AMCHAM EU
AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Consistency necessary in EU environmental policy-making

INFORMATION PAPER

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email:info@amchameu.eu

Secretariat Point of Contact: Leah Charpentier, leah.charpentier@amchameu.eu; 02 289 1015

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Introduction

In order to facilitate economic growth, improve the business environment and attract new investment, stimulate innovation and provide jobs, a consistent and certain regulatory environment is necessary.

Several pieces of EU environmental legislation overlap and there is potential for legal discrepancies in national implementation and long-term legal uncertainty for industry. In addition, we have recently noticed examples of EU regulation that is not based on adequate scientific risk analysis or impact assessments.

Recently the same substances have been subject to different EU regulatory approaches:

- The REACH Regulation, as a piece of framework legislation, analyses substances in several ways under its evaluation, Authorisation and Restriction procedures;

- The Restriction of Hazardous Substances (RoHS II) Directive, a sector specific directive, regulates certain hazardous substances in electrical and electronic equipment (EEE) and its substance scope will be subject to assessment this year;

- The Water Framework Directive (WFD) identifies priority hazardous substances for which concentration limits are aimed at the reduction or removal of these substances from surface water. These concentration limits are set out in the Environmental Quality Standards (EQS) Directive. A proposal was made for the inclusion of pharmaceutical substances in the scope, while DG Health and Consumers has only just initiated an investigation into the impact of pharmaceuticals on the environment.

- There is legal uncertainty over possible overlap between the Directive on the eco-design of energy-related products (ErP), the construction materials and F-gas regulations.

- Different legal terminology and definitions have been adopted between the above-mentioned RoHS II Directive and the Waste Electrical and Electronic Equipment (WEEE II) Directive.

AmCham EU strongly encourages the EU institutions to ensure that there is consistency between EU environmental laws and that a coherent approach — based on scientific evidence and taking into consideration socio-economic impact — is followed when evaluating substances and choosing the most adequate risk management regulatory tool to avoid duplication of efforts and regulatory overlap.

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1. REACH: Overlap between REACH Authorisation and Restriction processes

REACH has entered into a new phase with the application of the Authorisation and Restrictions processes and it is important to ensure that each of these processes is applied in full respect of the fundamental principles underlying REACH, such as sound science-based processes and proportionality. In particular, it is important to ensure that the Authorisation and Restriction processes under REACH, which represent different risk management options, are used alternatively, possibly successively, but not simultaneously, outside of exceptional circumstances. AmCham EU is particularly concerned that a prior decision in the Restriction process may prevent companies from having their authorisation requests duly considered. The first precedent has been recently created by the Danish proposal for restriction of four phthalates, while the same substances are included in the REACH Authorisation Annex XIV.

The adoption of a prior restriction would therefore de jure or de facto significantly factor into any Authorisation decision, a situation that would certainly trigger legal challenges, as well as confusion in the supply chain. AmCham EU calls on the European Chemicals Agency (ECHA) and the European Commission to adopt a suitable policy that avoids unnecessary and damaging overlaps and duplications between different Risk Management Options.

Need for sound scientific and socio-economic impact assessment before restriction of substances

AmCham EU would also like to draw the regulator's attention to the paramount importance of robust scientific background and economic feasibility analyses before substances are proposed for restriction. Therefore we underline the importance of the procedure laid down in Article 68(1) of the REACH Regulation, with proper scientific and socio-economic evaluations done by the ECHA committees. This would guarantee effective and proportionate legislation, while also giving industry legal certainty and clarity on the decision-making process.

2. High Aromatic Oils: Need for a full regulatory process and adequate tests before any extension of the ban

Another example of the need for a full scientific and socio-economic impact assessment before a regulatory action is the case of high aromatic oils (PAHs). AmCham EU is concerned about the call for a fast track procedure (Article 68.2) to address PAHs under REACH for a broad range of consumer goods. We worry about the precedent that would be set by rapidly moving forward on such a wide-ranging proposal, without the due process that is in place and mandatory scientific review. AmCham EU believes that a normal REACH procedure (according to Article 68.1) would provide the opportunity to gather additional scientific and technical knowledge to the benefit of consumers and

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manufacturers alike, as well as to identify the appropriate test methods should a decision on a PAHs ban be adopted.

3. Overlap between the Directive on Environmental Quality Standards (EQSD), the Water Framework Directive and other existing legislative acts

The Directive on Environmental Quality Standards sets the environmental quality standards (EQS) for surface water, and the Water Framework Directive (WFD) foresees the adoption of specific measures against water pollution. The EQSD lists substances that are considered harmful to the aquatic environment either as priority substances, with measures aiming at their reduction, or as priority hazardous substances that should be phased out.

In January 2012, the European Commission published an EQSD legislative proposal to update the list of substances. We are concerned that the substances proposed for inclusion as priority substances, or priority hazardous substances, have already been subject to other pieces of EU legislation that introduced specific risk management measures.

For example, phthalates have been included in REACH Authorisation Annex XIV, which means that the substances cannot be produced, imported or used by companies unless a 'use specific' authorisation is granted. Prioritising DEHP as priority hazardous substance (PHS) under the EQS Directive can therefore be perceived as incoherent with the REACH Authorisation process. The PHS status under EQS Directive means that the substance needs to be eliminated from surface waters, while REACH Authorisation allows companies to continue using the substance.

We encourage the European institutions to look simultaneously into these pieces of legislation to avoid any regulatory overlap and foresee solutions to avoid any incompatibility among these pieces of legislation (closed loop use, treatment technologies availability and affordability, etc).

Three pharmaceutical substances were also added to the priority substances list[1]. While at the same time, as part of the WFD revision process, DG SANCO initiated an investigation of the impact of pharmaceuticals in the environment as called for by the pharmaceutical legislation. The report on the results of the investigation is due by the end of 2012/beginning of 2013, and would have been be the appropriate starting point for determining a European policy on pharmaceuticals in the environment, taking into account both public health and environmental concerns.

Any debate around the impact of these pharmaceutical substances in the environment needs to be based on sound scientific evidence. The debate must

[1] **Diclofenac**, an anti-inflammatory for major pain relief in acute and rheumatic conditions; **Ethinyl-estradiol**, the estrogenic component in practically all modern formulations of combined oral contraceptive pills; **Estradiol**, a natural estrogenic hormone produced by women and many animal species, and used in the treatment of menopausal disorders and prevention of osteoporosis, and as the estrogenic component in some combined oral contraceptive pills.

focus on the medical need and should also include a socio-economic assessment of potential measures to be taken.

4. Regulation of metals and their compounds

Metals and their compounds are potentially subject to three different EU regulatory processes. AmCham EU is keen to ensure that current and future policies and regulation are consistent for compliance and enforcement purposes.

The REACH Regulation (EC/1907/2006) analyses metals and their compounds in several ways under its evaluation, Authorisation and Restriction procedures. The RoHS II Directive (2011/65/EU) regulates certain hazardous substances including lead, mercury and cadmium. Additional metals and their compounds such as beryllium, antimony, indium and gallium will be studied for possible future restriction. The new 'Roadmap for a Resource Efficient Europe' (COM (2011) 571) will assess similar metals in a study that begins this year. An example of a compound that could be regulated in three different ways is gallium arsenide, a critical substance used for a specific purpose in microscopic quantities in semiconductor manufacturing with no technical substitution possibilities.

DG Enterprise and Environment is responsible for the above legislation and policy initiatives. Other Directorates-General are also assessing the same metals, for example, DG CONNECT in relation to the ICT sector, as well as the JRC and DG Research under FP7.

AmCham EU is keen to work with EU regulators to ensure a coherent approach minimising industry's compliance challenges and avoid development of different regulatory proposals and compliance processes covering the same substance. This should also serve to ease the burden on national authorities in terms of facilitating enforcement.

5. Overlaps with Ecodesign Directive (2009/125/EC) and Construction Materials Regulation (305/2011)

AmCham EU notes that substantial legal uncertainty could ensue if the use of certain materials is restricted or discouraged under the Ecodesign of Energy Related Products Directive(s) and the Construction Products Regulation. These materials have been duly registered under REACH, including exposure scenarios for specific applications when required. Concrete examples include certain insulation materials, heat transfer fluids and polymers (plastics). In our view, no restrictions should apply to the use of specific substances and/or materials in the context of these legal instruments, and REACH should take precedence. In the case of fluorinated greenhouse gases (which are also regulated under the EU F-gas regulation 2006/842), the detailed Ecodesign rules grant a 'bonus' to fluids with a lower GWP with the intention to compensate for their inherently lower energy efficiency. As a result, manufacturers are discouraged to use the best fluid to obtain the highest energy efficiency.

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6. RoHS II and WEEE II

In December 2008, the European Commission proposed to recast both the Waste Electrical and Electronic Directive (WEEE) (2002/96/EC) and Restriction of Hazardous Substances (RoHS) Directives (2011/65/EU), which previously applied to the same scope of electronic equipment, as defined in the WEEE Annex. The recast process went on to debate, and agree, to amend and separate the scope of the two Directives – each now being defined in their own legislative text/Annexes.

Both Directives list types of equipment that are excluded from the scope. Both Directives exclude 'large-scale fixed installations', but the WEEE exclusion is specified as: 'large-scale fixed installations*, except any equipment which is not specifically designed and installed as part of these installations*.'

Currently a Member States working group is working on developing an FAQ document for RoHS II, which would give a further explanation to the definition of 'large-scale fixed installations' and list groups of equipment that could be defined as such, and those that cannot. It is to be expected that such an FAQ explanation will strongly influence the way in which the WEEE definition is understood.

AmCham EU recommends that, as very similar legal terminology and definitions are being developed for different Directives, possibly in completely isolated work-streams, the objectives and purposes of the WEEE legislation be taken into consideration. Industry hopes this would avoid legal discrepancies in national implementation and long-standing uncertainty for industry.

Conclusion

Legal discrepancies and uncertainty because of overlapping legislation are obstacles for business. They inhibit the ability to innovate and compete, and may potentially have unintended consequences for consumers. Achieving the EU 2020 targets and initiating smart, sustainable and inclusive growth requires smart regulation. We are committed to working with the European Commission, Parliament and Member States to ensure that new legislative proposals are consistent with existing EU regulation. A balanced and coordinated legal framework will accelerate business developments that meet citizens' needs and foster growth.

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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 U.S. investment in Europe totaled $2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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