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SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consultation response

AmCham EU comments on the second French national strategy on endocrine disruptors (SNPE 2)

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AmCham EU welcomes the opportunity to comment on the draft documents for a second national strategy on endocrine disruptors (SNPE 2). We share the commitment expressed in the draft SNPE 2 to protect human health and the environment from endocrine disruptors. We believe this can be best achieved through robust weight of evidence science-based assessments and effective risk management. In this context, AmCham EU supports using the 2002 WHO/IPCS definition as the cornerstone for identifying endocrine disruptors for regulatory purposes, coherent with the criteria that have recently been adopted at the EU level for plant protection products and biocidal products.

We would like to highlight the following specific comments related to some of the key elements and actions in the draft SNPE 2:

1. A list of endocrine disruptors based on a category approach would be inconsistent with the existing EU regulatory framework.

The draft SNPE 2 proposes establishing a list of substances based on a category approach that would include "known", "presumed" and "suspected" endocrine disruptors. This list would then be used as a basis for further measures, including regulatory proposals brought by France at the EU level, initiatives aimed at promoting prevention and caution during use, or further assessments.

AmCham EU would encourage French authorities to pursue an approach which is coherent with the EU regulatory framework for endocrine disruptors, based on the WHO/IPCS definition. According to this definition, to be identified as endocrine disruptors substances must display an adverse effect, an endocrine mode of action, and a biologically plausible causal link between the two. A category approach with known, presumed and suspected endocrine disruptors is not compatible with the WHO definition as adopted by the EU in the criteria, which identifies a single group of endocrine disruptors which clearly fulfil the definition based on robust data and a rigorous assessment of that data.

The option of introducing a category approach was considered at the EU level when criteria were defined to identify endocrine disruptors under the EU regulations on plant protection products and biocidal products. A category approach was ultimately excluded, on the grounds that these would create regulatory uncertainty and cause unnecessary concern. As a consequence, reintroducing categories at the national level in France would potentially distort the EU single market and create confusion with regard to which substances are actually of concern and should be regulated.

2. Endocrine disruptors should be regulated at the EU level, to maintain a level playing field and ensure a coherent approach based on the WHO/IPCS definition.

Endocrine disruptors are already being identified at the EU level under REACH Article 57f, which allows substances to be listed as Substances of Very High Concern due to "equivalent level of concern". Substances are regularly assessed for potential endocrine disrupting effects through the Community Rolling Action Plan (CoRAP) and discussion on specific substances also takes place in the ED Expert Group hosted by the European Chemicals Agency (ECHA) and with the participation of experts from EU member states including France, as well as participation by experts from industry and non-governmental organizations. More than 80 substances (ongoing or completed assessments) have been included under REACH substance evaluation due to potential endocrine disrupting concerns, with many of these being reviewed by the ECHA ED Expert Group. The ECHA ED Expert Group has also a plan to review potential ED effects of all main biocidal actives, and consequently is significantly increasing the duration of expert meetings in 2019.

Substances identified as endocrine disruptors can then be placed on the Authorisation List or restricted in certain applications through REACH, as well as under the existing extensive sectoral EU legislation on plant protection products, biocidal products, cosmetics, food contact materials, and medical devices, and electrical and electronic goods.

The European Commission has recently announced plans to carry out a cross-cutting fitness check on EU legislation covering endocrine disruptors. Action 33 of the draft SNPE 2 envisages engaging at the EU level to promote a horizontal definition of endocrine disruptors based on categories. AmCham EU strongly advises against pursuing a category approach, as this was already discarded at the EU level due to concerns around regulatory uncertainty and potential confusion. Rather, any initiatives aimed at securing a horizontal definition for endocrine disruptors should be coherent with the WHO/IPCS definition, which forms the basis for the criteria currently defined for plant protection products and biocidal products. AmCham EU would strongly encourage French authorities to support a coherent, science-based EU regulatory framework for endocrine disruptors based on the WHO/IPCS definition.

3. Classification and labelling should be managed through GHS and CLP.

Action 5 in the draft SNPE 2 relates to exploring options for setting up a labelling system based on pictograms signaling the presence of endocrine disruptors in products and articles.

AmCham EU would stress that, as pointed out in the draft SNPE 2, classification and labelling of chemicals is currently managed internationally via the Global Harmonised System (GHS) and at the EU level via the CLP regulation. We would note that, as part of its comprehensive fitness check on endocrine disruptors, the European Commission has already committed to examining the feasibility of classifying endocrine disruptors under GHS. We would therefore encourage French authorities to avoid duplicative and potentially incoherent classification and labelling initiatives at the national level.

4. Adverse effects from endocrine disruptors are already captured under GHS and CLP.

When considering the merits of including endocrine disruptors under GHS and the CLP regulation, it is important to note that these systems are designed to classify adverse effects of chemicals rather than their modes of action. Indeed, adverse effects that are caused through endocrine modes of action are already captured under GHS and CLP, for example when it comes to substances that are carcinogenic, mutagenic and toxic to reproduction (CMR). In the EU, classification for such adverse effects can lead to additional regulation through REACH (e.g. SVHC listing), as well as market restrictions under EU sectoral legislation (e.g. medical devices, cosmetics). Broadening the scope of GHS and CLP to classify modes of action (including endocrine modes of action) would create a significant precedent and raise a number of issues, including potential double regulation for the same adverse effects.

It is also important to note that in other regions, hazard classification serves primarily as a communication tool. Communication to individuals handling chemicals throughout the supply chain has to be simple and impactful. Hence, in classifying a substance it is not necessary (nor we believe helpful) to assess all the different potential modes of actions that can lead to a given adverse effect. The chemical Industry has to make sure that the labels on our materials are easily understood and thus impactful in communicating proper handling. Consequently, we are very concerned that using modes of actions as hazard classes in themselves would lead to confusing and overly complicated classifications.

Based on the elements above, AmCham EU would caution against using GHS and CLP to classify and label endocrine disruptors.

5. Endocrine disruptors are already regulated at the EU level in a wide variety of products.

Actions 22 and 23 in the draft SNPE 2 envisage assessing the presence of endocrine disruptors in consumer products with a view to proposing new regulatory initiatives.

AmCham EU would note again that endocrine disruptors are already regulated in consumer products through REACH or other sectoral EU legislation including on plant protection products, biocidal products, cosmetics, food contact materials, medical devices, and toys. In such cases, endocrine disruptors are either regulated as such or based on the adverse effects they cause, for example carcinogenicity, mutagenicity or reproductive toxicity

(CMR). This appears to be a fundamental misunderstanding of some politicians and environmental non-governmental organizations in this debate, in that the extensive EU regulations which regulate substances for adverse effects (including those which can arise from an endocrine mode of action) are not acknowledged. We would urge all lawmakers and stakeholders to become fully informed with regard to the extensive regulations which are already in place in the EU and which regulate based on adverse effects including regulation of those substances which act via an endocrine mode of action.

AmCham EU would encourage French authorities to pursue regulation on endocrine disruptors in consumer products at the EU level, based on the WHO/IPCS definition, to ensure coherence and predictability across the Single Market.

6. A stronger scientific basis is needed to support policy-making on endocrine disruptors.

Endocrine disruptors have been the object of intense debate within the scientific community. For example, we recognise the ongoing debate amongst some scientists concerning the existence of safe thresholds when referring to endocrine disruptors. However, the same doubt in current scientific practice can applies to other modes of action and all hazard characterisations performed. In the absence of robust scientific data supporting a change to the current paradigm on the use of thresholds, endocrine disruptors should be considered in the same way as other modes of action and be subject to risk assessment with thresholds being established via a knowledge of the dose-response. Otherwise, the implication is that no food, drug nor otherwise used natural or man-made chemical can ever be stated to be of negligible concern by any regulatory agency.

The draft SNPE 2 also refers to the issue of combination effects. The relevance of combination effects of chemicals relates to situations where there is a common mode of action. However, although these effects may apply to certain endocrine disruptors, we would like to stress the point that such effects are rare and not specific to endocrine disruptors. It should also be noted that multiple substance exposure can be inhibitory and not just additive or synergistic. While this topic needs more research, we believe that it is best addressed in a systematic way within the EU's broader program on chemical safety.

With respect to substitution it is important again that this is based on risk assessment and not just substitution based on ideology, and that alternatives have been adequately assessed for technical and economic feasibility as well as health and environmental safety. This indeed is the role of companies and other stakeholders within the EU and global marketplace, with regulations including those on health and environment, providing the framework for supporting competition leading to improved and more effective products meeting consumer needs.

With respect to support action 3 in the draft SNPE 2 we support related to the development and OECD validation of new test methods to assess substances for potential endocrine disrupting properties at EU and OECD level rather than at national level. In terms of focus, those endpoints where potential gaps have been identified should be prioritised (e.g. neurotoxicity). Furthermore, development of alternative methods to replace animal testing could also be an important area of collaborative research. While some efforts are underway, including those being made by industry, this area requires larger scale projects supported by substantial funding e.g. via funding from the EU Horizon 2020. Sufficient time and budget should be allocated to the development of new test methods in order to ensure their quality and reliability with development and validation at international level.

When it comes to further research on endocrine disruptors, we strongly recommend that research funds are not only targeted towards mode of action identification for endocrine disruption, but also towards methods which enable risk assessment. Otherwise, regulatory agencies will not be able to make use of the results stemming from new methods to address public concerns relating to food items, other natural materials or drugs. This will also greatly enhance the uptake of the new methods in other regions which apply science-based decision-making to chemicals management. Risk assessment is essential in order to avoid the loss of the benefits of valuable substances, which can be used safely based on risk assessment. This also provides regulatory predictability and a more stable environment with the associated implications for jobs, investment and global competitiveness.