

## CLIENT ALERT

### Identifying Endocrine Disruptors in the European Union

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The EU's [Plant Protection Products Regulation](#) and [Biocidal Products Regulation](#) require the establishment of scientific criteria for identifying substances that have endocrine-disrupting properties (endocrine disruptors). The European Commission is conducting a comprehensive impact assessment to analyze different approaches for identifying endocrine disruptors. Completing this impact assessment and identifying scientific criteria will be a significant development, because thus far the EU has not developed a consensus approach for the best method to identify endocrine disruptors. As a result, instead of applying a single set of science-based criteria to identify endocrine disruptors, different regulations use different approaches.

As discussed in its June 14 [roadmap for impact assessment](#) (Roadmap), the European Commission will consider four policy options: (i) continuing to use the current mix of approaches, (ii) using the 2002 World Health Organization/International Classification for Patient Safety (WHO/ICPS) definition of an endocrine disruptor, (iii) using the WHO/ICPS definition and adding categories to reflect the level of evidence of the endocrine-disrupting activity (known to disrupt, suspected to disrupt, endocrine-related activity, but not at the level of the first two categories), and (iv) using the WHO/ICPS definition and adding the degree and nature of the risk based on potency. The European Commission will also consider three regulatory options: (i) continuing to use the current regulatory approach, (ii) introducing risk assessment concepts into sectorial legislation, and (iii) introducing socioeconomic considerations, including risk-benefit analysis, into sectorial legislation.

From September 2014 to January 2015, the European Commission consulted with the public about the options detailed in the Roadmap and gathered information for its impact assessment, including scientific articles, studies, reports, views, and legal opinions. It received more than [27,000 responses](#), which were published on the European Commission Directorate General SANTE website at the beginning of February.

In July 2015, the European Commission [published a report](#) setting out its analysis of the responses. In general, respondents expressed diverging views on how to define the scientific criteria and how to regulate endocrine disruptors. Overall, the responses suggested that there is a need for the EU to establish definitive criteria for identifying endocrine disruptors, and many respondents supported use of the WHO/ICPS definition as a starting point. Authorities in non-EU countries noted that any decision on endocrine disruptors must respect the principles of the World Trade Organization.

The results of the impact assessment will likely not be known before 2017. However, any criteria that are established for identifying substances with endocrine-disrupting properties will likely impact other legislation as well, such as the REACH Regulation, Cosmetics Regulation, and Water Framework Directive.

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