Hazard v. Risk in EU Chemicals Regulation

*Kristina Nordlander, Carl-Michael Simon and Hazel Pearson**

Hazard is the potential of something to cause harm; risk is the likelihood of harm occurring. Chemicals regulation is largely focused on minimising risks associated with chemicals – and rightly so. However, in the EU the hazard classification of individual chemicals can impact significantly the regulation of products containing those chemicals, regardless of the actual risks that the products may pose to human health or the environment. This can lead to undesirable consequences, such as restrictions on the use of safe products, substitution towards less safe products, and disincentives to innovate. Such hazard-based regulation tends to be at odds with World Trade Organization rules and has raised significant concern with EU trading partners. This journal is an ideal forum for discussing how the EU can move towards a better and more coordinated legal framework for the regulation of chemicals.

I. Introduction

Chemicals regulation should aim to strike the right balance between minimising risks to humans and the environment while maintaining the benefits to society of chemical substances. In order to strike that balance, regulators should assess the *risks* that chemicals may pose to human health or the environment.

Such a risk assessment, as applied in the EU, consists of three components: hazard identification and characterisation, appraisal of exposure, followed by the risk assessment itself (which we shall describe in greater detail below). In plain terms, 'hazard' typically refers to the intrinsic properties of a chemical, such as toxicity, while 'exposure' addresses the likelihood and degree to which a human or environmental receptor will be exposed to the intrinsic hazards of a chemical. 'Risk assessment' puts the two together, attempting to understand the 'real world' danger posed by a chemical based on its intrinsic hazards in the light of anticipated exposure.

There is, in theory, a clear division between the EU chemicals rules that relate to hazard and those that focus on risk. The primary rules that relate to identifying hazardous properties of chemicals are found in the Dangerous Substances Directive (DSD)[1] and the Dangerous Preparations Directive (DPD),[2] which are gradually being replaced by the United Nations globally harmonised system of classification and labelling (the GHS)[3] in the form of the CLP Regulation.[4] Once the intrinsic properties of a chemical have been identified, further regulatory measures and controls based on an assessment of its real world risks can be put in place. In the EU, rules on risk assessments of chemicals or products are found in, for example, REACH,[5] the Plant Protection Regulation,[6] and the

* Kristina Nordlander is a Partner, and Hazel Pearson is an Associate, at Sidley Austin LLP in Brussels. Carl-Michael Simon was until recently an Associate at Sidley Austin LLP. The views expressed in this article are exclusively those of the authors and do not necessarily reflect those of Sidley Austin LLP, its partners, or clients. The authors would like to thank Chris Bell, Sidley Austin LLP, Washington DC for his comments on an earlier draft. This article has been prepared for academic purposes only and does not constitute legal advice.

1 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 1967 L 196/1, as amended.

2 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ 1999 L 200/1, as amended.

3 See <http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html>.

4 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, etc., OJ 2008 L 353/1.

5 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), etc., OJ 2006 L 396/1, as amended.

6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309/1.

Cosmetics Regulation.[7] There is also the special case of the Medicinal Products Directive,[8] in which product authorisation is linked to the establishment of a positive risk/benefit balance.

However, in practice in the EU, the regulatory decisions that are supposed to assess the risks of chemicals and products frequently rely solely or primarily on identified intrinsic hazards, without an actual assessment of risk that fully takes exposure into account. Despite a major revamp of EU chemicals legislation in recent years (including the introduction of REACH and the CLP Regulation), there are still many automatic and direct links between the classification of chemicals based on hazard and downstream product regulation, without any (or sometimes only a limited) evaluation of exposure and risk. While regulation based on hazard alone may arguably be justified in the absence of data on exposure and risk, the introduction of REACH, and particularly the new use and exposure data that will result from its registration obligations, strengthens the argument for risk-based regulation.

This article examines the role of hazard, exposure and risk in EU chemicals legislation. It provides a critical assessment of cases where intrinsic hazard identification (without risk assessment) can lead to inappropriate regulatory consequences downstream, and discusses possible solutions for addressing such problems.

II. Concepts of hazard, exposure and risk in the context of risk assessments

As mentioned above, the concepts of hazard and exposure are central components of risk assessments in the EU. This section explores the meaning of the key concepts and their relationship for purposes of risk assessment.

Hazard identification and characterisation[9] means identifying the nature and severity of the possible adverse effects that a chemical can cause humans (e.g. carcinogenicity, eye irritation, reproductive effects) or the environment (e.g. effects on fish, birds, vegetation). Hazard identification is based on the intrinsic properties of that chemical and the adverse effects associated with those properties. The fact that the hazard evaluations focus solely on the intrinsic properties of a chemical is critical, in that these evaluations do not take into account the possibility, nature or extent of any actual human or environmental exposure to the chemical.

Characterising the nature and severity of the identified potential adverse effects typically involves determining the quantity (dose) of a chemical to a human or environmental receptor that has a specific adverse effect. Thus, the hazard of a chemical is generally established in terms of the dose of that chemical which causes (or may cause) a particular adverse effect. Establishing the dose-response relationship is critical, since for many chemicals there are safe and even necessary doses to ensure a healthy public and environment, even if those same chemicals at higher doses may begin to cause adverse effects. The dose-response relationship for a particular chemical may vary depending upon the route of exposure (e.g. oral, inhalation, dermal) and the specific adverse effect at issue (e.g. a chemical might be an eye irritant at certain concentrations, and cause breathing problems at another). Hazard evaluations also typically address acute (short-term) and chronic (long-term) adverse effects.

This brief summary does not, of course, do justice to the complex topic of hazard identification and characterisation.[10] One might be surprised by the number of assumptions that are stacked on top of each other to reach what would otherwise appear to be confidently 'scientific' and objective conclusions. Accordingly, many hazard evaluations, either implicitly or explicitly, have varying levels of uncertainty associated with their conclusions. Those directly involved in the regulation of chemicals (whether regulators, industry, or other stakeholders) should become well-

7 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ 2009 L 342/59.

8 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311/67.

9 For simplicity's sake, we have combined in one step what is sometimes described in two: (1) identifying the adverse effect(s) associated with chemical and (2) established the dose-response relationship between the chemical and the adverse effect.

10 There are many challenging technical issues that can arise in the course of understanding the hazards posed by a particular chemical, ranging from the accuracy and validity of laboratory tests, extrapolating from animal tests valid conclusions about adverse effects to humans (not to mention the highly-charged issue of whether animal tests should be used at all), linear v. non-linear dose-response relationships, to understanding the chemical's 'mode of action' on human and environmental receptors (i.e. how the chemical actually causes the adverse effect). Of particular interest are the assumptions made or models used when there is insufficient data regarding the toxicity and properties of the 'target' chemical, and information or conclusions are 'read across' from other chemicals on which there is more data.

versed in these technical issues in order to improve the quality of decision-making and risk management.

Exposure assessment is the evaluation of the nature and probability of human or environmental exposure to the chemical. This is an important step because, as we have seen, the hazard identification and characterisation step involves only the intrinsic properties of the chemical, without reference to whether human or environmental receptors are ever actually exposed to the properties that are linked to possible adverse effects. In the case of human exposure, this includes assessing the potential routes of exposure to the chemical (e.g. through skin contact, inhalation or ingestion), the conditions of each of those exposures (e.g. in food, water, ambient air, products) the likelihood that any (or each) of those exposures will occur and the potential frequency and duration of those exposures. As with hazard evaluations, this is a complex evaluation with numerous technical challenges. For example, the mere presence of a chemical in a product or material does not necessarily mean that there is human exposure to the chemical. Quantifying exposures can be quite difficult if one is dealing with multiple routes of exposure over the life cycle of the chemical (or the products containing the chemical), and reaching agreement on reasonably anticipated chemical uses and exposures is not easy. Again, a careful evaluation of assumptions and uncertainties is critical to the regulatory and risk management decision processes.

Risk assessment is an effort to determine the likelihood that adverse effects (or significant adverse effects) may occur in the light of the intrinsic hazards of a chemical and the anticipated exposures to the chemical. At the highest level, this is a straightforward concept: having determined the doses at which the chemical may cause various adverse effects (the hazard characterisation), are human and environmental receptors actually being exposed to such doses in a manner that is likely to cause the adverse effects of concern? The result of this analysis is frequently expressed in terms of probabilities or relative risk, such as the probability of increased incidences of cancer over a lifetime, or a conclusion that using a particular product might increase the likelihood of a particular adverse effect by 25 %. The risk might also be evaluated and expressed differently for different human or environmental receptors. For example, occupational risks are frequently addressed separately, so increasingly are the risks to children and other 'vulnerable populations'.

With apologies to the scientific and academic communities, risk assessment is both a science and art. Risk assessment certainly requires the rigorous and objective analysis of data. However, there may be weaknesses or gaps in the data that can only be addressed by applying professional judgment. The various assumptions and uncertainties carried over from the hazard characterisation and exposure assessments also affect the risk assessment; extrapolating from that work to reach probabilistic conclusions necessarily creates additional uncertainties. Further, risk assessments often take into account, implicitly or explicitly, socio-political policies such as the precautionary principle.

The precautionary principle has an important and recognised role in the regulation of chemicals in the EU. It is now enshrined in Article 191 of the Treaty on the Functioning of the European Union, and REACH is explicitly based on it.[11] It can be applied in cases where it is not possible to complete a comprehensive risk assessment because there is insufficient data, and where the regulator therefore makes conservative assumptions about potential hazards, exposures or risks to decide on risk management measures despite an absence of hard data. However, importantly, the precautionary principle can only be invoked once a scientific assessment (as complete as possible) has been made.[12] Therefore, arguably, the precautionary principle plays no role in hazard identification and characterisation.

For all of these reasons, the outcomes of risk assessments should not necessarily be accepted at face value, and the underlying data, analyses and assumptions should be carefully scrutinised in order to fully understand the conclusions that are being asserted.

One key function of any risk assessment is to ascertain the risks associated with the reasonably anticipated uses of a chemical so that regulators, industry and others may make informed risk management decisions. Once the risks associated with a chemical have been assessed, this information can be used to determine how best to manage and regulate the chemical. In this regard, it is important to understand that determining the acceptable level of

11 See REACH, Article 1(3) and recitals (9) and (69).

12 "*The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.*" Communication from the Commission on the precautionary principle, COM(2000) 1, section 6.1, p. 16.

risk is not the function of the risk assessment itself, which simply attempts to identify the ranges of risk. The decision as to what constitutes acceptable risk is a socio-political, not a scientific, decision.

Obviously the exact approach to how risk is regulated varies between different pieces of legislation. There is, for example, worker protection legislation that is intended to limit exposure of workers to certain chemicals in the occupational setting, and also a range of product-specific legislation, such as the Cosmetics Regulation, which are intended to address risks associated with consumer products. Some such product-specific legislation is analysed in greater detail below, but first we consider the EU rules that are used to determine the hazardous properties of chemicals.

The ultimate purpose of a risk assessment is to better understand the likelihood of adverse effects in the 'real world' associated with the reasonably anticipated uses of a chemical. For example, a chemical with intrinsically hazardous properties which is present in a consumer product in low concentrations and a low likelihood of exposure may actually pose no appreciable risk to users of that product or to the environment. On the other hand, there are concerns that exposures to even very low concentrations of certain chemicals may, over a long period of time and in certain applications (e.g. food or drink containers), cause adverse effects of concern to human health and the environment.

As will be shown, concerns arise when risk management measures and product regulation are based primarily or solely on hazard. This paper first explains how hazard identification and characterisation are done in the EU. It then considers examples of chemicals and product regulations that are based primarily on either hazard or risk.

III. Chemicals are classified according to hazard in the EU

In the EU, hazard identification and characterisation are principally carried out by a process known as 'classification'. According to the Dangerous Substances Directive, the object of classification is to identify all the physicochemical, toxicological and ecotoxicological properties of chemical substances[13] and mixtures[14] which may constitute a risk during normal handling or use.[15] Once the intrinsic properties of a chemical have been identified, and the chemical classified, the chemical can then be appropriately labelled and packaged, and its uses assessed and regulated as necessary.

The language used in the DSD is interesting because it suggests that the approach to classification is not (or should not be) purely hazard based. The only intrinsic properties that can lead to the classification of a substance under the DSD criteria are those "*which may constitute a risk during normal handling or use*".[16] Strictly speaking, this assessment would require knowledge of the likely uses of the substance in question in the EU as well as some assessment of exposure and therefore risk. Indeed, the Legal Service of the European Commission has advised national experts on classification and labelling that:

"In order to identify the potentially dangerous intrinsic properties of a substance, one shall take into account (at least) the following elements:

- *The form under which the substance is normally used or may be used ...*
- *The normal behaviour of the persons that are handling/using the substance...*
- *Foreseeable and realistic accidents ...*

While identifying the intrinsic properties of a substance, we shall not take into account unrealistic scenarios:

- *We shall not consider as an intrinsic property a property that occurs when the substance is deliberately used in an unintended way with an intention to kill/harm ...*
- *The effect of concentrations that are far above the maximum physically possible concentration in human."*[17]

This approach makes sense, as it serves no purpose to warn against properties that cannot be relevant

13 Under EU chemicals legislation, 'substance' generally means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. See CLP Regulation, Article 2(7) and REACH, Article 3(1).

14 Under EU chemicals legislation, 'mixture' (or 'preparation' as it was known prior to the CLP Regulation) generally means a mixture or solution composed of two or more substances. See CLP Regulation, Article 2(8) and REACH, Article 3(2).

15 DSD, Annex VI, para. 1.1.

16 DSD, Annex VI, para. 1.1.

17 European Commission, "Summary Record from the Session on Classification of Boric Acid and Borates of the Meeting of the Technical Committee on Classification and Labelling of Dangerous Substances and Preparatory Meeting for the Technical Progress Committee of Directive 67/548/EEC, Arona, September 8, 2005", dated 20 February 2006 (ECBI/43/05 Rev. 1), p. 18.

to humans or the environment in 'real world' conditions. However, our experience is that the European Commission has tended to ignore this criterion in its classification decisions under the DSD. Substances are often classified – including as CMR ('carcinogenic', 'mutagenic' and 'toxic to reproduction') – with no knowledge of their actual or normal uses, and thus about expected exposure scenarios. Several court cases that are currently pending on this issue may lead to some further clarity.[18]

The CLP Regulation does not contain the 'normal handling and use' language. But it does introduce a similar concept in several provisions that focus on the form in which a chemical is put into a product on the market for use. For example, Article 9(5) on the evaluation of hazard information for substances and mixtures states:
"When evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used."[19]

On the other hand, the official Introductory Guidance on the CLP Regulation explains:
"*Similar to DSD, one of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a classification as hazardous... The classification of chemicals is to reflect the type and severity of the intrinsic hazards of a substance or mixture. It should not be confused with risk assessment which relates a given hazard to the actual exposure of humans or the environment to the substance or mixture displaying this hazard. Nevertheless, the common denominator for both classification and risk assessment is hazard identification and hazard assessment.*"[20]

To sum up, despite language in both the DSD and CLP Regulation suggesting that the likely exposure from reasonably expected and normal uses of substances must be assessed as part of a classification decision, the main approach adopted in EU chemicals regulation is that a chemical should be classified on the basis of hazard. The 'class' of the classification describes the nature of the hazard (e.g. explosive or toxic to the environment), while 'categories' describe the severity of the hazard. For example, there are three categories of the hazard classes 'carcinogenic', 'mutagenic' and 'toxic to reproduction' (CMR).[21]

As already mentioned, the EU rules on the classification, labelling and packaging of chemicals are currently in a transitional phase and the system comprising the DSD and DPD is being replaced by the CLP Regulation. There are significant differences between the old and new systems – both substantively (e.g. in the specific classification criteria) and procedurally. That said, both systems fundamentally rely on hazard to classify chemicals.[22]

Under both the DSD and the CLP Regulation, if a chemical is classified in a certain hazard category or class, it must be packaged and labelled in accordance with the corresponding requirements. Such labelling requirements can include hazard symbols or 'pictograms' (such as the skull and crossbones, the 'exploding man' or the 'dead fish' labels), or hazard statements[23] (e.g. "*May cause cancer*") or precautionary statements[24] (such as "*Keep out of reach of children*").

IV. EU regulation based on hazard assessment

Apart from labelling and packaging, the DSD, the DPD and the CLP Regulation do not explicitly regulate the use of chemicals associated with certain hazards. However, the classification of chemicals under the DSD, the DPD and the CLP Regulation will in many cases have automatic – and commercially highly significant – consequences for the use of hazardous chemicals or products that contain them. In some cases, these regulatory consequences may apply just due to the classification of the chemical without any further exposure-based risk assessment that would

18 See, for instance, C-14/10 *Nickel Institute* and C-15/10 *Etimine* (both pending).

19 Emphasis added. See also CLP Regulation, Articles 5(1), 6(1) and 8(6) and DSD, Article 4.

20 European Chemicals Agency, "Introductory Guidance on the CLP Regulation", ECHA-09-G-01-EN, 25 August 2009, at pp. 7–8.

21 Under the DSD, the three categories of CMRs are: category 1 – proven CMR based on human data; category 2 – CMR based on animal data; and category 3 – suspected CMR. Under the CLP Regulation, there are also three analogous CMR categories, but they are known as categories 1A, 1B and 2.

22 For instance, under Article 3 of the CLP Regulation, *"a substance […] fulfilling criteria related to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex."* The CLP Regulation includes the hazard classes found in the DSD, as well as certain other new ones that originate from the GHS.

23 Under the DSD/DPD, the standard phrases on the nature of special risks from substances were called R-phrases.

24 Under the DSD/DPD, the safety precaution phrases relating to the handling and use of dangerous substances were called S-phrases.

take into account real world risks associated with the particular use that is being regulated. This is particularly true for chemicals that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR). Below we identify some of those consequences, focusing on CMRs, under three relatively recent pieces of EU chemicals and product legislation.

1. REACH

Some of the key provisions of REACH are based on risk assessments such as the chemical safety report that in many cases has to be included in the registration dossier,[25] or the evaluation of chemicals by Member States under Title VI, Chapter 2. Nevertheless, hazard classification of chemicals under the DSD or the CLP Regulation can trigger automatic consequences under REACH.[26]

For example, once added to a list in Annex XVII of REACH, any chemicals that are classified as CMR category 1A or 1B under the CLP Regulation (the equivalent to categories 1 and 2 under the DSD), or mixtures that contain such chemical substances, may not be sold to the general public above certain concentrations and must be labelled: "*restricted to professional use*".[27] This restriction does not apply to medicinal products, cosmetics or certain fuels, mineral oils and artist's paints.

Through this provision, REACH thereby imposes severe restrictions on the sale of chemical substances and mixtures on the basis of their hazard classification rather than on assessment of the actual risk they may pose to humans in a particular situation.

A second hazard-based restriction in REACH is that a chemical substance classified as CMR category 1A or 1B under the CLP Regulation is considered under REACH to be a 'substance of very high concern' or 'SVHC'. All SVHCs come automatically within the scope of the authorisation rules in REACH. This means that they are eligible to be placed on the Candidate List which could eventually result in forced substitution and in companies having to obtain temporary authorisations based on socio-economic justifications in order to be able to carry on using them. Most categories of SVHCs (i.e. PBTs, vPvBs[28] and those of equivalent concern) can only be placed on the Candidate List if a detailed dossier has been prepared in accordance with Annex XV of REACH. This dossier includes information on exposures, risks and alternatives to the chemical. In contrast, chemicals that are in the CMR category 1A or 1B can be considered SVHCs and added to the Candidate List without the need for such a dossier, merely needing reference to their classification.[29]

The decision to make a chemical substance ultimately subject to authorisation is only taken after an extensive risk assessment. However, as discussed below, the very fact of being publicly identified as a potential SVHC can itself have significant market consequences.[30] In the case of CMR substances, these consequences can occur without any consideration of exposure or whether the substance in question presented any real risk.

2. Plant Protection Regulation

Hazard classification also has important consequences under the recently adopted Plant Protection Regulation.

Under that Regulation, which will apply from 14 June 2011, an active chemical substance that is classified as mutagenic category 1A or 1B under the CLP Regulation must not be approved for use in a plant protection product. Similarly, an active chemical substance that is classified as a carcinogen category 1A or 1B or as toxic to reproduction category 1A or 1B must not be approved for use in a plant protection product unless exposure to humans is limited and residue levels are below certain default values.[31]

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25 REACH, Annex I sets out the rules for preparing chemical safety reports and states that "*The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks...*" (para. 0.1).

26 NB. One of the purposes of REACH, and the registration obligations in particular, is to generate more information about chemical substances in order to facilitate their classification.

27 See REACH, Annex XVII, Entries 28–30.

28 'PBT' means 'persistent, bioaccumulative and toxic', 'vPvB' means 'very persistent and very bioaccumulative'. See REACH, Annex XIII for the criteria for their identification.

29 REACH, Article 59(2) and (3).

30 This was an argument that was made by the applicants in a recent request to the General Court for the suspension of a decision to add the chemical acrylamide to the REACH Candidate List – although the President of the General Court dismissed the Application citing that the applicant did not demonstrate that it would lose market share and have to close its production plant as a result of the listing. See Order of the President of the General Court of 26 March 2010 in Case T-1/10 R, *SNF SAS v. European Chemicals Agency (ECHA)*, (not yet published) para. 51.

31 Plant Protection Regulation, Annex II, para. 3.6.

The Plant Protection Regulation thus links the approval of chemical substances for use in plant protection products to their classification, which reflects the substance's intrinsic hazardous properties. For carcinogens there is scope for limited exceptions to these restrictions, which introduce an element of risk consideration on the basis of the likelihood of exposure to humans or the concentration of the chemical in the environment. However, the basic approach focuses on hazard rather than risk.

3. Cosmetics Regulation

The EU rules on cosmetics are in the process of changing. While Article 4b of the Cosmetics Directive[32] simply prohibits the use in cosmetic products of chemical substances classified as CMR 1 or 2 under the DSD, Article 15 of the recently adopted Cosmetics Regulation allows some limited respite from the consequences of hazard classification.

From 1 December 2010, the date from which the Cosmetics Regulation applies, a chemical substance classified as CMR 1A or 1B under the CLP Regulation may be used in cosmetic products, but only if each of four specific criteria are met:

(1) the substance complies with food safety requirements as defined in Regulation (EC) No 178/2002 on food law,[33]
(2) no other suitable alternative substances available,
(3) an application has been submitted for a particular use of the product category with a known exposure, *and*
(4) the substance has been evaluated and found safe by the EU Scientific Committee on Consumer Safety (SCCS).[34]

Chemical substances classified as CMR 2 under the CLP Regulation (i.e. suspected CMRs) are also, as a rule, banned from use in cosmetic products, but may be used if they have been evaluated by the SCCS and found safe for use in cosmetic products.[35]

The possibility of derogation from the automatic link between the hazard classification of cosmetic ingredients and the ban of their use in cosmetic products is welcome when compared to the present outright ban on the use of chemicals classified as CMR 1 or 2 under the DSD. The derogation adds the possibility of exposure and risk consideration, to what would otherwise be purely hazard-based product restriction.

However, the relevant provision of the Cosmetics Regulation remains very much hazard-based, with only limited scope for exemptions. Again, the exact reason for this approach is not obvious, especially since there is a clear risk assessment procedure in the current and future EU cosmetics rules. A possible reason may be that the legislators assume that there will be a certain level of exposure to hazardous chemicals if they are used in cosmetic products and thus a certain risk – but this approach does not take into account the actual concentrations of the chemical that are in the cosmetic product.[36]

The fact that the SCCS has concluded that a CMR category 1A or 1B chemical is safe is not sufficient in itself to allow that chemical to be used in a cosmetic might indicate that the legislators do not fully trust EU scientists to assess the risk of chemicals with accuracy. Or it may simply be a sign that certain legislators prefer a 'zero risk' approach to regulation.

Moreover, in a step moving further away from risk-based regulation, the Cosmetics Regulation also includes specific labelling and pre-market notification requirements that apply to any substance that may be classified as a 'nano-particle'. Those non-specific requirements apply to all cosmetic products that contain nano-particles, regardless of whether there is any evidence that they pose a risk to human health, and even regardless of their hazard classification. To the extent this approach has no scientific basis, it is difficult to even characterise this as a precautionary approach to the regulation of cosmetics containing nano-particles.

32 Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ 1976 L 262/169.

33 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31/1.

34 Cosmetics Regulation, Article 15(2).

35 Cosmetics Regulation, Article 15(1).

36 In the case of carcinogens, it is also possible that this regulation is based on an assumption of a linear dose-response relationship, whereby there is no dose at which there is no risk of cancer from a carcinogen. However, there is considerable scientific dispute over the validity of a linear dose-response assumption for carcinogens, with many scientists arguing that, at least for some chemicals, there are threshold concentrations that must be exceeded before there is any risk of cancer.

V. Regulation based on risk evaluation

Although there is a range of EU legislation that links product regulation to hazard classification, there are also a number of examples of EU product legislation that focus on risk rather than hazard.

1. The Medicinal Products Directive

The best example is probably the Medicinal Products Directive[37], which acknowledges that medicinal products may be associated with risks for human health, but allows the marketing of such products if the positive therapeutic benefits outweigh these risks. An over-the-counter medicinal product, e.g. aspirin, will thus be allowed on the market if the benefits associated with the product outweigh the risks, regardless of whether one of its chemicals has a certain hazard classification.

Admittedly, the marketing of medicinal products is preceded by scrupulous testing and investigation of potential benefits and risks, and is not a model that can be used for all categories of products. This extensive testing may be a reason why legislators are confident that the relevant risks are correctly assessed. The fact that medicinal products are only approved when there are demonstrable benefits may also be a reason why legislators are willing to accept that medicinal products contain hazardous chemicals and are likely to pose risks, but still allow them on the market. Put differently, since the regulation of medicinal products (unlike the regulation of, for example, cosmetics) is not aimed at eliminating risk, there is no reason to restrict market access on the basis of hazard.

2. The General Product Safety Directive

Another good example of risk-based product regulation is the General Product Safety Directive (or GPSD).[38] The GPSD is intended to ensure that products that are placed on the market in the EU, and which are not covered by more specific EU legislation, are safe.

Article 2(b) of the GPSD defines a 'safe product' by reference to risk:

"'safe product' shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons ..."

The above definition makes no reference to the potentially hazardous properties of a chemical in a product, but the 'composition' of a product is a factor to be considered when assessing the 'safety' of products.

Thus, while the hazard classification of a chemical used in a product would be relevant for the assessment of the safety of that product under the GPSD, that classification would not be *determinative* in assessing whether or not the product is safe.

VI. Hazard-based product regulation is a concern

While the classification of chemicals in accordance with hazard is a necessary part of a regulatory regime, it is the authors' contention that it should only be the first step in assessing and managing their risks, and regulating their use in products. As outlined below, downstream product legislation that automatically restricts the marketing or use of a product, solely or primarily as a consequence of a hazard classification of a chemical it contains, can give rise to concern for a number of reasons.

1. Restrictions on safe products

As mentioned, the intrinsic hazard of a chemical found in a product does not determine by itself whether or not that product is 'safe', i.e. the extent to which it poses risks to humans or the environment. Rather, the risk to human health, for example, associated with a hazardous chemical in a product will also depend on the nature and extent of any potential human exposure to that chemical from the reasonably anticipated uses of that product.

37 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311/67.

38 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ 2002 L 11/4.

As has been seen, a number of the instances where chemicals are regulated solely on the basis of hazard relate to CMRs. While CMRs are rightly a priority for regulatory action, this does not justify taking a purely hazard-based approach. CMRs are not the only substances with potentially severe adverse effects for human health and the environment – witness the concern over PBTs, vPvBs and endocrine disrupters. Yet for PBTs and vPvBs the REACH authorisation rules apply a risk-based approach far earlier than for CMRs. Given the inherent uncertainties in classification discussed above and the high stakes both in terms of adverse effects to human health and the environment and to the market for them, arguably an even more rigorous and thorough approach to their regulation should be taken.

It follows that if downstream legislation restricts the marketing or use of a product based solely on the intrinsic properties of a chemical found in that product, rather than on the actual risk of harm posed by the product, then by definition that downstream legislation could restrict the use of products which are safe (i.e. which pose no appreciable risk).

Critics of the recently adopted Plant Protection Regulation fear that it will have exactly this effect – i.e. that it will lead to restrictions on the use of products that are relatively safe and that may have beneficial human and environmental effects.[39]

Similarly, cosmetic products that contain any substance classified as CMR 1A or 1B under the CLP Regulation would probably be restricted under cosmetics rules, even though the very same products could be sold safely as medicinal products (there are cases of cosmetic products, e.g. toothpastes, being sold as medicinal products in some EU Member States and as cosmetic products in other Member States).

2. Restrictions on beneficial products and loss of consumer benefits

Product regulations that are linked solely to the intrinsic hazard of a chemical it contains, rather than to the actual risk posed by the product, may lead to unnecessary restrictions on beneficial products, and this would entail a loss of consumer benefits, discourage innovation, and would not necessarily reduce the risks to consumers.

Take the example of products that contain ethanol (i.e. alcohol). Ethanol is known to be harmful to pregnant women and is suspected of having carcinogenic properties. But ethanol is (and has historically been) widely used for a wide range of applications; from food and drink to preservatives to printer inks, and as an effective disinfectant in cleaning agents (including in hospitals).

There has been much discussion about the possible classification of ethanol in accordance with its intrinsic properties, but it has not (yet) been classified as a CMR chemical. Such a classification would be highly contentious. Leaving aside the implications for food and drink (which are exempted from the scope of the DSD, DPD and CLP Regulation),[40] if ethanol were to be classified as CMR category 1A or 1B under the CLP Regulation, it would follow that under REACH products (including cleaning agents or disinfectants) containing ethanol above a certain concentration could not be sold to the general public. This could lead to unintended and unwanted results – for example restrictions on the sale of ethanol-containing cleaning agents could increase the risk of the spread of bacteria (including bacteria that are resistant to antibiotic or biocides).

Such a classification would also result in ethanol being banned from all cosmetic products under the Cosmetics Directive. This would have very severe consequences for cosmetics consumers (and producers, distributors, retailers etc.) – ethanol is after all very commonly used in cosmetic products, not least in fragrances.

Similarly, excessive restrictions on plant protection products reduce other benefits to society. An example of this would be where excessive restrictions on plant protection products lead to lower crop yields (for example, where safe and effective plant protection products are phased out without adequate replacements).

3. Restrictions on use of one product lead to increased use of another product with equal or greater risks

When the use of certain products is prohibited, the users of that product are likely to turn to other prod-

39 See, for example, Dr. James Gilmour, "Risk not hazard for good pesticides regulation", 16 October 2008 available on the Internet at <http://euractiv.blogactiv.eu/2008/10/16/risk-not-hazard-for-good-regulation/>.

40 See DSD, Article 1(2)(d), DPD, Article 1(5)(d) and CLP Regulation, Article 1(5)(e).

ucts to meet their needs. It should not be assumed that the substitute products will pose lower risks than the banned or restricted products. The use and exposure patterns of substitute products may produce greater risks, even if the ingredients pose fewer intrinsic risks (for example, a less hazardous, but less effective, product may have to be used in increased volumes, and thereby lead to greater risks).

To give an example, if out of three main plant protection products used for a specific purpose in the EU one of them were to be banned under the new Plant Protection Regulation, the use of the other two products would be expected to increase. It is quite possible that more intensive use of certain plant protection products would increase the overall risks to human health and the environment from the use of those products (by increasing human exposure to or soil accumulation of those chemicals). Of course, the converse could also be true. This issue would probably be best resolved through carrying out comprehensive risk assessments of each of the products.

4. Stigmatisation and loss of incentives to innovate

Hazard-based regulation can also lead to significant demand stigmatisation. This occurs when particular chemicals, processes, or technologies become identified with potential hazards to human health, public safety, or the environment, regardless of actual risks. Consumers and industrial users may then confuse hazard and risk, and take precautionary actions to avoid the stigmatised product or technology. This would lead to a reduction in demand for it, even if there were no basis in science or risk for such reactions.

One example of consequences of this kind is the designation of CMR chemicals as SVHCs under REACH based solely on their hazard classification. Although legally there are no automatic product restrictions flowing from their designation as a SVHC, at least until they are added to the Candidate List for authorization, there can be significant market and stigmatisation consequences. Many companies in Europe and around the world have corporate responsibility and product stewardship policies that prohibit or limit the use of particularly hazardous chemicals in their products, or which prescribe the substitution of SVHCs with less hazardous substitutes. Such stigmatisation can also lead public authorities to 'blacklist' products containing SVHCs from lists of approved products for green and public procurement. This effect is amplified by other, well publicised 'black lists' of SVHC chemicals that companies are encouraged to avoid, such as the NGO-sponsored Substitute It Now or 'SIN' list.[41]

Hazard-based regulation and stigmatisation can also lead to the loss of incentives to innovate. If companies learn that any product that contains a chemical with a certain hazard classification may in the future be subject to authorisation or restrictions under REACH (even if the product is safe), they will be more inclined to avoid doing research on materials with such hazard classifications. It could be argued that such stigmatisation would in fact spur innovation in 'green chemistry'. But where stigmatisation is based on hazard rather than risk, some potentially beneficial 'green' products could be lost, even though they may use hazardous chemicals in a way that effectively manages their risks. For instance, the nickel metal hydride batteries that are used to power low-emission hybrid electric vehicles can only be produced using chemicals that are classified as CMRs.

Although it is true that it may take many years for a chemical that is a SVHC to become fully subject to authorisation under REACH (or indeed this may never happen at all) the mere threat or possibility of it happening can still be a significant disincentive to invest or innovate in products and technologies relying on that chemical. Indeed, such long-term uncertainty can be more problematic for certain businesses (including those with long product or investment cycles) than a quick decision one way or the other.

VII. Hazard-based product regulation is at odds with WTO law

As well as leading to unintended and unwanted consequences, some product regulation based on hazard classification may also not be compliant with the rules of the World Trade Organization (WTO), and the Agreement on Technical Barriers to Trade (the TBT Agreement) in particular.

As an example, Article 2.2 of the TBT Agreement provides that:

41 See <http://www.chemsec.org/list/>. See also Order of the President of the General Court of 26 March 2010 in Case T-1/10 R, *SNF SAS v. European Chemicals Agency (ECHA)*, (not yet published).

"Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products."

Any assessment of whether a technical regulation that applies to a product is more trade restrictive than necessary to fulfil a legitimate objective should thus consider the *risks* arising from not regulating that product in such a way. Moreover, the assessment of the risks should consider the *end-uses* of the relevant product.

As a consequence, there have been a number of instances in recent years of key EU trading partners raising concerns about EU classification decisions under the DSD and the CLP Regulation on the grounds that they do not meet the requirements of Article 2.2 of the TBT Agreement.[42]

VIII. Conclusions and recommendations

The identification of the hazardous properties of chemicals is a necessary step towards determining the risks that those chemicals pose to human health or the environment when used in certain products. However, hazard identification is not by itself a sufficient basis either for assessing risk, or for regulating products. Other international organisations and countries generally support a risk-based approach to chemicals and product regulation. These include the OECD[43] and the United States, where hazard classification is only the start of the assessment of a chemical and does not lead to regulatory decisions – these are taken under different legislation depending on factors including actual uses.

The EU approach to product regulation is piecemeal and uncoordinated. There are examples of chemical and product legislation that restrict the use of products purely on the basis of the hazard classification of one of their constituent chemicals, regardless of whether and to what extent the product presents an actual risk to humans or the environment. On the other hand, some legislation, such as that for medicinal products, is firmly risk-based. Nor does there appear to be any consistent trend as to whether product regulation is moving towards a more hazard or risk-based approach: some amendments to the Cosmetics Regulation when compared with the Cosmetics Directive generally show a promising move towards risk-based regulation, but the provisions regarding nano-materials go in the opposite direction. In addition, the revision of the plant protection products rules has also moved towards a more hazard-based approach. It will be interesting to see what impact the increased legislative power of the European Parliament (as a result of the entry into force of the Lisbon Treaty) will have on the adoption of hazard versus risk-based product regulation in the EU.

While a hazard-based regulatory approach may minimise the use of certain dangerous chemicals, it is a blunt instrument that does not necessarily reduce the risk for humans or the environment, and it has other negative consequences. In addition, such hazard-based regulation can unnecessarily restrict the international trade in safe products, in violation of WTO law.

In the past, there was perhaps a stronger justification for regulating chemicals and products solely on the basis of hazard: exposure data was limited and risk assessments could be long and expensive processes. However, REACH marks a step-change in EU chemicals regulation. The REACH registration process will ensure that there is far more information about chemicals and their uses will be available to regulators. The information requirements are particularly strict for CMRs. Accordingly, the justification

42 See, for example, the comments of Canada, Cuba, China, Ecuador, Colombia, Dominican Republic, Venezuela, Japan, Mauritius, Brazil, Indonesia, Philippines, Australia, Korea, Botswana, Zimbabwe, South Africa, Turkey, India, Chile, United States and Russia, as recorded in the minutes of the TBT Committee meeting of 5–6 November 2008, criticising the EC's proposed classification of borates and nickel compounds.

43 For example, the OECD has recently launched an online 'toolkit' for assessing and managing environmental risks of chemicals. The toolkit site describes the work flow of environmental risk assessment and management for chemicals, providing links to relevant OECD products that can be used at each step. The OECD toolkit is available on the Internet at <http://www.oecd.org/document/54/0,3343,en_2649_34373_44909430_1_1_1_1,00.html>.

for solely hazard-based regulation, even of CMRs, is now harder to maintain.

On the basis of this introductory overview of hazard-based product regulation in the EU, we would argue that product regulation based solely on hazard should be avoided as an overly blunt and unnecessarily trade-restrictive instrument. Instead, product regulation should be based on sound and transparent risk assessment. Legislative amendments to give effect to this change should be supported by actions to increase regulators' and other stakeholders' trust in risk assessment processes.

A first welcome step would be to apply properly the legal criteria that are already available in the classification and labelling legislation – the DSD, DPD and the CLP Regulation. The various regulatory consequences that flow more or less automatically from classification decisions under EU law would be less problematic if the likely exposure-based risk to humans or the environment during conditions of normal handling and use of the substance in question were taken into account already at the classification stage. If this were done, it would be more legitimate for products to be regulated on the basis of their classification (or the classification of their constituent substances). For example, if a chemical is only toxic for inhalation, but is placed on the market exclusively as a solid, then the absence of the inhalation exposure scenario should be taken into account when deciding its classification. Similarly, if the key routes of exposure that are related to toxicity will not occur – or at least cannot occur at any significant level during reasonably expected use – then it should be carefully considered whether or not the legal requirements for a particular classification are being met.

This journal is an ideal forum for discussing a better and more coordinated framework in the EU for regulating risks, including risks from hazardous chemicals in products.