CONSULTATION ON THE REGULATORY FITNESS OF CHEMICALS LEGISLATION (EXCLUDING REACH)

The Royal Society of Chemistry (Transparency Register ID Number 622934711000-42) welcomes the opportunity to contribute to the European Commission consultation on the regulatory fitness of chemicals legislation (excluding REACH).

The Royal Society of Chemistry is the world's leading chemistry community, advancing excellence in the chemical sciences. With over 55,000 members and a knowledge business that spans the globe, we are the UK's professional body for chemical scientists; a not-for-profit organisation with 175 years of history and an international vision for the future.

The RSC's Royal Charter obliges it to serve the public interest by acting in an independent advisory capacity, and we would therefore be happy for this submission to be put into the public domain.

We would be happy to provide further information in connection with any of the points in the following submission. Please contact: Dr Steven Lipworth, Environment, Health & Safety Policy Adviser, Burlington House, Piccadilly, London W1J 0BA Tel: +44 (0) 207 440 3337 (lipworths@rsc.org).

1) Effectiveness of the EU legislative framework at meeting its four objectives.

It is difficult to develop a view on the overall effectiveness of EU legislative framework at meeting its four objectives namely; protecting human health, protecting the environment, ensuring a well-functioning internal market and stimulating competitiveness and innovation. This is because the framework covers a wide range of complex legislation. Others may be better placed to provide examples on the extent to which specific pieces of legislation have met the four stated objectives and whether gains in a particular objective have been at the expense of others, for example if environmental protection measures have impacted on innovation or competitiveness or not. The consensus among our members who responded to this consultation was that overall the legislative framework had made an effective contribution to meeting its objectives and that this was reflected in improvements over time in human wellbeing (increases in life span) and in environmental health (e.g. the return of fish and mammals to previously polluted waters) when compared to other major industrialised counties outside the EU which do not have comparable regulatory frameworks, e.g. China.

2) EU chemicals legislative framework and risk management measures.

EU chemicals legislation needs to move away from hazard-based approaches towards a risk-based approach. Clearly hazardous chemicals have the potential to cause harm to humans and the environment but this is not inevitable. Good management practices can

prevent significant harm being caused. Restricting the use of chemicals simply and solely on the basis of their hazardous properties and potential to cause harm if misused could deny European citizens major benefits and lead to a loss of chemical diversity which in turn could impact negatively on innovation and invention. Chemicals management needs to be informed by evidence. We would support Option 1 that EU chemical and chemical-related legislation should in general be more oriented towards specific risk assessments that differentiate more between chemicals depending on their use.

3) Relevant considerations in chemicals regulatory decision-making.

The question is framed in a way that it confuses risk assessment with aspects of risk management. Mixture/combination effects and the impact of chemicals on vulnerable groups are part of risk assessment not risk management, whereas impact on competitiveness relates to risk management decisions.

Hazard identification, exposure assessment, toxicity assessment and risk estimation and evaluation can all be grouped under the term risk assessment. This is primarily a scientific process. Risk management is primarily based on societal and ethical value preferences about acceptability of the estimated risks. Many methods have been developed for integrating scientific, economic, cultural, ethical and other considerations into the risk management process with varying degrees of success. Essentially, these decisions consider whether a risk is so great as to be unacceptable; or whether the risk is so small that no further precautions are necessary; or if the risk falls between these two ends of the continuum, whether the risks could be incurred i.e. tolerable risks.

The degree of risk tolerated will differ from person to person and from country to country. Consequently, risk management decisions even when based on the same scientific data will rightly vary between societies. Socioeconomic considerations such as the assessment of impact (costs and benefits) of different regulatory options would also serve to provide a more comprehensive approach to informing chemicals regulatory decision-making.

The Royal Society of Chemistry has a long standing interest in regulatory decision making and has organised a series of events on aspects of risk assessment and risk management. Currently, our activities in this policy area are focused on improving methodologies for the socioeconomic assessment of the impact of chemicals regulation. On the 3rd of May 2016 The Royal Society of Chemistry and Network of REACH SEA and Analysis of Alternatives practitioners (NeRSAP)[1] ran a joint symposium on 'Improving Benefits Assessment of Chemicals Control Policy'. We would be pleased to share the output of this symposium as soon as this is available.

[1] NeRSAP http://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners

4) Implementation of the EU legislative framework for the management of chemicals

The Royal Society of Chemistry is not able to make specific observations on the implementation of the EU legislative framework. However, we would support transparency of procedures, expect all legislation to be sustainable, proportionate and workable as well as being consistently monitored and enforced equally across all member states once implemented.

5) Quality control of chemical safety data

Quality control is a fundamental requirement for the production of scientific data in general, including that related to safety for chemicals. Good laboratory practice (GLP) guidelines for toxicological testing are merely the codification of the good practice that all professional scientists should be following. Similarly, ISO & CEN standards should be followed in other areas such as analytical science.

Our Royal Charter[2] states that the object for which we are constituted is "the general advancement of chemical science and its application". As a professional body we maintain professional qualifications and set high standards of competence and conduct for professional chemists. This includes exercising attention to accuracy in chemical science investigations. As a chartered body, we have a special status with a paramount duty to serve the public interest while remaining completely objective.

6) EU legislative framework contribution to reduction of hazardous chemicals

We have not been made aware of any specific examples where the EU legislative framework for chemicals has contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives.

In many cases the analytical procedures have yet to be developed for the extraction and quantification of many substances of high concern in products. It is also important to note that whereas there is a level of control of substances in the products manufactured in the EU, the same does not apply to substances contained within imported products and used in the manufacturing processes outside the EU. This means it is very difficult to regulate these substances effectively.

Some of our members have expressed concerns that although substitution may have led to a reduction in levels of some hazardous chemicals, this does not necessarily equate to greater safety. This is because less may be known about the harmful properties of the substitute than the chemical which it replaced. Most substances have several hazardous properties and therefore in the search for less harmful substitutes care must be taken to ensure that a reduction in one risk is not replaced by an increase in another. For example, the main hazard associated with petrol is its flammability. However, petrol is poisonous as

[2] http://www.rsc.org/globalassets/02-about-us/our-charter/charter-by-laws.pdf

well as flammable. Our attention is focussed on its flammability since this is the most likely hazard to cause a problem, however it would be unwise to discount its other hazards when evaluating its suitability for different applications.

Chemical substitution decisions should be the result of comparative risk assessment and evaluation, which aims to optimise the choice of substances for a particular use, taking into account potential risks to health, wildlife and the environment and the benefits to society as a whole. The substitute must work adequately and ideally better than the original and should not lead to any materially important reduction in sustainability. This is not a trivial process and poses major scientific challenges including decisions on what to compare and about what level of risk is broadly acceptable. It requires considerable stakeholder involvement, including regulators, informed users, consumers and suppliers.

Another concern raised by members was the potential reduction in chemical substances primarily because of the high costs of testing rather than on the basis of their hazardous properties. In order to obtain quantitative information, a question was put to the European Biocidal Products Forum (EBPF) [3] of the European Chemical Industry Council European (Cefic) about the reduction in the number active substances used in biocides in the EU and the underlying reasons. The EBPF revealed that, in the period 2003 to 2015, the number of available active substances had declined from about 950 to 250. The main reason given for this reduction was that some of the companies that initially indicated that they would support these substances in the end decided not to register them for economic reasons.

7) Adequacy of EU legislative framework to address emerging concerns

Legislative frameworks will always have difficulty in dealing with advances in science and technology especially when these involve a paradigm shift in understanding as opposed to a continuing and iterative improvement in knowledge. There will nearly always be a significant information deficit and it is almost inevitable that regulatory actions will lag behind scientific developments. In addition, areas of initial concern may prove to be unfounded or alternatively may turn out to be worse than anticipated.

There are important differences between risks from chemicals and risks from other sources. Not all chemical effects are immediate. In some cases exposure to a chemical substance or compound today may not cause effects until many years later, such as developing lung cancer twenty years or more after breathing asbestos dust. Known long-term or chronic effects are a particular concern associated with some chemicals.

A further complication arises from the fact that toxicity usually depends on the species and exposure route as well as the amount involved, e.g. the pyrethroid insecticides (derived from chemicals made by plants as defences against insects) have little or no effect on humans but are very toxic to aquatic wildlife. Nonetheless, substances with toxic properties can be used safely and produce huge benefit to society when used appropriately, e.g. Warfarin is

[3] EBPF http://www.cefic.org/About-us/How-Cefic-is-organised/Fine-Speciality-and-Consumer-Chemicals/European-Biocidal-Products-Forum-EBPF/

used as a very effective rat poison but low doses are used clinically to prevent blood clots after a stroke or heart attack.

If the European Union is to remain at the forefront of innovation in both scientific understanding and the developments which may be eventually derived, it is essential that overly precautious regulatory action should not be used to inhibit the early stages of research, discovery and innovation. In general policy should consider control and licensing options, as opposed to prohibition, so that the potential benefits of new products are not lost. For example, the decision that the existence of endocrine disrupting properties should be sufficient to deny any agrochemical an authorisation seems to be misguided, particularly in view of the controversy amongst scientists about the significance of such properties. Furthermore, as stated above, many of the analytical methods needed to support effective control do not yet exist.

The Royal Society of Chemistry takes the view that policy should be informed by scientific evidence. To this end we have run workshops aimed at reviewing existing knowledge and identifying gaps to investigate emerging issues in order to better understand the risks they may pose and to reduce scientific uncertainty. For example the Royal Society of Chemistry ran two international expert workshops (in 2014 and 2015) on the low-dose effects of endocrine disrupting chemicals[4]. These workshops brought together leading international scientists with different disciplinary backgrounds and views to develop a research protocol that could produce evidence needed to resolve some of the issues in this contested area. The RSC would be pleased to share further information about this work.

8) Chemicals legislation: duplication, omissions, inconsistencies and contradictions

Residue compounds from pharmaceuticals in water and soil are increasingly identified as an emerging environmental concern[5]. This is consistent with the European Environmental Agency (EEA) and the World Health Organisation (WHO).

An example of potential duplication of legislation is the addition of three commonly used pharmaceuticals to the Priority Substances Directive watch list, namely two hormones (17alphaethinylestradiol and 17betaestradiol) and a painkiller (the non-steroidal anti-inflammatory drug - Diclofenac).

This leads to the option of using either water legislation, pharmaceutical legislation or a combination of both. The objective must be to avoid dual legislation (double jeopardy) so controls over use and disposal, rather than environmental legislation may be appropriate in terms of substances with high societal value i.e. source control. This would limit the impact of pharmaceuticals on water and lead to a reduction in the significant costs of end-of-pipe water treatments.

[4] http://rsc.li/ed-low-dose-effects

[5] The Water Science Forum and Environmental Chemistry Group and the International Network of Environmental Forensics Emerging Contaminants Conference (2015)
http://www.rsc.org/Membership/Networking/InterestGroups/WaterScience/past-events.asp

Table 1 EU Water-Related Directives Requiring Specific Standards for Specific Water Uses[6]

Water Reuse	Concern	Sewage Sludge Directive	Nitrate Directive	Water Framework Directive	Drinking Water Directive	Bathing Water Directive
Agriculture	Pollution of soil, groundwater and produce with chemical/bio-hazardous substances, Health risk for workers and consumers	x	x	x (ground water)	x	
Groundwater Recharge	Health concerns if potable re-use is intended		x	x	x	
Urban reuse	Health concerns regarding exposed persons			x	x	
Indirect potable re-use	Health concerns			x (surface & ground water)	x	
Recreational water use	Health concerns, infection risks for exposed persons					x
Environmental enhancement	Detrimental effects on the biocenosis			x (surface & fresh water)		
Aquaculture	Contamination of water and produce with chemical/bio-hazardous substances			x (fresh water & shellfish)		

There is also a lack of understanding at the user level between the requirements of water legislation, e.g. Water Framework Directive (WFD) and legislation that relates to food production (e.g. Common Agriculture Policy impacts) and legislation relating to energy use and production. In terms of water reuse there are a number of different standards in various directives potentially leading to confusion as to which apply.

9) CLP: Effectiveness of hazard communication

With respect to the symbols for bulk products (manufactured in the EU), the labelling gives a good indication of the minor risks associated with the chemical or mixture of chemicals and communicates the general hazard adequately, as long as this is combined with awareness training. This could of course always be improved. The risk assessments and data sheets available for individual chemicals normally contain sufficient information on the hazards and health effects.

Some of our members hold the view that the CLP system is too complicated and detailed, and lacks clarity. They note that Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) - withdrawn from 1 June 2015, clearly differentiated between Very Toxic and Toxic chemicals, with harmful and irritant available for less dangerous chemicals. CLP has the same symbol, signal word (Danger) and H code for Toxic category 1 (CHIP Very Toxic) and Toxic Category 2 (CHIP Toxic), and many of labels don't show the Category, so it is difficult to differentiate the toxicity of the contents of a given container.

[6] Table after Annex1 in "The Cost of Non-Europe Legislation, Thomas Zandstra European Parliamentary Research Service

Another practical issue is the size of small labels. Providing all the necessary information required by legislation on bottles below 25ml is virtually impossible.

10) Comprehensiveness of hazard classes in the CLP Regulation

Overall, the information generated provides sufficient detail for the reader to have an appreciation of the risks to health and the environment. However, the experience of the Nappy Science Gang citizen science project concerning the safe use of detergents for washing nappies [7] highlights potential problems relating to access to information needed to make informed decisions. The Classification, Labelling and Packaging (CLP) Regulation sets out minimum package labelling requirements. These requirements do not allow the consumer or manufacturer or retailer of garments, in this case nappies, to make informed decisions when recommending or purchasing detergents. This is because full ingredient details relating to proprietary formulations can only be made available to registered medical practitioners, in confidence, so in this case, neither CLP Regulations (EC 1272/2008) nor the Detergent Regulations (EC 648/2004) are helpful in ensuring that manufacturers and consumers have the information they require to inform their choice of detergents.

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[7] https://nappysciencegang.wordpress.com/