AmCham EU calls for robust scientific criteria to identify endocrine disruptors

Failing to adopt such criteria will impact public health, agriculture and trade

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) has been actively involved in providing input on chemicals policy, including on endocrine disruptors (ED) criteria since 2011. It is committed to the safe, environmentally-acceptable and sustainable use of chemical substances. It is AmCham EU's view that robust scientific evidence, fundamental principles of toxicology, and full hazard characterisation should be incorporated into the criteria for the identification of EDs. If not, many substances will be identified as EDs even though they present no risk in current uses. This could have potentially major unintended consequences for health, agriculture, trade, industry and the economy across Europe. A full risk assessment must also be applied to identify ED substances, which are of concern to human health and the environment. Substances identified as presenting an unacceptable risk should be subject to the appropriate regulatory action.

* * *

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2015, directly supports more than 4.3 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

* * *

POSITION PAPER

American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: [Stéphanie Brochard]; [sbr@amchameu.eu] +32 (0)2 289 10 15

15 June 2016

Introduction

The American Chamber of Commerce to the European Union (AmCham EU) is strongly committed to health and environmental protection, as well as addressing societal concerns based on robust science and 'better regulation', as outlined in the Interinstitutional Agreement on Better Law-Making. This same commitment applies to addressing the chemicals that potentially cause endocrine disruption. AmCham EU therefore supports the development of robust scientific criteria for the identification of endocrine disruptors (ED) of regulatory concern.

The development of robust scientific criteria within the framework of better regulation is essential to avoiding the unintended consequences of non-science based regulation. It will also provide predictability and legal certainty, which are key to ensuring competitiveness of industry in Europe. Unnecessarily stringent, non-science based criteria could result in unjustified bans on the use of multiple chemicals and have significant impacts in many key areas, some of which are outlined below. The potential unintended consequences and loss of societal benefits span a wide number of areas, which comprise but also go beyond the scope of the Biocidal Products Regulation (BPR) and the Plant Protection Products Regulation (PPPR). Some of these include:

- Public health and public hygiene;
- Agriculture and food production and supply;
- Trade;
- But also others such as manufacturing, innovation, circular economy including resource efficiency and sustainability.

Public health and public hygiene: guaranteeing the highest level of public health in Europe

Biocidal substances are critical to both our public and private health systems. Biocidal products serve as disinfectants for human, surface, equipment, veterinary, food and feed, as well as preservative and pest control uses. They prevent the spreading of infections by harmful micro-organisms in places where hygiene is critical, such as hospitals, dining areas and swimming pools. (In-can) preservatives not only protect the shelf life of products, but they also prevent bacterial contamination or mould development, which may lead to human infections.

Rodenticides are also essential for the protection of human and animal health and food stocks, as well as the prevention of all other damages caused by rodents. Insecticides meanwhile prevent insect-borne diseases such as malaria. Biocides are essential in our everyday lives for the purposes of prevention and protection.

Under the BPR, biocidal substances identified as EDs will be automatically prohibited with no further evaluation or assessment. This will be the case unless a specific exemption for public health reasons is granted, which has thus far never occurred. Even if an exemption was granted, such a substance would nevertheless be a candidate for substitution. Therefore, overly stringent non-science based criteria could result in broad bans of many biocidal substances that in turn could create major public hygiene and health problems in hospitals, public buildings, hotels, offices and homes.

A good example is the case of disinfectants. Hand disinfection serves, among other uses, to prevent nosocomial diseases (hospital-acquired infections) which affect hundreds of millions of patients in the world every year. The European Centre for Disease Prevention and Control (ECDC) reports an average prevalence of 7.1% of health care-associated infection in European countries. This means that around 4 million patients are affected every year in Europe leading to annual financial losses of approximately €7 billion per year in Europe[1]. Hand disinfectants, as well as other surface disinfectants, are essential for reducing this type of infection, as shown by the World Health Organization's (WHO) 'Clean Care is Safer Care' programme.

The absence of critical anti-bacterial and anti-viral substances could lead to a major increase in hospital-acquired infections and viral contamination. This would result in declining human health, increased suffering, and negative economic and societal impacts.

Agriculture and food production and supply: securing a future for European farming

The use of crop protection agents is essential in ensuring sustainable food production. If many are banned due to overly stringent non-science based ED criteria, then this could have major adverse impacts on food production and price, with associated negative consequences on health, the environment and society as a whole.

This risk is very high and has been assessed in a study[2] carried out in the UK. This study has shown that if potency is not considered when determining whether a substance is an ED, then the number of crop protection agents available could be reduced by as much as 40%. This would have enormous implications for the availability and supply of essential foods and their prices.

The example of azole fungicides is illustrative. Azoles are the backbone of crop protection in a number of key crops like cereals and cannot be easily substituted. After decades of use, they continue to protect wheat from a damaging disease called Septoria. While azole fungicides are known to affect endocrine activity, risk assessments have shown they can be used safely.

Inclusion of potency in the ED criteria would allow the continued safe use of azole fungicides, maintaining their benefits to EU food production and to society as a whole. If azole fungicides were no longer used for disease control, both the quality and quantity of wheat production would drop. Additionally, it would be difficult to ensure the (mandatory) control of mycotoxins – naturally-produced toxins from fungi found in cereals and apples for instance – since there are currently no alternatives available to farmers. The EU, who is currently a net exporter of wheat, would become a net importer. The global wheat supply would be disrupted, and price volatility would increase, with likely global adverse consequences on availability and affordability of basic food and feed as well as nutritional needs and social stability. With respect to food imports only, the cumulative value of food and feed imported into the EU, whose production relies on the use of crop protection substances that might be identified as ED, exceeds €65 billion[3]. [4]

[1] WHO fact sheet, available here.
[2] Extended impact assessment study of the human health and environmental criteria for endocrine disrupting substances proposed by the UK Health and Safety Executive, 2013. Available here.
[3] This global figure relies on a list of potential endocrine substances prepared by the UK CRD in 2009 and updated in 2013. That list predates the Commission '4-option Roadmap' and could be considerably longer if the final ED criteria are too stringent (e.g. straight WHO definition).

Trade: supporting international trade and avoiding the potential creation of non-tariff barriers

Many other countries and regions of the world are working on the assessment and identification of ED. They primarily include the Americas and Asia, specifically the United States, Canada, Brazil, China and Japan, all key EU trading partners. An approach to ED identification not based on internationally-recognised scientific principles, such as the definition issued by the WHO/International Programme on Chemical Safety (IPCS) in 2002, and testing methods based on international standards, such as the Organisation for Economic Cooperation and Development (OECD) framework for testing and evaluating ED (revised in 2012)[5], will inevitably lead to the creation of trade barriers between these trading partners. This is due to very different assessments of hazards and risks of chemical substances.

If these internationally-recognised scientific principles are not followed by the EU, many substances will be unnecessarily banned in Europe. This will have a widespread impact on the import of essential foodstuffs, automotive vehicles and their components, other vehicles, agricultural and construction equipment, electrical and electronic goods, pharmaceuticals and medical implants and devices, and other consumer articles.

Wider impacts: securing European-based manufacturing and innovation while delivering on the EU's sustainability objectives

All manufactured goods contain chemicals, and are produced using other chemicals. Unnecessarily stringent ED criteria that are not founded on sound scientific and socio-economic evidence could drive bans or restrictions on the use of multiple chemicals, without yielding any benefits for public health and societal wellbeing. This, in turn, would make it difficult, and sometimes impossible, for industry to innovate and manufacture products that consumers and governments need or want. Furthermore, the lack of proportionate criteria for ED identification and a fragmented approach among key trading partners would negatively impact investment security.

Effectively implementing the circular economy, resource efficiency and sustainability measures all depend on the ability to recycle and reuse many materials, such as construction materials preservatives, which contribute to the extended durability and performance of products. These preservatives provide energy savings and reduce carbon emissions.

The definition of EDs may have regulatory impacts well beyond biocides and crop protection agents, and affect various other sectors listed throughout this position paper. However, today, it remains unclear how the regulatory criteria developed to meet BPR and PPPR obligations will fit into other chemicals legislation. Unfortunately, not all pieces of legislation referring to EDs foresee a risk assessment step before a regulatory decision is taken. The development of criteria as required by BPR and PPPR should not lead to a situation where substances are directly banned following a hazard assessment, without any evaluation of the risk.

[4] Kyd D. Brenner LLC, Potential Trade Effects on World Agricultural Exporters of European Union Regulations on Endocrine Disruptors, 2014. Available here.
[5] Accessible here.

Conclusion

It is crucial that robust scientific evidence, fundamental principles of toxicology, and proper hazard characterisation be incorporated into the criteria for ED identification. If not, many substances will be identified as ED even though they present no risk in current uses. This could have potentially major unintended consequences for health, agriculture, trade, industry and the economy across Europe.

AmCham EU calls on EU policy-makers to work with other governments, and to base its proposal on existing work by the OECD and the WHO, to develop robust scientific criteria for identifying ED that fully take into account the internationally-recognised principles of toxicology, associated definitions and frameworks which include:

- Adverse effects and their severity and reversibility;
- Potency and dose response;
- Endocrine mode of action and causality;
- WHO definition of EDs;
- OECD Framework for the Assessment and Testing of Endocrine Disruptors.

A full risk assessment must also be applied to identify endocrine disrupting substances which are of concern to human health and the environment. Substances identified as presenting an unacceptable risk should be subject to the appropriate regulatory action.

Furthermore, AmCham EU underlines that although the criteria are being developed in the framework of the biocides and pesticides regulations, they will have a much broader impact across other key sectors and legislation which are not taken into account in the current impact assessment.