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Client Alert

International Trade/WTO, FDA & Life Sciences, and EHS Practice Groups

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European Union Releases Criteria to Identify Endocrine Disruptors

On June 15, 2016, the European Union (E.U.) issued its long-awaited Communication from the Commission to the European Parliament and Council ("Communication") on endocrine disruptors. The Communication was accompanied by an impact assessment and two draft measures, proposing criteria to identify endocrine disruptors for biocidal products (*e.g.*, hand disinfectants) and plant protection products (PPP) (*e.g.*, agrochemicals, including pesticides). Endocrine disruptors are substances, both natural and chemical, that can alter the functions of the hormonal system and cause adverse effects in people or animals. To become final, the draft measures need to be adopted by the European Commission under relevant procedures, which include engaging Member States and other E.U. institutions. While there will be opportunities for additional comments, many stakeholders remain concerned with the scientific basis for the E.U. regulations, particularly given their potential to significantly disrupt trade across many sectors.

Release of the draft criteria has been anticipated for some time. By way of background, December 2013 was the initial deadline by which the European Commission was supposed to have issued scientific criteria to identify endocrine disruptors to help implement legislation addressing biocidal products and PPPs. Thus, the draft criteria are more than two years late.

The original E.U. legislation for biocidal products and PPPs provides that endocrine disruptors shall not be approved for general use. Substances, however, can be approved by way of a derogation if, in the case of PPPs, there is negligible exposure, or, in the case of biocides, there is negligible risk. In the new draft measure for PPPs, the Commission also essentially proposes to apply the biocides standard ("negligible risk") to endocrine disruptor substances falling under the PPP regulation, thus potentially broadening the scope of the derogation. Thus, the proposed measures would help regulators identify endocrine disruptors in biocides and PPPs, and, in the case of PPPs, would change how they would be regulated once they are identified. The draft biocide and PPP measures, once finalized, will be relevant to new and existing active substances in biocides and PPPs.

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The E.U.'s current PPP and biocide legislation is among the strictest in the world, in part, because of the E.U.'s hazard-based approach to regulating chemicals. This hazard-based approach regulates chemicals on the basis of their intrinsic properties (without taking into account human or environmental exposure to a particular substance), whereas the alternative risk-based approach (as used by other jurisdictions) considers exposure. Under the hazard-based approach, a substance may be banned based on its intrinsic properties even if there are ways to mitigate exposure and risk.

Once the measures with the endocrine disruptor criteria are finalized, the criteria only will apply to active substances in PPPs and biocides. *See* Communication, at 8-9. As explained further below, for the time being, the measures will not directly affect other areas, but they could have indirect effects. Moreover, the scientific criteria set forth in the draft biocide and PPP measures will likely directly affect the E.U.'s mandatory review of substances with endocrine disrupting properties under the Registration and Authorization of Chemicals (REACH), the Cosmetics Directive, the Medical Device Directive, and the Water Framework Directive, all of which will take place in the near future.

Recommended Criteria for Identifying Endocrine Disruptors

The scientific criteria for identifying endocrine disruptors set forth in the draft measures for biocidal products and PPPs build on the World Health Organization's (WHO) definition of an "endocrine disruptor." 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 scientific criteria in the draft measures expand on this definition by defining "adverse effect" and addressing how to determine causality. Specifically, the draft measures provide that "[a]n active substance shall be identified as having endocrine disrupting properties with respect to humans" if it is a substance that meets all of the following criteria:

- it is known to cause an adverse effect relevant for human health, which is a change in the morphology, physiology, growth, development, reproduction, or, life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences;
- it has an endocrine mode of action; and
- the adverse effect relevant for human health is a consequence of the endocrine mode of action.

See Draft Biocides Measure; Draft PPP Measure.

Interestingly, the WHO definition of an "endocrine disruptor" is essentially risk-based, because it explicitly states that evidence of an "adverse" effect would be a criterion for endocrine disruption. Thus, it is unclear how the Commission will reconcile its own scientific criteria for identifying endocrine disruptors, which build on the risk-based WHO definition of "endocrine disruptor," with its general hazard-based approach to regulating these chemicals.

Potential Implications of the Draft Measures on Industry (Including the Cosmetics Industry)

The draft biocide and PPP measures are likely to have both direct and indirect effects on industry. As mentioned, once the biocide and PPP measures are finalized, the endocrine disruptor criteria only will apply to active substances in PPPs and biocides (at least for the time being). It remains to be seen how the European Food Safety Authority (EFSA) and the European Chemical Agency (ECHA) will implement and interpret these measures. If the implementation of the biocide and PPP measures leads to prohibitions or restrictions on certain substances when they are used in biocides and

PPPs, which is likely, this could result in obstacles for companies exporting biocide and/or PPP products to the E.U. Not only would these companies need to comply with the E.U. law for products sold in the E.U., they may also have to confront follow-on legislation in the United States or in any one of the 50 states. The prohibition or restriction of certain substances in the E.U. often results in increased political pressure on the United States and on the states to prohibit, restrict, or scrutinize the same substances. Indeed, the U.S. Toxic Substances Control Act (TSCA) modernization law, as enacted on June 22, 2016, requires EPA to initiate a minimum number of substance evaluations in the next six months, with further deadlines until all "high priority" substances are assessed. Several of the E.U. endocrine disruptor candidates also appear on the list EPA is required to prioritize, and EPA is likely to consider assessments in the E.U., Canada, and other countries as it expands its evaluation list.

In addition, if certain chemicals are prohibited or restricted for use in biocides or PPPs, it could have indirect effects on other industries, such as the cosmetics industry. These indirect effects could include: sourcing issues and related increases in costs; pressure from public interest groups on the federal government and/or states to enact laws prohibiting or restricting the use of the same chemicals for use in other products, such as cosmetics; and/or pressure from public interest groups, retailers, the federal government and/or states to reformulate.

Further, the criteria used for identifying endocrine disruptors in biocides and PPPs (along with the Commission decisions based on those criteria) may inform the manner in which the Commission ultimately reviews substances with endocrine disrupting properties under the Registration and Authorization of Chemicals (REACH), the Cosmetics Directive, the Medical Device Directive, and the Water Framework Directive. For example, the existing E.U. cosmetic regime, pursuant to Regulation (EC) No 1223/2009, already applies a hazard-based approach to regulating cosmetic ingredients by prohibiting the use of substances that are carcinogenic, mutagenic, or reprotoxic, and it directs the Commission to review substances with endocrine-disrupting properties. *See* Communication at 10. When the Commission conducts this review, it may attempt to harmonize its approach for reviewing endocrine disruptors under the cosmetic legislation with its approaches to reviewing the same substances under other regulations, such as the biocide and PPP regulations. Accordingly, the Commission's review of substances with endocrine disrupting properties that are present in cosmetics could be influenced by the scientific criteria for identifying endocrine disruptors in the draft biocide and PPP measures. Notably, the Commission's review of endocrine disruptors used in the E.U. for cosmetics also could affect ingredients used in U.S. cosmetics (as well as other products, such as sunscreen), because the E.U. defines the term "cosmetic" more broadly than the U.S. Food and Drug Administration.

Chemicals that ultimately could be affected include those identified in Annex 4 of the impact assessment that was issued with the draft biocide and PPP measures. In addition, the E.U. has compiled a Candidate List of Chemicals, which is a list of so-called "known" or "potential" endocrine disruptors that was populated based on available scientific literature prior to the development of the criteria to identify endocrine disruptors in the draft PPP and biocide measures. This list includes the following cosmetic ingredients, among others:

- Resorcinol, commonly found in hair dyes, shampoos and lotions, tanning products and topical dermatological treatments;[1]
- Butylbenzylphthalate (BBP), a cosmetic adhesive used in nail polish; and
- Di-n-butylphthalate (DBP), a solvent used in hairsprays, perfumes, and nail polish.

Finally, it should be noted that the E.U. approach to identifying endocrine disruptors in the draft biocide and PPP measures may not be entirely consistent with risk-based approach required in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures. Therefore, to the extent that the criteria are

finalized, and then implemented in a manner that erects trade barriers, they could be challenged at the WTO level. Already, close to two dozen Member countries have raised concerns with the E.U. approach.

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King & Spalding's Environmental, Health & Safety Practice advises and represents companies who manufacture, distribute, use, and transport products or materials regulated under EH&S laws and regulations, including the Toxic Substances Control Act, HazMat regulations, California's Proposition 65, and similar U.S., E.U., and other international laws. We assist clients in understanding and assessing the risks and opportunities associated with supply chain and product content regulation across jurisdictions in order to achieve strategies for compliance management in an increasingly competitive economic environment.

Please contact us if you have any questions about these developments.

[1] Resorcinol is also referred to as 1,3-Benzenediol, 1,3Benzenediol, 3-Hydroxyphenol, CI Developer 4, M-Dihydroxybenzene, M-Hydroquinone, M-Phenylenediol, Oxidation Base 31, Resorcin, and 1,3-Dihydroxybenzene. Currently, it is restricted in all types of cosmetics in Japan, and the E.U., to date, limits maximum concentrations of the ingredient and requires a warning label. The United States regulates the exposure to resorcinol for workers in manufacturing through mitigation measures, but not for salon workers.