Client Alert

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EU Regulation of Endocrine Disruptors is Due to Expand Further

Although endocrine disrupting chemicals (EDCs) have thus far not been defined with much precision, they are increasingly targeted in European Union (EU) policymaking, and have been labeled as a priority for regulation in the EU's 2020 Environment Action Program. Recently, however, the European Commission released two documents: (1) a report on how EDCs will be treated under the REACH authorization regime; and (2) a "roadmap" intended to clarify the definitional criteria. This alert briefly discusses these documents, and summarizes existing EU regulations targeting EDCs.

Current EU Regulation of EDCs

In 2006, the EU adopted a framework for the potential phase out of EDCs under the REACH Regulation. In 2009 and 2012, the use of EDCs was banned in plant protection products and biocides, respectively. These measures are hazard-based, which means that EDCs are banned or have to be phased out, regardless of the actual risks arising from these substances or the costs to society, including those associated with substitutes.

No sound impact assessment was done prior to the adoption of these requirements, nor were any clear criteria established to identify EDCs. Likewise, cost-benefit analysis was omitted. CropLife America recently estimated that EU regulation of plant protection products classified as EDCs has the potential to negatively impact 40% of agricultural exports from the United States, equivalent to more than $4 billion.

Authorization of EDCs under REACH

The REACH authorization regime is intended to phase out the most hazardous substances, including EDCs. Under this regime, a time-limited authorization to manufacture, import or use a substance may be granted if either of these two conditions is met:

- ***Adequate control***: A threshold of exposure exists below which the substance does not cause any adverse effect (safety threshold), and the risk management measures proposed by the applicant ensure that exposure remains below this threshold.
- ***Socio-economic analysis***: The socio-economic benefits outweigh the risks to human health or the environment, and no suitable alternatives exist.

The second option is the only one available for persistent, bioaccumulative and toxic (PBT) substances, and substances that do not have a safety threshold. For such substances, authorization is unavailable if there is any suitable alternative. The European Commission was required to assess by 1 June 2013 whether authorization of EDCs should also be limited to this second option. According to a recent report, the European Commission has decided that both options should be available for EDCs, but the default assumption is that EDCs have no safety threshold (and can thus be authorized only under the socio-economic route), unless the applicant demonstrates that the EDC concerned has a safety threshold. The European Commission recognizes this is a substantial burden that may be difficult to meet.

Thus far, 155 substances have been identified as candidates for authorization, including four EDCs, and 22 substances have been effectively subjected to authorization, but none based on endocrine disrupting properties.

European Commission's Current Thinking

Under the EU plant protection products and biocides regulations, the European Commission was required to establish criteria for the identification of EDCs by December 2013. It has not yet done so, but has now shared its thinking in a draft "roadmap" document. This draft also gives some indications on the direction of future policymaking on EDCs. The forthcoming EU policies may affect a wide range of industries and products, including plant protection products, biocides, chemicals, medical devices, cosmetics and packaging.

Identification and Regulation of EDCs

The European Commission endorses the definition of EDCs adopted by the WHO/IPCS. 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*."

There are, however, no clear operational criteria to determine whether a substance meets this definition. In the absence of such criteria, the EU plant protection and biocides regulations provide the following interim criteria: (1) *must* be considered as EDCs substances that are classified as carcinogenic, category 2, and toxic for reproduction, category 2; and (2) *may* be considered as EDCs substances that are classified as toxic for reproduction, category 2, and which have toxic effects on the endocrine organs.

In connection with its review of these criteria, the European Commission is conducting an impact assessment of various options which include:

1. ***Baseline***: No change to the current interim criteria.
2. ***WHO/ICPS definition***: EDCs would be identified based solely on their hazard, regardless of the magnitude of the hazard, any risk consideration, or the strength of the scientific evidence demonstrating that the WHO/ICPS definition is met.
3. ***WHO/ICPS definition and classification of EDCs based on the strength of the scientific evidence for fulfilling the WHO/ICPS definition***: EDCs would be ranked based on the available scientific evidence (e.g., human, animal or *in vitro* evidence), so that the European authorities could target more precisely those substances for which there is sufficient evidence of endocrine disrupting properties.
4. ***WHO/ICPS definition and potency as element of hazard characterization***: In addition to the WHO/ICPS definition, this option would take into account the potency of the substance. In comparison to other options, this option would exclude low potency EDCs for which regulation might not be warranted.

According to the European Commission, options 3 and 4 would reduce the impact of any regulation on the availability of substances on the market.

In addition, the European Commission is considering the following approaches to regulatory decision making:

A. ***Baseline***: No policy change, which would mean regulatory decision making would remain hazard-based.
B. ***Additional risk assessment***: Regulation of EDCs may be limited based on risk considerations, for example, if there is only a negligible risk.
C. ***Additional socio-economic considerations***: EDCs would be allowed to be placed on the market, despite their hazardousness, for example, if this would be essential to prevent adverse socio-economic impacts.

Options B and C would mitigate the current hazard-based approach and allow a more balanced strategy to address the risks raised by EDCs in line with the proportionality principle (i.e., the EU's obligation to act only when, and to the extent, necessary and without imposing an unnecessary burden on the industry).

Way Forward

The European Commission is expected to launch a public consultation on the proposed EDC identification criteria and regulatory approaches by the end of the year. It will likely finalize its impact assessment in 2015. The current – narrow – hazard-based approach suggests there is an opportunity to push for proportionate and risk-based regulation of EDCs, which also accommodates their socio-economic benefits. Agreed methods for determining safety thresholds of EDCs would be useful to prevent unnecessarily restrictive interpretations of the REACH authorization regime, but the European Commission's current thinking does not appear to contemplate any such guidelines.

How Hunton & Williams Can Help

Hunton & Williams has extensive experience assisting clients with all areas of law that affect the chemical industry. We advise clients on a range of regulatory matters, including compliance management, liability assessment, inspections and enforcement and legal remedies. Working closely with our clients and regulatory and technical experts, we ensure that clients' interests are effectively protected.

Hunton & Williams is a global law firm with a strong focus on regulatory law, and with qualified and experienced lawyers on both sides of the Atlantic, in its offices in Brussels, Raleigh and Washington DC.

Contacts

Prof. Lucas Bergkamp
lbergkamp@hunton.com

Daniel E. Uyesato
duyesato@hunton.com

Malcolm C. Weiss
mweiss@hunton.com

Nicolas Herbatschek
nherbatschek@hunton.com