POSITION PAPER

Endocrine-disruptors' criteria under the Biocidal Products Regulation (EU) No 528/2012

The European Commission published a proposal for a delegated regulation setting out scientific criteria for the determination of endocrine-disrupting properties, as required under the Biocidal Products Regulation (BPR). The criteria listed therein merely focus on the interaction between a substance and the endocrine system (i.e. 'endocrine mode of action'). Yet, that is not sufficient to consider a substance as endocrine disruptor. Other variables need to be accounted for in a proper risk assessment.

The **World Iodine Association (WIA)** represents the interests of the iodine value chain - from producers to end-users - towards industry and governmental bodies. The association acts as a central information platform about the uses of iodine in industrial applications, as well as in human and animal health and nutrition.

In the context of the ongoing procedure to set scientific criteria for endocrine-disrupting properties of biocidal products¹, WIA calls on the European Commission for:

1. A **risk-based approach** that looks at both hazard characterizations and exposure, to determine if a biocidal product has endocrine-disrupting properties; and
2. A **derogation** from potential future constraints or bans for **biocidal products, such as iodine**, that could be classified as endocrine disruptors. The EC must take into account that such substances **present a negligible risk and are essential to human hygiene and health**.

Regulatory framework & status quo of the political process

Article 5(3) Regulation (EU) No 528/2012 on biocidal products (BPR) requires the European Commission (EC) to set scientific criteria to identify endocrine disruptors. The EC published a first legislative proposal in June 2016. Following discussions with Member States' experts, the EC revised and adopted the proposal in early September 2017. If the Council of the EU and the European Parliament do not raise any objection by 4 November, the proposal will be adopted.

The position of WIA

If the EC proposal on endocrine disruptors' criteria would be adopted, there would be a risk that iodine be banned or restricted from accessing the European market. Therefore, **WIA does not support the EC draft**, and is in favour of a pragmatic approach to the use of biocidal products and the associated risks, as explained in the arguments below.

¹ The BPR and the endocrine disruptors' assessment target 'active substances' contained in biocidal products, and which are defined as 'substance[s] or micro-organism[s] that have an action on or against harmful organisms'. Iodine used as a disinfectant thus falls under the scope of the BPR.

1. A risk-based approach: The right set of criteria

The criteria listed in the EC text focus on the likelihood for biocidal products to interact with the endocrine system ('endocrine mode of action') to cause 'adverse effects' on an organism. Such definition is **not sufficient to classify a substance as endocrine disruptor**. That is even more so in a regulatory framework, as the latter aims to establish rules based on an assessed risk.

In order to establish a regulation that is fit for purpose and that protects human health and the environment, it is crucial to **follow a risk-based approach**. That means taking into account both the comprehensive hazard assessment of a biocidal product and the level of exposure.

Notwithstanding the specificity, the hazard assessment needs to evaluate the potency (dose level and duration), the severity and the (ir)reversibility of the adverse effect(s), as well as the lead toxicity effect (effect that occurs at the lowest dose). Those elements are referred to as hazard characterizations. The intrinsic hazard of the biocide must be measured together with the **level of exposure** to determine the actual level of risk to an organism or to human health.

Without a comprehensive risk-based approach, too many substances risk being classified as endocrine-disruptors, thus hampering their use and potentially barring them from being placed on the market. In addition, that could lead to public distrust in certain substances or products that are not lead to concerns, and that are even critical to hygiene and health.

WIA is, thus, calling on the EC to adopt a risk-based approach that takes into account both hazard characterizations and exposure to establish whether a biocidal product has endocrine-disrupting properties.

2. Derogation for substances essential to health: The case of iodine

Biocidal products that play a key role in human and animal health and hygiene should not be subjected to potential future constraints or market bans, if classified as endocrine disruptors. That is the case of iodine, an essential element to human life.

Various iodine applications directly contribute to health, hygiene or nutrition. For instance, it is frequently used in human and veterinary disinfectants and drugs. Even more, Regulation (EC) No 1925/2006 lists iodine as part of the vitamins and minerals that can be added to foods. Not only is it safe to use, but it is also essential to address nutrition-related health issues. The World Health Organisation (WHO), Unicef and the European Commission have recognised the need for food fortification - e.g. iodised salt - to effectively fight iodine deficiency disorders (IDD).

If iodine was to be identified as endocrine disruptor, potential market constraints or bans that could ensue would bring disproportionate penalties on a mineral otherwise regarded as safe for human consumption. Restrictions should not bear on substances that present a negligible risk - especially if the level of exposure is low-, and that positively contribute to preserving health and hygiene.

That is why WIA is calling for a **derogation** from potential future constraints or bans for biocidal products, such as **iodine**, that could be classified as endocrine disruptors. The EC must take into account that such substances present a **negligible risk** and are **essential to human hygiene and health**.