Position Paper

Chemicals in consumer products: The need for a European legislative framework ANEC position paper

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1. Introduction

Consumer organisations like ANEC have long been concerned about the use of hazardous chemicals in consumer products. Consumer organisations regularly inform consumers about the risks posed by chemicals contained in products based on e.g. comparative tests and new scientific evidence, and actively lobby at the national and European level to introduce or strengthen chemical requirements in product legislation and standards. Despite all these efforts, hundreds of chemicals which are potentially dangerous for health and the environment can still be found in many consumer products today[1].

In the EU the identification of the potential risks related to certain hazardous chemicals in consumer products sometimes leads to the adoption of regulatory provisions such as content limit values or a ban of the use of these chemicals in particular products. However, this happens only on a case-by-case basis depending on political will and industry lobbying. Moreover, where such provisions are adopted in legislation their application often applies to only a small number of substances and/or product groups (e.g. products for children under three years old).

ANEC therefore believes that a horizontal regulatory approach to address chemicals in products in a systematic way is dramatically needed at the European level. A new research report[2] commissioned by the Consumer Council at the Austrian Standards Institute (ASI) brings us light as to how to move towards such horizontal approach to regulate chemicals in consumer products.

2. New Austrian report recommends interesting ways forward

A new research of the Consumer Council at the ASI looks into the issue of chemicals in products in a horizontal manner, identifies shortcomings of European product regulation with respect to chemicals and outlines several options for a way forward. ANEC strongly believes this study provides an excellent basis for the European Commission to consider taking action for regulating hazardous chemicals in consumer products in a more consistent and effective manner.

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[1] Stiftung Warentest (Germany) recently published a report showing that 80% of the 50 toys tested were contaminated with hazardous substances.

[2] Study commissioned by the Consumer Council at the Austrian Standards Institute: 'Chemical requirements for consumer products, October 2010: Proposals for regulatory measures to improve chemical safety for consumers'. The study can be downloaded at: http://www.verbraucherrat.at/download/chemicalsproducts.pdf

The **purpose of the study** was to:

- review the chemical requirements in selected product legislation including:
  - General Product Safety Directive (GPSD) 2001/95/EC
  - Directive 89/686/EEC on Personal Protective Equipment (PPE)
  - REACH Regulation (EC) No 1907/2006
  - Toy Safety Directive (TSD) 2009/48/EC
  - Construction Products Directive (CPD) 89/106/EEC
  - Directive 2002/95/CE on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS)
  - Ecodesign requirements for Energy-related Products (ErP) Directive 2009/125/EC
- identify and discuss the gaps in this European legal framework
- review in greater detail the provisions of REACH[3] with respect to consumer products (/articles) with a particular focus on nanomaterials
- make recommendations for addressing chemicals in products in a consistent manner through changes in the European regulatory framework

The **study identified several shortcomings in existing European legislations**. Chemical requirements for consumer products are indeed:

- Missing entirely in the General Product Safety Directive (GPSD). This Directive contains only a generic requirement that products shall be safe and offers the possibility to adopt only temporary emergency measures (which were unfortunately rarely taken in case of chemical risks)
- Hardly addressed in the Personal Protective Equipment (PPE) Directive (only a short provision requires that materials shall not adversely affect health[4]) and in the Ecodesign for Energy-related Products (ErP) Directive and related implementing measures (which merely focus on energy efficiency)
- Inadequate in REACH (consumer articles hardly addressed, consumer information provision regarding the chemical content of products very limited) – *see Annex I*

[3] Regulation concerning the Registration, Evaluation, Authorisation and restriction of CHemical substances

[4] Article 1.2.1.1. "*PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health*."

- Not sufficiently ambitious in the Toy Safety Directive (e.g. high content of CMR substances allowed and several other categories of dangerous substances not even mentioned) and the RoHS Directive (too few substances restricted: mercury, cadmium, chromium VI, PBB and PBDE)
- Just referred to as 'declaration requirements' linked to regulations in Member States in the Construction Products Directive (with the option of not declaring chemicals in case there are no national requirements) and no possibility to establish product requirements (limit values)

Moreover, none of these regulations allow for establishing restriction measures for hazardous chemicals or adapting existing ones quickly where the need arises by using a Committee procedure (Comitology). Only the proposed revised RoHS Directive[5] and the restrictions track of REACH (Annex XVII) may allow for adapting the existing chemical requirements and the Toy Safety Directive includes a restricted committee procedure only for certain purposes[6].

Finally, generic phrases in product related legislation such as "producers shall be obliged to place only safe products on the market[7]" or "products must not adversely affect human health" are not sufficient to compensate for the shortcomings identified above. Such legal provisions are indeed often difficult to interpret and comply with for producers/importers as far as chemicals are concerned at least. In addition, such provisions place a big burden on enforcement authorities which have to prove that a substance contained or released from a product is posing a risk to consumer health. Hence, often no action is taken[8].

With the above, the study clearly demonstrates that **the current European legal framework regarding chemicals in products is insufficient** to ensure a high level of safety to consumers and the environment. The study thus concludes that **the adoption of a new regulatory framework for chemicals in consumer products is necessary**. Generic safety provisions, when already present in product specific legislation, need to be complemented by clear-cut restrictions for substances of concern such as specific limit values in order to ensure a high level of safety for consumers and benefit manufacturers and enforcement authorities.

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[5] An updated version of the RoHS Directive, known as "RoHS Recast", has been under consideration since 2008.

[6] e.g. to establish limits for toys intended to be used by children up to 3 years of age or intended to be placed in the mouth, elements or fragrances

[7] Article 3 of the GPSD (Directive 2001/95/EC)

[8] This is for instance confirmed by the RAPEX notifications related to chemicals which are mainly the result of non-compliance with existing limit values rather than the result of a proper risk assessment by authorities. This is notably due to the vagueness of the generic safety requirements of the GPSD.

Identification of the best regulatory option to address chemicals in products

The study looks at various possibilities for establishing a regulatory framework for chemicals in consumer products. In particular, the study considers the following options:

1. Expand/revise existing product directives to (adequately) cover chemicals in all relevant consumer products
2. Introduce specific chemical legislation for every sector following the RoHS model
3. Adopt a horizontal directive for chemicals in products
4. Extend reach to address chemicals in consumer products in a comprehensive way
5. Extend the ErP directive to include generic and specific chemical restrictions in principle for all kinds of products

The first two options would necessitate the adoption of quite a few pieces of legislation for different product categories, or amendments to existing legislation. This would not only be time-consuming and burdensome but would also not facilitate the application of a horizontal approach.

The third option, i.e. the adoption of a horizontal directive for chemicals in products, may be useful but its adoption would probably face strong opposition and take many years before making its way out.

The fourth option which is to revise the REACH Regulation in order to integrate more stringent provisions for chemicals in consumer products also seems unrealistic. REACH is indeed already a very complex legislation, and the European Chemicals Agency ECHA is overburdened with administering the system.

Thus, the fifth and last option envisaged, which consists of an extension of the scope of the ErP Directive to cover all relevant consumer products (whether or not energy related) and address all environmental aspects, including chemicals, seems the most realistic one:

First, because the broadening of the scope of the ErP Directive is already foreseen in the Directive itself. Article 21 of the Directive indeed reads that, in 2012: "*the Commission shall assess, notably, the appropriateness of extending the scope of the Directive to non-energy-related products, in order to significantly reduce environmental impacts throughout such products' whole life cycle*".

Moreover, the ErP Directive requires considering the full life cycle of a product and all significant environmental aspects. It is true that the work has so far merely focused on energy efficiency and that efforts are needed to ensure that all relevant

environmental aspects of products are addressed in product-specific implementing measures. Considering the potential risks for human health and the environment, the use of hazardous chemicals deserves particular attention in this implementation process. This could be stressed further in the Directive after its review in 2012.

This development of the ErP Directive would also be in line with the Commission's political will to increase coherence between existing schemes as it would somehow mirror the implementation process of the EU Ecolabel Regulation. This would offer opportunities for synergies and efficient resource use as both baseline and excellence criteria for various product groups would be developed simultaneously.

Finally, this approach would allow establishing chemical requirements going beyond the current limitations of specific product legislation. For instance, it could allow establishing indoor air emission requirements for products such as furniture, carpets, floor coverings, paints, laser printers or air fresheners which are currently covered by various other pieces of legislation. It could also allow addressing human health and/or environmental aspects of products.

Adopting a horizontal approach for chemicals

Within the ErP Directive, the study suggests to adopt a horizontal approach to chemicals. In practice, this would translate into the introduction into the ErP Directive of positive lists of chemicals (e.g. only chemicals which have been previously approved may be used for specific purposes and in certain products), negative lists of chemicals (e.g. list of chemicals which are subject to a ban or limit values) or a combination of both.

However, a substance-by-substance evaluation process, on a product-by-product basis would be far too time consuming thereby resulting in consumer exposure to unwanted chemicals for long periods until restrictions can be imposed. The study therefore considers that a first step should be to exclude substances of very high concern (SVHCs)[9], as well as some other categories of chemicals classified as dangerous, in all consumer products subject to ecodesign requirements.

This generic exclusion should be based on content (e.g. 0,1% for any homogenous part of the product) or, where appropriate, on migration or emission levels. It should also be made possible to allow exemptions for specific substances or specific use. It should, conversely, also be made possible to adopt more specific or stringent requirements for chemicals not covered by generic restrictions, for special

[9] SVHC are defined in Article 57 of REACH and include substances which are Carcinogenic, Mutagenic or toxic to Reproduction (CMR), Persistent, Bioaccumulative and Toxic (PBT), very Persistent and very Bioaccumulative (vPvB) and substances identified as of equivalent level of concern as those listed before (e.g. endocrine disrupters).

product groups (e.g. products emitting substances into the indoor environment, toys).

In cases where exemptions are given or stricter restrictions imposed, a risk assessment by an independent scientific committee (e.g. SCCP) should be required. The risk assessment models used should take into account combination effects of chemicals (as a result of exposure to different chemicals with similar mode of action) and the consumer's multiple exposure to the same chemical via different routes.

The legal framework should also include the possibility of adopting or changing the chemical requirements by using a committee procedure and foresee a systematic assessment of the occurrence of chemicals in (certain) products.

Moreover, a product declaration scheme should be established for all consumer products. It is suggested that all SVHCs and other chemicals classified as hazardous[10] with a content of 100 ppm and above should be declared.

Finally, an adequately funded and more effective market surveillance system ought to be in place.

Next steps

The study recommends the above proposals to be considered as a starting point for a debate on how to address chemicals in consumer products in European legislation.

In view of such debate, a complementary study has been commissioned by the Consumer Council at the ASI. This new study will investigate additional pieces of European product legislation. Results are expected in spring 2011.

3. ANEC conclusions and recommendations

ANEC shares the major findings of the report, particularly as regards the need for a new regulatory approach to be developed for chemicals in consumer products at the European level.

In particular, ANEC agrees with the report that:

- The current European regulatory framework for consumer products does not ensure a sufficient level of consumers' protection against exposure to dangerous chemicals
- For many consumer products including products to which consumers are exposed on a daily basis such as clothes, furniture and child-care articles,

[10] According to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

there are virtually no chemical requirements in the European legislation - apart from a few restrictions under REACH

- Where chemical requirements are included in product legislation (e.g. in electric and electronic equipments or in toys), they lack ambition
- REACH itself has many flaws and cannot be considered an appropriate instrument to fill in existing regulatory gaps in product legislation
- There is no community approach to address chemicals in products in a systematic manner
- Enforcement cannot be expected to work in absence of clear-cut chemical provisions for products
- A new European regulatory framework is needed to address chemicals in products in a consistent, horizontal manner. For instance, such a framework could take the form of a framework directive which would allow establishing chemical provisions for one or more product groups in form of implementing measures using a committee procedure with balanced stakeholder representation
- The study's recommendation to broaden the Ecodesign Directive to cover every consumer products with an environmental and health improvement potential could be a suitable horizontal framework for addressing chemicals in products. However, other options, such as the development of a generic directive for chemicals in products, should not be dismissed at this early stage
- In any case, the new legislative framework should allow for the introduction of chemical provisions which are best adapted to the risks to human health. This could be a generic ban[11] (e.g. for CMR substances), restrictions of use[12], positive lists (clearly the preferred option from a consumer perspective) or negative lists. In addition, a systematic evaluation of chemicals in products ought to be performed, declaration of content envisaged and effective enforcement ensured
- Establishment of chemical rules for products should not be delegated to industry dominated standards bodies but need to be adopted at the regulatory level
- The new legislative framework should be developed using the necessary chemical and toxicological competence, for instance gathered within an

[11] based on content, migration or other kinds of release
[12] substance, article or user group specific

independent scientific committee as well as using the relevant product expertise. It should therefore provide the possibility to establish sectoral sub structures

- Elaboration of chemical requirements should be consistent with the development of the Ecolabel criteria if they exist (although they should be set at a lower level, of course)
- Nanomaterial specific provisions including appropriate product declaration and tracking requirements for consumer articles ought to be urgently adopted

In conclusion, ANEC believes a discussion on the best way to develop a European horizontal approach towards addressing chemicals in consumer products should be initiated at the political level, in cooperation with all relevant stakeholders.

ANNEX I

The particular example of REACH

The study looks into the REACH Regulation, with a particular focus on nanomaterials. It identifies many shortcomings with the system which show that REACH cannot ensure a high level of safety for consumers in particular in relation to chemicals in consumer products.

For instance, the data requirements in REACH depend primarily on the production or import volume of a substance and only to a limited extent on the hazardousness of the substance. Registration of substances also mainly relies on industry self-assessment. Only a small fraction of registration dossiers will be (independently) evaluated by ECHA and the Member States.

Moreover, the implementation period of the REACH Regulation is extremely long. It will indeed in particular takes decades before every substances of very high concern (SVHC) such as CMR chemicals will be subject to proper independent assessment via authorisation or restriction routes (up to 60 years estimated).

REACH hardly covers chemicals in consumer articles i.e. only to a limited extent. For instance, it requires registration of substances in articles only if the substance is present in those articles in quantities above 1 tonne per year and if the substance is intended to be released. Notification of the use of a SVHC is furthermore required if the substance is present in those articles in quantities exceeding 1 tonne per year and if the substance is present in those products above a concentration of 0,1 % weight by weight (w/w) and only if the substance has been included in the candidate list, unless the manufacturer/importer can exclude exposure to humans or the environment.

The REACH Regulation unfortunately does not include any stronger instruments for excluding chemicals from products such as the option of a generic ban of CMR (or other categories of) substances in certain articles or positive lists of chemicals which are considered safe. Substances in articles may only be banned based on substance specific assessments using the restrictions path (included in annex XVII). The REACH provisions can thus not ensure elimination of dangerous chemicals from consumer products (particularly in the short term) and cannot compensate for deficits in product regulation.

Regarding nanomaterials, REACH also presents many loopholes. REACH only requires registration for substances produced in amounts above 1 tonne per year. Not all substances and certainly very few nanosubstances are therefore included. However, the parent substances of many nanosubstances have already been pre-registered – many of them in the band > 1000 tonne/year and above.

REACH information requirements and other provisions (e.g. preparation of a chemical safety report) also depend on the tonnage threshold, making

nanomaterials often exempted from any registration requirement or subject to few information requirements.

However, a nanomaterial that has a bulk counterpart have has to comply with the information requirements applicable for the total production volume of both the nano and bulk forms. For instance, if this total amount exceeds 1000 tonnes per annum, the substance will be registered with the most extensive data set and the registration dossier should theoretically also include specific data regarding the nanoform of the substance (or be updated as soon as a nano form of the substance is placed on the market). However, although a wide set of data may be required it is far from clear whether the foreseen toxicity tests have to be performed for both the bulk substance and the nano form.

Whilst the Commission considers the current regulatory framework sufficient to address risks relating to nanomaterials and only in need of some modifications at the implementation level, this position seems more than doubtful and is also not supported by the EU Parliament.

In addition to standard information requirements nano specific data may have to be defined in a flexible way e.g. by an independent scientific committee.

Only a small fraction of registration dossiers will be evaluated by ECHA and the Member States. However, it is advisable that dossier and substance evaluations are carried out for all nanosubstances.

Existing testing methods on nanosubstances may not be appropriate and will have to be adapted.

The Commission takes assurance in market surveillance for compliance with legal requirements regarding nanosubstances/materials. However, in absence of clear-cut assessment rules the enforcement bodies will encounter difficulties in taking action.

The study concludes that the REACH Regulation ought to be adapted taking into account the points above. It also needs to be complemented by provisions in consumer product regulation – such nano specific provisions are currently widely missing - including approval procedures as e.g. these required in the Cosmetics Directive.

APPENDIX – About ANEC and other documentation

A.1 About ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and conformity assessment as well as related legislation and public policies. ANEC was established in 1995 as an international non-profit association under Belgian law and represents consumer organisations from 31 European countries. ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

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