



Contribution to the European Commission's Public Consultation on
Defining criteria for identifying Endocrine Disruptors
in the context of the implementation of the Plant Protection Product Regulation and Biocidal
Products Regulation

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The American Chemistry Council (ACC)¹ is pleased to provide the following comments on the EC's Public Consultation on "Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation" (the "Consultation"). While the Consultation addresses defining the criteria for identifying endocrine disruptors (EDs) for purposes of plant protection and biocidal product regulations, ACC understands the proposed criteria could set a precedent for other EU regulatory programs.² ACC is also concerned that certain proposed EC approaches for identifying EDs, including the proposed regulatory categorization of ED chemicals, would trigger unnecessarily negative and far-reaching impacts on global commerce. These comments address those concerns and suggest approaches for minimizing unwarranted negative trade impacts and improving U.S.-EU regulatory cooperation.

ACC is particularly concerned that the proposed approach for identifying and categorizing EDs differs substantially from the approach taken by the U.S. Environmental Protection Agency (EPA) over the last 15 years to screening and testing chemicals for adverse endocrine activity. At a time when U.S. and EU leaders have committed to enhancing trans-Atlantic regulatory cooperation under the Trans-Atlantic Trade and Investment Partnership (TTIP), we are concerned that significant differences between the way that EDs are treated in the U.S. and EU could undermine efforts to enhance trans-Atlantic regulatory cooperation, and could have wide-ranging negative impacts on U.S.-EU trade.

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

² The Roadmap document for the Consultation states that an objective of the initiative is "ensuring possibility to apply these criteria across all relevant Union legislation."



ACC supports approaches to regulating chemicals that identify and assess chemical hazards, assess chemical exposures and fully assess chemical risks. Generally, current EU legislative approaches turn on identifying substances as “endocrine disruptors.” At a very basic level, approaches that regulate on the basis of simply identifying chemicals that may interact with a component of the endocrine system equates to regulating based on a particular mechanism or mode of action rather than an actual adverse effect. This, along with the fact that some EU approaches do not consider exposure and risk, creates a significant inconsistency in U.S. and EU regulatory activities, and consequently has potential negative trade impacts.

While the U.S. and EU may adopt different legislative approaches for regulating endocrine active substances, ACC believes it would be possible to minimize unwarranted negative trade impacts and improve U.S.-EU regulatory cooperation by utilizing a definition of ED that includes demonstrating adverse effects and by more fully characterizing risks and hazards when identifying EDs. ACC believes Option 4 presented in the Roadmap, with the inclusion of additional factors, provides the most appropriate approach and framework for minimizing negative trade impacts. Under “Approaches to regulatory decision making” presented in the Roadmap, ACC believes a combination of Options B (incorporation of further elements of risk assessment into legislation) and C (further socio-economic considerations) will help to promote coherence between the U.S. and EU regulatory approaches.

This document provides a number of general comments that address various issues related to the Consultation. ACC also comments on each of the specific policy options and regulatory approaches proposed in the Roadmap.

1. General Comments

a. The U.S. Approach to Regulating Endocrine Disruptors

For nearly four decades the U.S. predominantly has used risk-based approaches for regulating hazards posed by potential exposures to chemicals, including endocrine active substances. In 1983, the National Academy of Sciences (NAS) published *Risk Assessment in the Federal Government Managing the Process* (commonly referred to as the “Red Book”).³ The NAS suggested a four-step process for assessing risk: hazard identification, dose-response assessment, exposure assessment, and risk characterization (which combines the exposure and dose-response assessments). The results of the risk assessment (primarily the risk characterization) would be used along with other considerations (e.g., political, economic, social, policy, and cost-benefit) to determine agency decisions and actions, such as chemical regulation. The NAS termed this last, and separate, step “Risk Management.” EPA has integrated the NAS principles of risk assessment into its practices.⁴

³ National Academy of Sciences (1983), *Risk Assessment in the Federal Government: managing the Process*. National Academy Press, Washington, DC.

⁴ See, U.S.EPA (1984), *Risk Assessment and Management: Framework for Decision Making*, EPA 600/9-85-002, Washington, DC. See also, U.S.EPA (2004), *An Examination of EPA Risk Assessment Principles and Practices*, EPA/100/B-04/001, Washington, DC.



U.S. legislation in 1996 required EPA to develop validated test methods to measure estrogen activity in pesticide chemicals. Since that time, EPA has been developing and implementing a program to screen and test chemicals for endocrine activity. EPA's program, the Endocrine Disruptor Screening Program (EDSP), uses a two-tiered process to identify chemicals that have the potential to interact with components of the endocrine system, and, for those chemicals that have such potential, to assess their risks.⁵ EPA's EDSP applies the NAS and EPA risk assessment principles for assessing and managing risks. EDSP Tier 1 (screening) utilizes a battery of shorter term *in vitro* and *in vivo* assays to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems. EDSP Tier 2 (testing) utilizes more apical animal assays to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified in Tier 1. Using a risk-based approach, EPA will use the results of the EDSP to manage (e.g., regulate) risks posed by EDs.

It is important to recognize that the Tier 1 EDSP assays have been designed to maximize their ability to detect a response and intentionally minimize false negative results. Thus, by design, such assays will frequently produce false positive results. Further, many of the EDSP *in vitro* assays utilize very high concentrations of test substances that would not be attainable *in vivo*. Even the concentrations utilized in the *in vivo* EDSP assays may not be relevant to potential human and environmental exposure. For these reasons, not only is it important to identify the potential for substances to interact with components of the endocrine system (an EDSP Tier 1-type determination), it is necessary to establish dose-response relationships and determine adverse effects (EDSP Tier 2-type determinations).

Knowledge of the types of adverse effects induced, the doses associated with these effects and the slope of the dose response curves is critical for understanding what types of risk are posed at different levels of exposure and for establishing safe exposure levels in various media (air, water, food, soil) and products to ensure protection of both human health and the environment. In other words, effective regulation is dependent upon understanding not just mode of action, but must consider the nature and type of effects induced, the potency (slope of the dose-response curve) of a substance and environmentally relevant exposure levels.

EPA uses a Weight of Evidence (WOE) approach for assessing EDSP and other data to determine both whether a substance interacts with the endocrine system and whether those substances cause adverse effects. Consistent with the U.S. approach, the EC's Endocrine Disrupters Expert Advisory Group (ED EAG) recently issued a report stating that WOE approaches should be applied in the evaluation of both adverse effects and mode of action.⁶ According to the ED EAG those approaches should weigh all available evidence and consider the quality, reliability and relevance of individual studies as well as reproducibility of reported effects, the pattern of effects across and within studies, number of species showing the same or

⁵ See, U.S.EPA (2009), Endocrine Disruptor Screening Program; Policies and Procedures for initial Screening, 74 Fed Reg 70248, April 15, 2009.

⁶ European Commission, JRC Scientific and Policy Reports, Report of the Endocrine Disrupters Expert Advisory Group: *Key scientific issues relevant to the identification and characterization of endocrine disrupting substances*, 2013



similar effects, time of onset of effects and life stage affected. The ED EAG stated that the consideration of these factors is important in a WOE approach to both ED identification and characterization.

In Policy Option 2, the Roadmap outlines WOE-type factors to consider when determining whether substances exhibit endocrine-mediated adverse effects. It appears the Roadmap proposes to apply these factors to all of the proposed options. ACC agrees with the need to utilize a WOE approach to integrate and interpret scientific evidence related to EDs. WOE should also be used to determine the existence, nature and magnitude of risks posed by exposures to EDs.

ACC urges the EC to develop clear and transparent criteria for determining data quality and study reliability. The EC should also develop a clear, systematic approach for conducting WOE analyses.

b. Criteria for Identifying “Endocrine Disruptors” Must Include a Finding of Adverse Effects

The U.S. and WHO/IPCS definitions of “endocrine disruptor” incorporate a finding of adversity. A definition of ED that requires a finding of adverse effects recognizes that, while substances may have the potential to interact with the endocrine system, such interactions will not necessarily lead to any adverse health or environmental effects. Within endocrine systems, natural variations in hormone levels and reversible or transient changes that are not considered adverse have been well documented. The endocrine system is complex and seeks to maintain homeostasis in a continually variable and fluctuating natural environment. Substances can interact with the endocrine system by a variety of mechanisms, including direct effects on hormone dependent or producing tissues, on enzymes involved in the excretion of a hormone, on enzymes for hormone synthesis and through agonistic or antagonistic hormone receptor binding. Evidence that a substance interacts with a component of the endocrine system through one of those mechanisms, however, does not provide any information on whether that substance causes other biological changes, which may, in turn, cause adverse health effects. By adopting a definition of endocrine disruption that includes evidence of adverse effects in an intact organism and not simply evidence of endocrine activity, the U.S. focuses on the most important considerations for protecting public health and the environment.

It is inappropriate and inconsistent with scientific evidence to assert that endocrine disruption equates merely to evidence of the potential of a substance to interact with components of the endocrine system. The term “endocrine disruptor” implies adverse effects, and thus should not be used to describe results from assays such as those included in EPA’s EDSP Tier 1 battery. Activity in such assays may be appropriately described as endocrine activity, but not endocrine disruption, since such assays evaluate mechanistic endpoints only, and not adverse, apical effects. As noted by EPA, a positive response of a chemical in ToxCast and T21 endocrine assays, or in similar high throughput screening assays or computational methods “does



not necessarily mean that it will cause toxicity or an adverse health outcome. Careful review is required to determine the use of the data in a particular decision context.”⁷

Unless adverse effects are considered when defining EDs, the public will unnecessarily believe any interaction with the endocrine system is adverse. This has the potential to lead to unjustified disparagement of chemical products and to adverse impacts on local and global commerce. This problem becomes more acute when the regulation of EDs is not risk-based, and instead is based on hazard identification without consideration of potency or dose-response. **For these reasons, substances should not be identified as endocrine disruptors unless they cause an adverse effect through an endocrine mode of action.**

ACC agrees with the EC’s proposal to use the WHO/IPCS definition of “endocrine disruptor” to the extent the definition requires an alteration of the endocrine system causing an adverse effect. This definition recognizes that while a simple interaction of a substance with the endocrine system might provide some evidence of a potential mode of action, a mere endocrine interaction is insufficient to identify potential endocrine-related hazards. This recognition is especially important when regulatory schemes (such as some of the EU regulatory schemes) require actions based on a substance simply being identified as an ED.

Unlike some EU regulatory schemes (such as provisions of PPPR and BPR), the simple identification of a substance as an endocrine disruptor does not have a direct regulatory impact in the U.S. The regulation of endocrine active chemicals in the U.S. requires at a minimum both a determination of potential to interact with the endocrine system and production of adverse effects at physiologically relevant doses. This is seen in EPA’s two-tiered approach for assessing EDs (the EDSP), which utilizes a screening tier to determine whether a substance has a potential to interact with the endocrine system and a testing tier to determine whether a substance exerts an adverse effect. The EC can help promote coherence between the U.S. and EU approaches to regulating endocrine active substances by using the WHO/IPCS definition of endocrine disruptors thereby incorporating adversity in its regulatory decisions.

c. Identification of Endocrine Disruptors Should Include Elements of Risk Assessment

As discussed above, the regulation of EDs in the U.S. does not turn on merely determining whether a substance is defined an “endocrine disruptor” (i.e., hazard identification) irrespective of potency and dose. The EPA considers a number of factors in addition to hazard identification, including specificity of action, human and wildlife relevance, dose response, lead toxic effect, severity of effect, irreversibility, lead toxicity, potency, thresholds, exposure and other factors to assess the risks posed by chemical substances, including EDs. Those considerations are incorporated, along with exposure assessment, into a risk assessment, which is then used as a scientific basis for regulation. In managing risks (e.g., regulating EDs), EPA would consider factors such as cost-benefit, which includes socio-economic factors, and other policy-related factors.

⁷ <http://actor.epa.gov/dashboard/>



The ED EAG's recent report concluded that adversity, endocrine mode of action and causal link to adversity, specificity, and human and wildlife relevance are factors that should be considered for identifying a substance as an endocrine disruptor. The ED EAG found that other factors are also important to consider, but in the context of characterizing EDs. Those factors include severity of effect, irreversibility, lead toxicity, and potency. ACC agrees that all of these factors are important for assessing risk posed by EDs and for regulating EDs. Indeed, in the U.S., all these factors would be considered when regulating EDs.

The ED EAG appears to distinguish between factors relevant for identification of a substance as an endocrine disrupter and factors relevant for the characterization of endocrine disrupters. ACC is concerned that because of this apparent distinction, EU regulation (especially those based solely on ED identification) might exclude consideration of the ED characterization-related factors. To the extent EU regulations do not consider the characterization-related factors, those regulations would conflict with U.S. regulations that consider all the ED EAG factors when assessing ED risks and regulating EDs. **ACC believes some inconsistency between EU and U.S. regulations can be avoided if the EC includes all of the ED EAG factors when identifying EDs (i.e., the EC should include both factors for identification and factors for characterization into its identification procedures). Of course some inconsistencies may still exist given that the U.S. also considers exposure when regulating chemical substances. Nonetheless, considering all the ED EAG factors when identifying EDs will better align EU and U.S. regulatory approaches for managing EDs.**

While the Roadmap does not clearly state whether and how risk characterization factors would be incorporated when identifying EDs, it appears Policy Option 4 envisions inclusion of at least one of these factors, potency, in the regulatory process. Also, regulatory Option B (introduction of further elements of risk assessment into sectorial legislation where management measures for placing substances on the market are mainly based on hazard identification) appears to address the need to include the risk characterization-related factors in ED regulation. **ACC urges the EC to consider all elements of risk assessment when identifying EDs in order to lessen unnecessary adverse impacts on global trade. For these reasons, ACC supports adoption of Policy Option 4 (with inclusion of additional risk factors) and adoption of Regulatory Approach Option B.**

d. The EC Should Not Create Categories for “Potential EDs” and “Endocrine Active Substances”

ACC believes the EC should not categorize EDs as proposed in Policy Option 3. The Roadmap proposes categorizing ED into three categories (EDs, suspected EDs, and Endocrine Active Substances) based on the strength of evidence for determining whether a substance is an ED. ACC does not understand how creating the additional categories of suspected endocrine disruptors and endocrine active substances can inform regulatory decisions in the EU, and this is certainly not required to meet the requirements of the relevant sectorial legislation. Rather, creating such categories will likely lead to confusion of the public, who will likely assume any listed substance under any of the three categories are “endocrine disruptors” that pose a real risk



to human health and the environment. This is likely to lead to unwarranted product disparagement and may lead to calls to regulate all three categories of substances without a scientific basis. That would result in the unwarranted regulation of substances based on a mode of action rather than scientific evidence that the substance poses a threat to human health or the environment at environmentally relevant levels of exposure.

As discussed above, ACC's concern arises from the understanding that "endocrine activity" describes a possible mode of action, not an adverse effect. Therefore, creating the category of "endocrine active substances" appears inconsistent with prevailing views concerning the definition of EDs and the EC's proposal to use the WHO/IPCS definition to identify endocrine disruptors, which requires a finding of an adverse effect. There also is no need to create the category of "suspected EDs". The EC and the ED EAG have outlined reasonable criteria for assessing ED-related evidence. The EC should not undermine these efforts by constructing other categories that may legitimize the use of and provide inordinate weight to information and results from non-standardized, non-validated, short-term, mechanistic studies and other insufficient data.

ACC is concerned the creation of lists of "suspected EDs" and "endocrine active substances" would likely precipitate decisions to stop using those listed products or promote the switch to alternatives whose effects may be less well understood. In turn, those decisions could result in significant and unwarranted dislocations in the economy. In addition, those decisions could have the effect of denying access to useful products and technologies and exposing the public to unknown and potentially more serious risks if the replacements to these products and technologies are less well understood. **In sum, creation of additional categories of EDs will serve no useful regulatory purpose given current EU legislation and would unnecessarily confuse and alarm the public.**

2. Specific Responses to the Consultation

a. Policy Options – EU Criteria to Identify EDs

i. Option 1: No Policy Change

The EC should not adopt Option 1. The interim criteria are not based on scientific evidence, and (particularly in the case of the BPR) do not determine whether an identified substance has an adverse effect causally linked to an endocrine-mediated mechanism. ACC does not view the interim criteria as being adequate for regulatory purposes.

ii. Option 2: WHO/IPCS definition to identify ED

The EC should not adopt Option 2 without the addition of additional elements of risk characterization such as potency and those identified by the ED EAG (severity of effect, irreversibility, and lead toxicity). While ACC supports the use of the WHO/IPCS definition of ED (excluding the WHO/ICPS definition of a potential ED) and aspects of a WOE approach for assessing data, it believes Option 2 as it stands does little to identify substances that actually pose



a hazard to human health or the environment. Under some of the current EU legislative schemes, Option 2 as written could lead to the regulation of common substances such as caffeine, soy, pain medications such as paracetamol and other substances that pose little or no human health or environment hazard. This, in turn, could lead to unnecessary negative economic and trade impacts.

The addition of risk characterization elements as outlined above would bring Option 2 closer to the U.S. approach for regulating endocrine active substances, which is risk-based. Use of Option 2 as currently written would likely precipitate decisions to stop using safe substances (albeit substances which, in some screening assays, may show the potential to interact with a component of the endocrine system) and promote the switch to alternative substances whose effects may be less well understood. In turn, those decisions could result in significant and unwarranted dislocations in the economy and could have the effect of denying access to useful products and technologies, and expose the public to unknown and potentially more serious, risks.

iii. Option 3: WHO/IPCS definition to identify EDs and introduction of additional categories.

The EC should not adopt Option 3. While ACC supports the use of the WHO/IPCS definition of endocrine disruptors, it strenuously objects to the creation of additional categories of EDs, which will be misunderstood and possibly misapplied. As discussed above, listing “suspected EDs” and “endocrine active substances” does not inform EU regulation of EDs. ACC believes creating categories of EDs may confuse the public, who will likely assume any listed substance under any of the three proposed categories are “endocrine disruptors” and pose a real risk to human health and the environment. This may lead to unwarranted product disparagement and may lead to calls to regulate all three categories of EDs, resulting in the regulation of substances based on a mode of action rather than evidence that the substance poses a risk to human health or the environment.

ACC believes creating categories of EDs undermines the EC’s general approach for identifying EDs, which requires a finding of adverse effects and use of scientifically supportable methods for screening and testing EDs, and requires reasonable methods for assessing ED-related data. ACC is also concerned that the categories may be used to legitimize the use of and provide inordinate weight to information and results from non-standardized, non-validated, short-term, mechanistic studies and to other insufficient data.

As discussed above, ACC is concerned the creation of lists of “suspected EDs” and “endocrine active substances” would precipitate decisions to stop using those listed products or promote the switch to alternatives whose health and environmental effects may be less well understood. In turn, those decisions could result in significant and unwarranted dislocations in the economy. In addition, the decisions could have the effect of denying access to useful products and technologies and expose the public to unknown and potentially more serious risks.

In sum, ACC believes creation of additional categories of EDs will serve no useful



regulatory purpose given current EU legislation, but will unnecessarily confuse and alarm the public. Further, ED categorization is contrary to the U.S. approach for managing endocrine disruptors and, therefore, may lead to unnecessary negative trade impacts and inconsistent U.S.-EU regulatory approaches.

- iv. Option 4: WHO/IPCS definition to identify EDs disruptors and inclusion of potency as an element of hazard characterization (hazard identification and characterization)

ACC believes Option 4 is the most reasonable of the four proposed options, but it should not be adopted as presently written. First, for the reasons discussed above, ACC maintains it is imperative that the EC use the WHO/IPCS definition of ED, which incorporates the concept of adverse effects. ACC also supports the use of a WOE approach, which is implied in Option 4 (the EC should consider referencing in Option 4 the WOE factors discussed in Option 2). Second, the EC's proposal to consider elements of hazard characterization (which include many elements of risk assessment) when identifying EDs will help to harmonize conflicting EU regulatory approaches for managing EDs by lessening the distinction between legislation that takes risk into account and legislation that considers only hazard identification. It is important to note, however, that hazard characterization is just one element of risk characterization. Because the U.S. utilizes a risk-based approach for managing EDs, consideration of elements of risk assessment when identifying EDs in the EU will also help promote coherence between EU and U.S. approaches to managing EDs. Finally, for the reasons discussed relative to Option 3, ACC supports Option 4 in that it does not propose additional categories of EDs.

The Roadmap is not clear as to whether, for Option 4, potency would be considered for purposes of identifying EDs. The Option simply proposes the inclusion of potency in hazard characterization. **Option 4 should clearly state that elements of risk characterization would be considered in identifying EDs, i.e., that both hazard identification and risk characterization are elements of identifying EDs.**

Further, ACC believes the EC should expand Option 4 to include other elements of risk characterization, in addition to potency, when identifying EDs. At a minimum, the EC should incorporate all the elements of risk characterization identified by the ED EAG (severity of effect, irreversibility, and lead toxicity) in addition to potency. By incorporating into ED identification the elements of risk characterization, EU regulations for EDs will not only focus on real hazards to human health and the environment, they will better align with risk-based U.S. regulations. This will help to avoid unnecessary adverse trade impacts.

ACC remains concerned that the EC's policy options do not provide for full risk assessments including exposure and dose-response assessments. This will remain a significant difference between EU and U.S. regulatory approaches for EDs and could result in negative trade impacts. Nonetheless, inclusion of risk assessment elements in the identification of EDs will help to promote better coordination between U.S. and EU regulation and may lessen negative trade impacts.



b. Policy Options – Approaches to Regulatory Decision Making

i. Option A: No Policy Change

The EC should not adopt regulatory Option A. Option A will maintain different, potentially conflicting, approaches for regulating EDs. A result of the current policy is that different regulatory decisions might be made for the same substance. ACC is concerned that inconsistent approaches for regulating EDs will create significant uncertainties in the global marketplace. ACC also believes it would be confusing for the public to understand different regulatory decisions concerning the same substance.

ACC believes the EC should take this opportunity to incorporate elements of risk assessment (Option B) and risk management (Option C) into its regulatory decision-making. This will allow the EC to better focus on managing risks to human health and the environment while promoting alignment between EU legislative approaches. Adoption of Options B and C will also help promote alignment between U.S. and EU legislative approaches.

ii. Option B: Introduce further elements of risk assessment into sectorial legislation

The EC should adopt Option B for modifying current regulatory decision-making. As discussed above, ACC strongly supports risk-based approaches for regulating chemicals, including EDs. One approach is to include elements of risk into the identification of EDs (*see*, ACC's response to Option 4). That approach has become necessary because current EU legislation uses inconsistent approaches and some EU legislation does not take risk into account.

ACC also encourages the EC to include additional elements of risk assessment such as exposure assessment and dose-response assessment. Risk is a function of both hazard and exposure. There are countless examples of substances with high hazards that are used safely to provide beneficial products for humans and the environment. In those instances, uses are controlled so that exposures remain at levels below that which would produce risks to health or the environment. This would allow the EU, consistent with the U.S. approach, to focus its regulatory activities on actual or potential risks posed by EDs to human health and the environment.

iii. Option C: Introduce further socio-economic considerations including risk-benefit analyses, into legislation

The EC should adopt Option C, which proposes inclusion of socioeconomic considerations, such as risk-benefit analyses, into sectorial legislation. Socioeconomic considerations, including risk-benefit analyses (sometimes referred to as cost-benefit analyses) are key considerations for managing risk in the U.S. Socioeconomic considerations allow regulatory bodies (at the risk management stage) to weigh scientific data concerning risks posed by substances and societal harm when making informed decisions on how best to protect human



health and the environment. For example, regulators may determine that managing minimal risks or risk estimates derived from minimal data may not outweigh the potential for causing economic harm, which in turn might seriously impact the health and wellbeing of the public. Or regulators may determine the unavailability of regulated products would have a disproportionate adverse effect on the wellbeing of the public. Regulators may also determine that risks posed by substances that may replace regulated substances have a comparatively greater adverse effect on the public and, therefore, decline to regulate.

Risk assessments, including exposure and dose-response assessment, are first required before applying socioeconomic consideration in a meaningful manner in risk management decision-making. It is important to understand the certainty and magnitude of health and environmental risks as well as the certainty and magnitude of societal effects resulting from regulation. In all, the goal should be to minimize all risks and maximize all benefits, both relating to health and to societal impacts. For this reason, risk assessments (including assessments of potential exposures and dose-response) must be conducted. ACC believes, therefore, the EC should adopt both Options B and C.

