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

POSITION STATEMENT

Simplification and clarification are needed in consumer product safety and market surveillance

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Introduction

The American Chamber of Commerce to the European Union (AmCham EU) is fully supportive of the European Commission's proposal for an EU Consumer Product Safety and Market Surveillance Package. A simplified and effective legal framework would have several benefits, and the use of regulations rather than directives is welcome, as it would ensure consistent application across all Member States. For consumers it would mean guarantees for safe products and accurate product information, while for business it would enhance competitiveness, by ensuring that all relevant economic operators play by the same rules.

However, the proposed framework remains complex and includes a number of separate horizontal instruments (Consumer Product Safety Regulation - CPSR, Market Surveillance Regulation - MSR, Regulation 765/2008 on accreditation). The draft package could therefore be further improved, notably by clarifying the relationship between the CPSR and vertical legislation, as well as with the continued application of Decision 768/2008/EC on a common framework for the marketing of products. **It is essential that the new legal framework clarifies, for both market operators and authorities, which rules apply to which product, especially in the case of products that are already subject to EU harmonised legislation.**

In early June 2013, draft reports and draft opinions were issued from the rapporteurs in the Committee on the Internal Market and Consumer Protection (IMCO) and Committee on International Trade (INTA). AmCham EU is greatly concerned about the changes proposed by the IMCO rapporteurs, including numerous references to the precautionary principle, proposals for a CE+ mark, a mandatory auditing scheme and other proposals that are likely to be impracticable or counterproductive, as also described further on in this paper.
Of key concern to AmCham EU is the confusion between 'safety' and 'compliance'. First, the CPSR is only about 'safety' (compliance with provisions for health protection and safety) and should not be coupled with compliance with non-safety requirements that are already covered by other EU legislation.

Second, while it is legitimate, and indeed welcome, for the MSR to require market surveillance authorities to also check compliance with non-safety requirements, such as environmental or eco-design requirements, the two notions of 'safety' and 'compliance' should not be confused. **Formal non-compliance, as defined in article 9.2 of the MSR, should not trigger the same consequences as a situation posing serious (safety) risks** (e.g. CE mark, as a failure to comply should neither require a notification on RAPEX nor an alert to the general public). Formal non-compliance should not be included in definitions related to risks or serious risks. Corrective measures should nevertheless be taken immediately to rectify formal non-compliance, issues and products showing evidence of the latter should be inspected thoroughly.

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Finally, AmCham EU is concerned by what the Parliamentary reports propose in terms of penalties. While AmCham EU agrees that penalties should be a deterrent, they should not be based on company size or turnover, which would make them discriminatory and unfair. **Penalties should be effective, proportionate and dissuasive.**

Consumer Product Safety Regulation (CPSR)[1]

Scope and relationship with vertical/sector-specific legislation (chapter 1)

Consistency between the general framework and sector-specific regulations must be ensured in the CPSR:

- A number of regulated products (e.g. food and medicinal products) fall outside the scope of the regulation.

- Other sectors (e.g. cosmetics, toys) that have been attended to by Decisions 768/2008/EC are still within the scope of the CPSR. For these, the new CPSR will 'only' add country of origin labelling (which is already required for cosmetics).

- For other sectors not yet subject to revision under Decision 768/2008/EC, but subject to EU harmonised rules, it is not clear:

    - Whether the Commission intends to continue to use Decision 768/2008/EC, or if it will let the CPSR provisions apply; or

    - Whether chapters 2 to 4 of the CPSR will apply at all. Indeed, article 2.4 specifies these chapters 'shall not apply to requirements designed to protect human health and safety laid down in Union harmonised legislation or pursuant to it'. However, clause 8 of the preamble seems to indicate that a review of equivalence will be needed ('the obligations of economic operators should not apply where harmonised EU legislation includes equivalent obligations'). The IMCO rapporteur also proposes that chapters 2 and 3 also apply to regulated products for those aspects, risks or categories of risk not covered by those requirements.

      AmCham EU does not support this latter proposal since it would add more complexity in the EU legislative framework and reduce legal certainty. Beyond this, the question is whether it is appropriate to have similar provisions both in the CPSR and vertical legislation, in the latter case with possible adjustments.

[1] Proposal for a regulation of the European Parliament and of the Council on consumer product safety, 13.02.2013, COM(2013) 78 final (here).

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For AmCham EU, it is essential that the new legal framework bring legal certainty as to which rules apply to which product. This requires authorities to take on one of the following options:

- Exclude from the scope of the CPSR all products subject to harmonised legislation so that they are subject only to vertical legislation, adapted as needed by the application of Decision 768/2008; or

- Clarify that chapters 2 to 4 do not apply to any product already subject to EU harmonised legislation, without condition of equivalence or comparison of requirements.

For the sake of legal certainty, AmCham EU strongly believes that a clarification of the scope of the CPSR is needed. It should be clear what rules apply to what product without first going through a complex sector by sector analysis of equivalency, or a comparison of sector specific provisions against those of the CPSR.

Precautionary principle (chapter 1)

AmCham EU does not believe that it is necessary to include references to the precautionary principle within the CPSR, as it is already an inherent component of the risk assessment requirements. If, however, if the principle is referenced, it should be to confirm that the provisions of the regulation are 'underpinned by the precautionary principle', as does article 1.3 of REACH, or article 8.2 of the GPSD.

The precautionary principle should also not be part of the definition of a 'safe product', as proposed by the IMCO Committee rapporteur in amendment 38, or likened to a 'standard', as proposed by the rapporteur in amendment 45, for example. This principle should only apply in the face of scientific uncertainty, as specified in the Commission Communication on the precautionary principle.

Indication of origin (chapter 1)

The CPSR would require any product within its scope to bear country of origin labelling. Country of origin can be very difficult to determine and to track through inventory systems. We do not believe that this requirement is necessary. For example, in some cases producers have unique date and batch codes on products to aid in a safety investigation, and this labelling requirement would not meaningfully add to product safety.

The proportionality, applicability and effectiveness of this requirement on the traceability of products should be thoroughly assessed before being introduced in EU legislation. An alternative solution could be to regulate the conditions under which country of origin labelling indications could be made to avoid misrepresentations, and leave companies free to label country of origin on a voluntary basis.

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CE marking + (chapter 1)

AmCham EU does not believe that the introduction of a CE+ mark, whether on a mandatory or voluntary basis, associated with third party testing by accredited laboratories, would bring clarity to consumers or improve product safety in any way. It would also be completely disproportionate to impose it on all consumer products. Furthermore, its addition to chapter 1 of the proposal would make the new requirement applicable to sectors in which third-party testing is already mandatory.

An effective use of already existing marks (e.g. 'Umweltengel' in Germany) would strengthen consumer trust, safe cost and support the new legislation within a shorter time frame rather than implementing something in addition.

Obligations on economic operators (chapter 2)

The CPSR has integrated provisions on obligations on economic operators from Decision 768/2009/EC. That is not to say that they should not be reconsidered or that lessons should be drawn from the application of these provisions. In general, the applicability of these rules to specific sectors, under the CPSR and delegated acts, should be proportionate to the risks involved.

AmCham EU calls for clarifying that a distributor does not need to hold physically the technical documents at their premises. There is trade sensitive information in technical documentation that manufacturers are not eager to share with the distributor. Other legislation can serve as an example in this regard. For instance, the Toy Safety Directive has clarified that distributors should only be responsible for making available the technical documentation upon a reasoned request by market surveillance authorities.

Notification of products presenting a risk (chapter 2)

Article 8.9 requires manufacturers to immediately take corrective action for products that are not safe, or not in conformity with the Regulation, and to notify market surveillance authorities. The same obligation applies to importers (article 10.7) and distributors (article 11.5). Importers and distributors are required to notify the manufacturer or importer as well as market surveillance authorities.

AmCham EU considers that importers and distributors should only be required to contact authorities 'if appropriate' provided that they inform manufacturers and importers first, who would then bear the responsibility of taking the appropriate measures and notify authorities if indeed there is a safety issue. The competence to evaluate the risk of products indeed lies with manufacturers more than with distributors.

Article 13.1 exemption from notification for 'isolated cases' (chapter 2)

The CPSR now codifies in article 13 an interpretation of the circumstances under which a notification is not needed, essentially when the risks of a limited number of products have been fully controlled. While this is laudable, it is not

clear as to whether or not it is necessary to meet all the criteria specified in order to avoid notification. To clarify this point, we recommend that article 13 mentions that notification only applies to products presenting a safety risk, and to clarify whether the three criteria are cumulative, and how to interpret the 'limited' number of products from the first criterion.

The new provisions could be deemed disproportionate and discretionary if interpreted strictly, especially the first criterion. The current Commission notification guidelines explain that the objective of the criteria for non-notification is to prevent a possible proliferation of notifications for products 'which do not require any verification, monitoring or action by the authorities…'

The role of European standards (chapter 3)

The CPSR should be the standard framework to assess product safety in the EU. The creation of additional EU standards must be proportionate and adequate for the risk they seek to address. Unnecessary burden should not be imposed on economic operators.

Penalties (chapter 4)

AmCham EU supports the Commission proposal to request Member States to adopt penalties that are effective, proportionate and dissuasive, and that they take account of recurrent infringements. However, AmCham EU opposes the concept that such penalties must be proportional to the size or turnover of the undertakings involved, as these measures would not ensure a level playing field. AmCham EU would support penalties that are proportionate to the benefits generated in the Member State of concern by the products found to be unsafe and proportionate to the risks involved by these products.

Pan-European accident and injury database

AmCham EU could support the development of a pan-European accident and injury data base, as it could be a useful tool to support the risk assessment work of companies and authorities. However, such a database would only be useful provided it collects appropriate information in an effective and systematic fashion establish on a legal basis, including information on the causes and circumstances of the accidents/injuries. Proportionality must be ensured. The database should not be available to the public as the information could be wrongly interpreted.

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Market Surveillance Regulation[2]

Scope and definitions (articles 1, 6.1 and amendments 17, 18)

AmCham EU is concerned that market actors that do not play by the rules today will not do so tomorrow. Proportionality is therefore of the utmost importance or industry in Europe will be put at a competitive disadvantage. There is a risk that responsible players will be the only ones to make the necessary adjustments and bear the burden of additional measures, while rogue traders will continue to violate regulations.

The scope of the proposed regulation is very broad and, unlike the proposed CPSR regulation, does not solely focus on consumer product safety, but includes consumer health, workplace safety and environmental protection. The European Parliament's draft report even broadens the scope to 'applicable Union legislation'. The MSR covers products subject to harmonised legislation, including consumer products (subject to the CPSR) as well as professional products, but contains a series of complex exclusions and exemptions that would require streamlining.

AmCham EU is concerned that the lack of proportionality could bring excessive and unnecessary burdens. The unintended impact of the combination of a broad scope together with a strict approach would make the system totally unworkable for both operators and market surveillance authorities without improving consumer safety.

Non-compliant products do not necessarily present a risk and should not be presumed to present a risk or be unsafe.[3] For instance, the wrong size of a mark, e.g. CE mark, is a failure to comply with the EU legislation. However, it does not represent a health and safety risk for the consumer. Therefore, it is not proportionate to notify such a non-compliant product on RAPEX or alert the general public. A way to overcome this confusion is for the regulation to make the differentiation between a **'formal non-compliance'** (i.e. non-compliance as defined by article 9.2) and a **'product presenting a risk'**. On the other hand, AmCham EU strongly agrees that corrective and proportionate action must promptly be taken to bring products into conformity.

We are also concerned by the introduction of new concepts and definitions such as emerging risks, which are unnecessary given that the precautionary principle already provides the safeguards to effectively manage risks arising from existing and emerging situations. Experience shows that the market is fragmented when it comes to market surveillance. The introduction of new principles and concepts will just add to the existing complexity. AmCham EU therefore believes that existing definitions and principles should be adhered to.

[2] Proposal for a regulation of the European Parliament and of the Council on market surveillance of products, 13.02.2013, COM (2013) 75 final (here)- Hereafter 'article'; Draft report on the Proposal for a regulation of the European Parliament and of the Council on market surveillance of products, 12.06.2013, PE513.324 (here) - hereafter 'AM'.

[3] See AmCham's statement page 2.

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Roles and responsibilities of economic operators (article 8 & AM 29, 35, 36, 37)

The proposed package aims to avoid fragmentation and improve legal certainty. AmCham EU believes that the two regulations should particularly avoid overlaps, including with harmonised legislation.

The new product safety package provides the necessary safeguards to identify the manufacturer. Adding the importer address on the product as well is neither proportionate nor does it bring any additional safety to consumers. This is added complexity and could jeopardise the free circulation of goods in the internal market. In harmonised legislation, there are specific instances when there is no importer and only one address should be affixed to the product. To help economic operators comply with this proposed regulation in a cost-effective way, AmCham EU proposes that manufacturers and importers established outside the Union should appoint a single representative established within the Union for the purposes of market surveillance, as proposed by amendment 36.

Control of products and exchange of information based on risks categorisation (articles 9.2, 9.4, 10.6 & amendment 38)

Unlike the CPSR's 'safety' focus, it is legitimate that the MSR also addresses compliance with EU harmonised provisions not directly related to safety, such as environmental or eco-design requirements. AmCham EU would welcome additional controls on the compliance of products, provided that these are effective, proportionate and non-discriminatory. Effective market surveillance is a critical factor in ensuring the economic and environmental benefits of existing legislation such as the Ecodesign Directive 2009/125/EC. In particular, it is important that producers can be confident there is a level playing field for business across the Single Market and that consumers are confident performance standards are valid. In large part, this will be achieved by strengthening market surveillance, thereby increasing compliance with existing legislation.

As explained above, AmCham EU is concerned about the confusion between 'safety' and 'compliance'. Articles 9 and 10 lay out the procedure for products 'presenting a risk'. However, it requires market surveillance authorities to carry out a risk assessment for products that 'may present a risk', which could include products that are in formal non-compliance with CE marking and other provisions (EC declaration of conformity, technical documentation and labelling of instructions). It is of the utmost importance that instances of formal non-compliance do not trigger the same consequences as situation of risks or serious (safety) risks.

In addition to the notification of products presenting a risk through RAPEX, article 10.6 provides that market surveillance authorities should publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website (to the fullest extent necessary) to protect the interests of product users. While this article includes provisions to avoid breaching confidentiality and data privacy rules, it is excessively general and may lead authorities to publish all sorts of

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investigation results and false positives without control. It should clarify that only products presenting risks or serious risks to the population should be subject to publicity measures if these measures are necessary to limit the risks involved and for no other reason.

In the event an infringement is observed despite existing safeguards, economic operators should be granted the right to be heard before any measure is taken, that is, unless the seriousness of the risk requires immediate action. When deciding which corrective actions should be taken, economic operators should be involved as they have a thorough knowledge of their products. There have been instances of counterfeit goods notified on RAPEX or products notified following a wrong risk assessment from market authorities. This can be due to the lack of education about legislation that is continuously evolving and is increasingly becoming technical. It is not fair that companies that play by the rules see their brands impacted by a notification on RAPEX following third party misconduct or lack of expertise.

There is expertise within companies and with sectoral experts in the Commission. The latter is familiar with the industry, their stakeholders and the relevant legislation. This pool of expertise should be further used and a process established to ensure a peer review of notifications before their publication on RAPEX. This will help spread the burden of managing the RAPEX system.

Customs checks (articles 14.1, 14.3, 15.2, 16.3)

Article 14 enhances the powers of customs authorities. AmCham EU recognises that there is a role for customs authorities to control some aspects of product safety and legal compliance. For instance, it should be incumbent on customs authorities to check the presence of type approval markings (such as CE/E) for products destined for the EU market.

On the other hand, it is not the role or competence of customs authorities to conduct laboratory tests and analysis. This should be done by experts from market surveillance authorities. Indeed, the legislation has become increasingly technical (e.g. chemicals requirements) and market surveillance have developed sector expertise through trainings, education programmes and dialogue with economic operators on sectoral legislation. Nevertheless importers should, upon reasoned request, be able to make available technical documentation. Second, AmCham EU opposes the suggestion that products that may be mislabelled at the time of import should be considered as presenting a potential risk for the reasons explained above. Companies can be organised in such a way that additional labels or marks will be affixed within the EU (e.g. distribution centres/warehouses) before being placed on the market and to bring them in conformity. These products should not be considered non-compliant, or presumed to present a risk and should not be blocked at customs.

Fines and sanctions (amendments 11, 41, 62)

It is important that the approach to fines and sanctions be proportionate to the seriousness of the risk. Responsible manufacturers already have good quality management systems in place that enable them to track potential safety patterns

once the product has been placed on the market, and voluntarily take corrective actions, should not be penalised. In addition, some companies may have high revenues but low profits. A very strict system based on a company's turnover would not have the same impact depending on different business models, and would not be fair. Lastly, it does not seem consistent to have these provisions on both the CPSR and MSR

AmCham EU calls for a proposal that outlines the principles for sanctions, in respect of the subsidiarity principle, and that allows for a consistent approach between the CPSR and MSR. The Commission should set out minimum amounts for penalties, as well as the conditions and methods for their collection.

Cooperation between industry and market surveillance authorities (chapter 4, amendments 56, 57, 58 and 60)

The new regulation proposes a number of measures to coordinate various market surveillance authorities and customs authorities, and to implement early alerts. Proposals in this sense also include the creation of a communication system for market surveillance (ICSMS) and of the European Market Surveillance Forum (EMSF). The latter could have a particularly positive impact, as through the EU multiannual action plan for the surveillance of products (COM(2013)76), it is foreseen to have a growing importance. In this context, the work of the administrative committees (ADCOs) is of particular importance, not only because it would give the opportunity for effective coordination, but also because it will give industry the opportunity to share its experience and knowledge for the market surveillance of specific products.

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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 US investment in Europe totalled €1.9 trillion in 2012 and directly supports more than 4.2 million jobs in Europe.

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