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BRIEFING PAPER

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Chemicals Regulation

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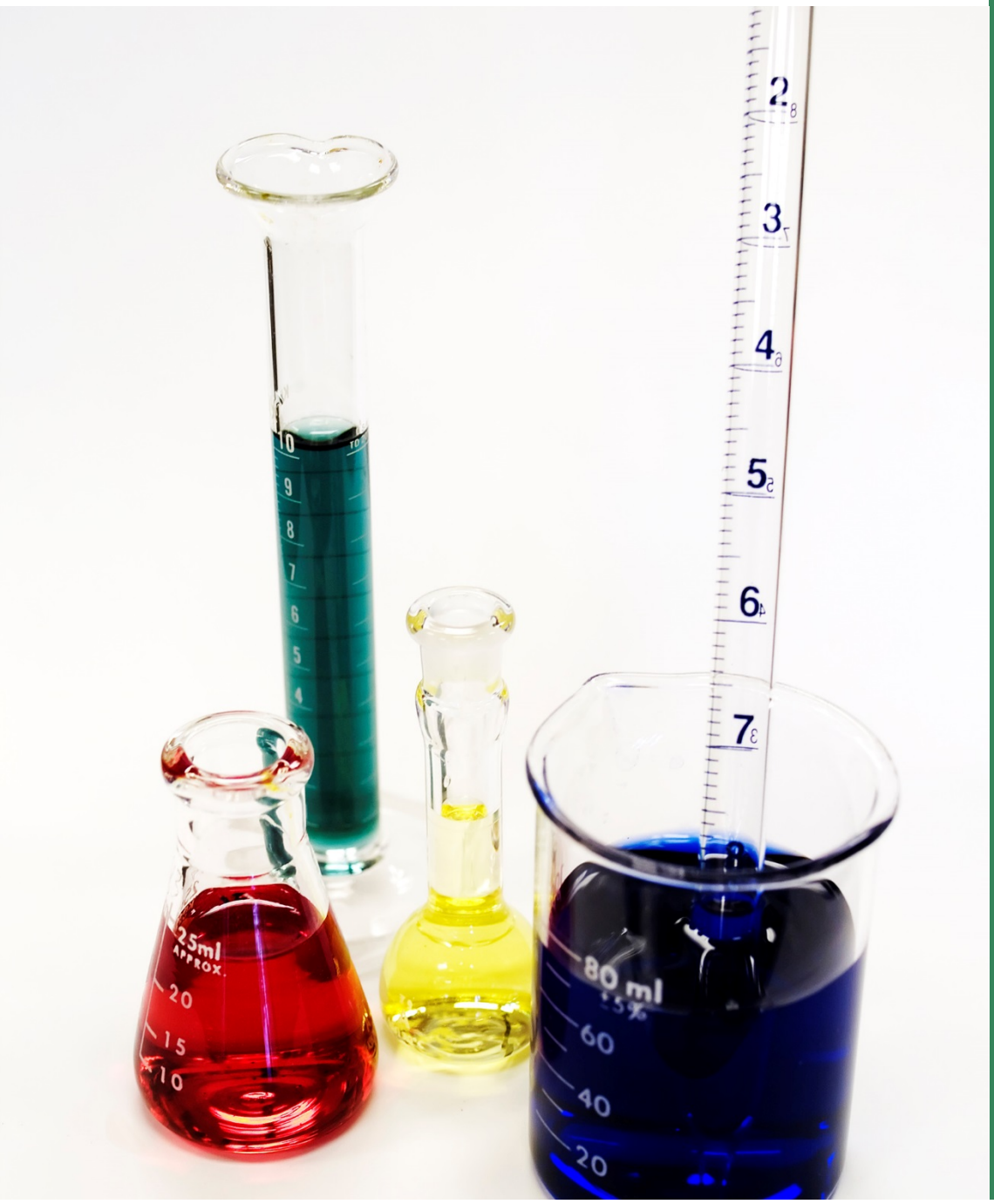

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Summary

With a few exceptions, the regulations that govern chemicals in the UK originate from the European Union (EU). EU regulations, unlike directives, apply directly to UK law and statutory instruments are used to assign the appropriate authority to enforce them. There are, however, regulations such as the *Control of Substances Hazardous to Health (COSHH) Regulations*, which bring EU directives into UK law and others such as the *Control of Pesticides Regulations* that are UK in origin.

The *Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation* is concerned with the registration of chemicals (referred to as substances) and their authorisation for placement on the European Market. In order for this to occur the hazards posed by the chemicals and the systems that can be put in place to prevent them must be stated.

The *Classification, Labelling and Packaging (CLP) Regulation* is in place to ensure that the hazards posed by chemicals are effectively communicated to the users. A part of this is standardising the symbols and warning that are associated with hazards. This manifests itself in the EU's adoption of the globally harmonised system (GHS), which is published by the UN.

The *Control of Substances Hazardous to Health (COSHH) Regulations* place duties on employers to prevent or reduce the exposure of people to substances that are hazardous to health. These include best practices, safety equipment and first aid procedures.

The *Cosmetic Products (CP) Regulation* is responsible for ensuring that chemicals used in cosmetics are safe for consumers. They require manufacturers to carry out safety assessments for their products, with specific safety assessments for products that are intended for external intimate hygiene and use on children under 3 years old.

The *Biocidal Products (BP) Regulation* governs the use of products that contain chemicals, which protect humans, animals, materials or articles against harmful organisms like pests or bacteria. They are in place to ensure these chemicals are safe for humans and the environment, whilst improving the functioning of the biocidal products market.

Whist these regulations are in place to ensure our safety, they are sometimes criticised for hindering industry. The use of chemicals regulations for pharmaceutical substrates, but medicines regulations for pharmaceuticals themselves has been cited as an example of this.

The fact that chemicals regulation is almost entirely EU in origin poses questions of what may happen in the event the UK leaves the EU. Modification to chemicals regulation would likely be low on the list of legislation to be changed, but may provide the Government with the means for any significant deregulation of the sector.

1. Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation

There are many pieces of legislation that govern the regulation of chemicals. However, the current briefing will focus on the main regulations, giving details on what they cover and which pieces of legislation they are underpinned by.

The *Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation* is concerned with the registration of chemicals (referred to as substances) and their authorisation for placement on the European Market.[1] In order for this to occur the hazards posed by the chemicals and the systems that can be put in place to prevent them must be stated.

REACH is a European Community (EC) Regulation and applies to the manufacture or import of chemicals in quantities greater than or equal to (≥) 1 tonne per year. REACH defines a chemical/substance as:

> […] chemical elements or compounds in the natural state or obtained by any manufacturing process.[2]

REACH affects most companies across the European Union (EU), with substances that exceed the 1 tonne per year threshold having to be registered with the European Chemicals Agency (ECHA). As a registrant they must supply information on the hazards the chemicals pose and how to manage the potential risks. Distributers have duties to communicate this information and users have duties to follow the guidance supplied. REACH can be subdivided into identification, registration, evaluation, authorisation and restriction.[3]

1.1 Identification

The accurate identification of a substance is essential in ensuring both the correct test data is available and that different registrants are able to register jointly for the same substance. This will help ensure the sharing of information; enabling robust hazard and risk assessments and the quick evaluation of whether a substance is included in the authorisation list, the list of restrictions or has a harmonised classification and labelling.[4]

1 European Market means the market of the EU and EEA (EEA 130/2011) countries.
2 Tolley's Health and Safety at Work Handbook, 2016, section R25
3 'Understanding Reach', ECHA, Accessed: 14 July 2016
4 'Identification', ECHA, Accessed: 18 July 2016

1.2 Registration

Registration ensures that manufacturers and importers collect information on the properties of the substances they manufacture or import;[5] this is submitted to ECHA in the form of a registration dossier.[6]

Substances encompass isolated chemicals, mixtures of chemicals and those contained within articles. However, some substances regulated by other legislation are exempt from REACH.[7]

Data Sharing

There can only be one registration per substance, where more than one company places a substance on the market a joint registration must be made. This allows for the reduction in registration costs and the prevention of unnecessary animal testing.

A registration dossier must be compiled in order for a company to register a substance. As part of this, a technical dossier must be provided for substances placed on the EU market at quantities ≥1 tonne per year. This includes the properties, uses and classification of the substance as well as guidance on its safe use. For quantities ≥10 tonnes a chemical safety report is required. This contains the classification and hazardous effects of the substance and a chemical safety assessment, which includes a description of exposure scenarios.[8]

Sharing of data must occur before registration and assess if the substance has adverse effects on human health and the environment. Reliable test results or other scientifically justified evidence are used for this purpose. Data sharing can be undertaken via an inquiry or substance information exchange forums (SIEFs).[9]

Inquiry and SIEFs

An inquiry involves checking with ECHA to see whether a substance has already been registered. It is used for new substances and phase in substances that were not pre-registered. Phase in substances were available on the EU market prior to REACH and are thus subject to a special transitional regime. If phase in substances were pre-registered then SIEFs are used instead of the Inquiry service.

Inquiry allows companies who have previously registered or enquired about a substance to be put in contact and thus submit a joint application. An enquiry should also be submitted when a registration is in need of an update due a tonnage band increase.[10]

1.3 Evaluation

ECHA and Member States assess the registration dossiers and testing proposals to make sure they are of sufficient quality. Three main areas are evaluated:

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5 'Registration', ECHA, Accessed: 18 July 2016
6 'Registration dossier', Accessed: 10 August 2016
7 'Registration', ECHA, Accessed: 18 July 2016
8 Tolley's Health and Safety at Work Handbook, 2016, Section R25
9 'Data sharing', ECHA, Accessed: 18 July 2016
10 'Inquiry', ECHA, Accessed: 18 July 2016

- Examination of testing proposals submitted by registrants
- Compliance check of the dossiers submitted by registrants
- Substance evaluation

ECHA must also publish a report on the progress they have made over the previous year, providing recommendations to potential registrants to help improve future applications.[11]

1.4 Authorisation

The authorisation procedure is only used for controlling the risks of substances of very high concern (SVHCs) and progressively replacing them with suitable alternatives. SVHCs can be classified as:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction [(CMR)] […]
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) […]
- Substances identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause an equivalent level of concern as with CMR or PBT/vPvB substances[12]

Member States or ECHA, at the request of the European Commission, can suggest a potential SVHC. The health and environment effects are then considered and if of sufficient concern the substance is added to the candidate list. Priority is usually given to substances that are PBT; vPvB; widespread in use and used in high volumes.

A draft recommendation is then compiled; included in this is a sunset date. This the date after which it is prohibited to place the substance on the EU market, unless an authorisation is granted or there is an applicable exemption. Anyone can comment on the draft within 3 months of its publication; following this the Member State Committee gives an opinion on the recommendation. ECHA then gives its recommendation based on these comments and the opinion of the Member State's Committee and passes this on to the European Commission for a final decision of what substances should make the final authorisation list.[13]

Authorisation can be granted where a manufacturer, importer or downstream user can demonstrate the adequate control of the risks associated with the substance or where the socio-economic benefits of its use outweigh the potential risks and no alternative is available.

Applications for authorisation must contain a chemical safety report, an analysis of possible alternatives and a plan to substitute for these if applicable. It can also contain a socio-economic analysis. The application will be reviewed by ECHA's Risk Assessment Committee (RAC) and the Committee for Socio-Economic Analysis (SEAC), who will provide their

11 'Evaluation', ECHA, Accessed: 18 July 2016
12 'Authorisation overview', ECHA, Accessed: 19 July 2016
13 'Recommendation for inclusion in the Authorisation List', ECHA, Accessed: 19 July 2016

opinion. There is then a two month window for the applicant to reply before the RAC and SEAC make their final opinion, which informs the European Commission's final decision.

Requirements are attached to a successful application and both authorisation holders and downstream users must comply with these. There is a time-limited review period and the holders must submit a report 18 months before it ends. Authorisations can be reviewed at any time, if there has been a change in the risks or socio-economic impacts or if new information is available on alternative substances.[14]

1.5 Restriction

REACH allows for the restriction of the supply of substances to the European Union and their subsequent use within it. This is undertaken when concerns arise over the risks of a substance to human health and the environment. A Member State or ECHA can commence the restriction procedure and the restrictions can apply to substances already covered by the Authorisation list.

The intention to restrict a substance is made public in advance of the preparation of the restriction proposal, with a dossier needing to be submitted within 12 months of this. The dossier contains background information, including the identity of the substance, details of the risks, any alternative substances and any potential environmental and human health benefits.

Once received, the dossier is published and made publicly available for consultation for 6 months. Nine months after publication RAC and SEAC must provide their opinions on the human health and environmental aspects of the dossier. Their opinions and the comments from the consultation are provided within 12 months of publication to the European Commission. Member States may also provide their opinions on the enforceability of the restrictions.

The European commission reviews the opinions and comments and provides a list of amendments to annex XVII of REACH, which the Member States and the European Parliament scrutinise prior to the final decision.[15]

1.6 Enforcement

The enforcement of the REACH Regulation falls within the remit of the Health and Safety Executive (HSE). However, there are other authorities who are also responsible:

> Under regulation 2, the enforcing authorities are: (a) the Department of the Environment (b) the Environment Agency (c) the Health and Safety Executive (d) the Health and Safety Executive for Northern Ireland (e) a local (consumer safety) authority (f) a local (health and safety) authority (g) the Scottish Environment Protection Agency and (h) the Secretary of State.[16]

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14 'Applications for Authorisation', ECHA, Accessed: 19 July 2016
15 'Restriction', ECHA, Accessed: 19 July 2016
16 'Explanatory note for *the REACH Enforcement Regulations 2008*', SI 2008/2852

1.7 Legislation

The REACH (Appointment of Competent Authorities) Regulations 2007 appointed the Secretary of State responsible for upholding the REACH Regulation (EC No. 1907/2006)[17], which established REACH and the ECHA[18]. There have been subsequent amendments to the EC regulation and thus resulting amendments to the REACH (Appointment of Competent Authorities) Regulations 2007:

- *The REACH Enforcement Regulations 2008* – Appoints authorities who are responsible for enforcing REACH.[19]
- *The REACH Enforcement (Amendment) Regulations 2013* – Amends the 2008 Regulation, making the Office of Rail Regulation a new enforcement authority, allowing the marketing of asbestos containing articles where the entity concerned has an exemption certificate and requiring the secretary of state for England to produce a report on the operation of the regulations.[20]
- *The REACH Enforcement (Amendment) Regulations 2014* – Allows an exemption for the use of dichloromethane paint strippers by approved professionals.[21]

17 *The REACH (Appointment of Competent Authorities) Regulations 2007*, SI 2007/1742
18 OJ L 396/1, 18 December 2006
19 *The REACH Enforcement Regulations 2008*, SI 2008/2852
20 *The REACH Enforcement (Amendment) Regulations 2013*, SI 2013/2919
21 *The REACH Enforcement (Amendment) Regulations 2014*, SI 2014/2882

2. Classification, Labelling and Packaging (CLP) Regulation

The *Classification, Labelling and Packaging (CLP) Regulation* is in place to ensure that the hazards posed by chemicals are effectively communicated to the users. A part of this is standardising the symbols and warnings that are associated with hazards. This manifests itself in the European Market's (EU's) adoption of the globally harmonised system (GHS), which is published by the United Nations (UN).

The standardised GHS labelling system means that workers and consumers know about the hazards associated with substances before handling them. For instance a substance classified as "acute toxicity category 1 (oral)", would include a hazard statement "fatal if swallowed", the word "Danger" and a pictogram showing a skull and crossbones.[22]

Those who place a hazardous substance on the European Market[23] must inform European Chemicals Agency (ECHA) of this within one month.[24]

2.1 Classification

Self-classification

Usually suppliers need to decide on the classification of a substance or mixture. This is termed self-classification and consists of 4 steps:

1. Collection of information.
2. Evaluation of information.
3. Review of the information with respect to the classification criteria.
4. The classification decision.[25]

However, the classifications of some substances and mixtures from previous legislation can be turned into CLP classifications if:

1. A substance was classified under the Dangerous Substance Directive or a mixture was classified under the Dangerous Preparations Directive before 1 December 2010 or 1 June 2015 respectively.
2. There is no additional data available for the proposed hazard class of the substance or mixture.[26]

It is essential for manufacturers, importers and downstream users to keep up to date with scientific and technical developments, in order to decide whether any of the substances or mixtures they place on the

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22 'Understanding CLP', ECHA, Accessed: 20 July 2016
23 European Market means the market of the EU and EEA (EEA 214/2014) countries.
24 'CLP's effect on companies', ECHA, Accessed: 20 July 2016
25 'CLP Classification', ECHA, Accessed: 20 July 2016
26 'CLP Classification', ECHA, Accessed: 20 July 2016

European Market should be re-evaluated in terms of their classification.[27]

Harmonised classification

Occasionally classification is undertaken at a European Community (EC) level. This is usually undertaken for the most hazardous substances, such as substances that are carcinogenic, mutagenic, respiratory sensitisers, toxic for reproduction, or active in biocidal/plant protection products.

Many substances need to be subject to harmonised classification and labelling, in order to protect human health and the environment. It is the suppliers of these substances who must apply this classification and labelling.

Member States and those who place substances on the European Market can ask for classification and labelling of substances to be harmonised, but not mixtures. All substances that were harmonised under previous legislation have been made so under the CLP Regulation.[28]

The intention to harmonise the classification of a substance must be made public and a dossier prepared. The dossier must contain an adequate justification for harmonising the substance's classification, as well as sufficient information of the hazards and uses of the substance.

A public consultation lasting 45 days is undertaken before the comments are passed onto member states or companies to provide their views. These are then passed onto ECHA's Risk Assessment Committee (RAC), who provide a scientifically informed opinion. The European Commission make the final decision, assisted by REACH's Regulatory Committee and various Member State representatives.[29]

REACH deals with the registration and authorisation of chemicals being placed on the European Market, which includes the supplying of information concerning their hazards. Whereas, CLP links these hazards to the substance or mixture through classification and communicates these hazards to the users via warnings and pictograms on the packaging.

2.2 Labelling

Suppliers must label a product in line with CLP Regulations when:

- A substance is classified as hazardous.
- A mixture contains one or more substances classified as hazardous above a certain threshold.[30]

The label needs to include certain content in a particular order and must include:

- The name, address and telephone number of the supplier

27 'CLP Classification', ECHA, Accessed: 20 July 2016
28 'CLP Classification', ECHA, Accessed: 20 July 2016
29 'Harmonised classification and labelling', ECHA, Accessed: 27 July 2016
30 'Labelling', ECHA, Accessed: 27 July 2016

- The nominal quantity of a substance or mixture in the packages made available to the general public (unless this quantity is specified elsewhere on the package)
- Product identifiers
- Where applicable, hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation.[31]

There are a few cases where special rules or exemptions apply:

- Some small (usually less than (<) 125 ml) or difficult to label products can be exempt from CLP Regulations.
- Any hazardous substance or mixture that is available to the general public must have packaging, which is child-resistant or displays suitable danger warnings.
- When transporting substances or mixtures classified as hazardous, a different set of rules are valid and these should be followed during labelling of the outer packaging.[32]

Alternative chemical name in mixtures

It is sometimes required that a company use an alternative chemical name, often in order to protect their intellectual property rights. However, this is only allowed in the following:

- When the substance does not have a Community workplace exposure limit [(WEL)].
- The use of the alternative name meets the need to provide enough information to take necessary health and safety precautions at the workplace and that the risks from handling the mixture can be controlled.
- The substance is classified only in certain hazard classes (see 1.4.1 (III), Annex I, CLP Regulation).[33]

Any alternative names approved by competent authorities prior to the 1st June 2015 can be used in the mixtures stated in the approval after this date.

Those who wish to use an alternative name for a substance will have to pay a fee, which is dependent on the company size and the number of mixtures in a request.[34]

2.3 The classification and labelling inventory

The classification and labelling inventory is a database consisting of all the classification and labelling information for the substances that have been registered or notified. The data are from companies' notification[35]

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31 'Labelling', ECHA, Accessed: 27 July 2016
32 'Labelling', ECHA, Accessed: 27 July 2016
33 'Alternative chemical name in mixtures', Accessed: 27 July 2016
34 'Alternative chemical name in mixtures', Accessed: 27 July 2016
35 'How to notify substances to the Classification and Labelling Inventory Practical Guide 7' section 3.3, ECHA, June 2012

or registration[36] dossiers and the database is maintained by ECHA. However, ECHA does not review or verify any of data.[37]

2.4 Enforcement

In the UK the CLP Regulation is enforced by the Health and Safety Executive (HSE) and by local Trading Standards Officers (TSOs).[38]

2.5 Legislation

The CLP Regulation (EC Regulation 1272/2008) is directly applicable to UK law. *The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015* repealed or amended legislation that were in place prior to the CLP Regulation, including *The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP Regulations)* and the associated European classification system and hazard warning symbols. The CLP Regulation use the globally harmonised system (GHS) published biannually (twice a year) by the UN Social and Economic Council.[39]

36 See Registration within the REACH section
37 'The Classification and Labelling Inventory', ECHA, Accessed: 27 July 2016
38 'Enforcement of the CLP Regulation', HSE, Accessed: 08 August 2016
39 *The Classification, Labelling and Packaging of Chemicals (Amendments to Secondary Legislation) Regulations 2015*, SI 2015/21

3. Control of Substances Hazardous to Health (COSHH) Regulations

The *Control of Substances Hazardous to Health (COSHH) Regulations* place duties on employers to prevent or reduce the exposure of people to substances that are hazardous to health. These include best practices, safety equipment and first aid procedures.

COSHH requires an employer to control substances hazardous to health.[40] The COSHH Regulations outline what a hazardous substance is:

> "hazard", in relation to a substance, means the intrinsic property of that substance which has the potential to cause harm to the health of a person […].[41]

Substances covered by the COSHH Regulations include substances that are very toxic, toxic, corrosive, harmful, irritant, listed in the CLP Regulation, biological agents, inhalable dust ≥ 10 milligrams per cubic metre (mg/m^3), respirable dust ≥ 4 mg/m^3 and those that have work place exposure limits (WELs).[42]

3.1 COSHH Framework

Many businesses use or create substances that can cause harm to their employees, contractors or other people. Therefore, they must prevent or reduce the exposure of people to such substances that are hazardous to health. This must be undertaken via the following COSHH Regulations (6-13):

- **Assessment of health risks (6)**: finding out what the health hazards are and deciding how to prevent harm to health (risk assessment).
- **Prevent or control of exposure (7)**: providing control measures to reduce harm to health.
- **Use of control measures (8)**: making sure they are used.
- **Maintenance, examination and testing of control measures (9)**: keeping all control measures in good working order.
- **Monitoring Exposure (10)**: monitoring of exposure, such as air sampling and use of WEL limits.
- **Health surveillance (11)**: providing health surveillance in appropriate cases.
- **Information, instruction and training (12)**: providing information, instruction and training for employees and others.

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40 'What is COSHH?', HSE, 8 July 2016
41 *Control of Substances Hazardous to Health Regulations 2002*, SI 2002/2677
42 Tolley's Health and Safety at Work Handbook, 2016, section H21

- **Accidents, incidents and emergencies (13)**: planning for emergencies.[43]

Assessment of Health Risks

Identifying what substances can cause harm and how these cause harm are the first steps to take in a COSHH risk assessment. These steps are followed by deciding on the measures that need to be taken in order to comply with COSHH regulations 7-13.[44]

A risk assessment must include information on activities that involve risks from hazardous substances, providing details on their form, such as powder, liquid, dust etc. It must also state which control measures are/should be in place and any improvements that can be implemented. On finishing the assessment, a record should be made (employers with < 5 employees are exempt from this) and the key findings communicated to the workforce.[45]

The recommendations must be implemented. This can be achieved through their allocation to competent individuals. Once implemented there must be a follow-up to ensure they are being followed and that no new risks have arisen. After these steps have been completed the assessment should be updated to show what has been carried out.[46]

Controlling or Preventing Exposure

The use of equipment and effective ways of working should be implemented to reduce or prevent exposure, including (in order of importance):

1. Eliminate the use of a harmful product or substance and use a safer one.
2. Use a safer form of the product, e.g. paste rather than powder.
3. Change the process to emit less of the substance.
4. Enclose the process so that the product does not escape.
5. Extract emissions of the substance near the source.
6. Have as few workers in harm's way as possible.
7. Provide personal protective equipment (PPE) such as gloves, coveralls and a respirator. PPE must fit the wearer.[47]

Use of Control Measures

Under the COSHH Regulations employers and employees must use control measures properly; these measures cover:

- correct use of local exhaust ventilation (LEV);
- compliance with specified systems of work;
- compliance with PPE requirements;

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43 'What is COSHH?', HSE, 8 July 2016
44 'A step by step guide to COSHH assessment', HSE, 2004
45 Tolley's Health and Safety at Work Handbook, 2016, section H21
46 Tolley's Health and Safety at Work Handbook, 2016, section H21
47 'Working with substances hazardous to health A brief guide to COSHH', HSE, October 2012

- storage and maintenance of PPE;
- compliance with requirements relating to eating and drinking [...];
- condition of washing and showering facilities and personal hygiene standards;
- whether defects are being reported by employees.[48]

Maintenance, examination and testing of control measures

Once procedures are in place to prevent exposure to hazardous substances an employer must maintain these. A person can be appointed to ensure these are maintained, they should:

- check that the process isn't emitting uncontrolled contaminants;
- check that the control equipment continues to work as it was designed;
- check that workers follow the right way of working.[49]

Any equipment that is used as part of the control measures needs maintaining; this includes LEV and PPE. The personnel who are responsible for this should be suitably qualified.[50]

Monitoring exposure and health surveillance

Monitoring and health surveillance usually entail air sampling, but can involve taking biological samples, such as hair or urine. WELs, which are set by the Health and Safety Executive (HSE), are often used in monitoring to determine whether the control measures are effective. Where there are diseases or conditions that are found to affect a workforce then the employees may need special health checks. Examples of relevant conditions and diseases include:

- Dusty or fume-laden air can cause lung diseases, eg in welders, quarry workers or woodworkers.
- Metalworking fluids can grow bacteria and fungi which cause dermatitis and asthma.
- Flowers, bulbs, fruit and vegetables can cause dermatitis.
- Wet working, eg catering and cleaning, can cause dermatitis.
- Prolonged contact with wet cement in construction can lead to chemical burns and/or dermatitis.
- Benzene in crude oil can cause leukaemia.[51]

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48 Tolley's Health and Safety at Work Handbook, 2016, section H21

49 'Working with substances hazardous to health A brief guide to COSHH', HSE, October 2012

50 'Working with substances hazardous to health A brief guide to COSHH', HSE, October 2012

51 'Working with substances hazardous to health A brief guide to COSHH', HSE, October 2012

Training

Training should be given to workers, so they know how to comply with the control measures decided:

- Employers should carry out practice drills for cleaning up spills safely and do this before any spillages happen.
- If workers need to use respirators they should receive training on their correct use, including how to fit them to their face.
- If workers need to use protective gloves they need to know how to put them on and take them off without contaminating their skin.[52]

Dealing with accidents, incidents and emergencies

An employer is responsible for putting in place procedures to provide adequate first aid in the event of an accident, incident or emergency. The COSHH assessment should include details of the types of hazards likely to arise during any accident, incident or emergency. There should also be details of the appropriate responses and remedial action to deal with the incident, accident or emergency, including the appropriate emergency services to contact, how to prevent further exposure to other workers and how to clean up the hazardous substances after the event.[53]

3.2 Enforcement

The Health and Safety at Work etc. Act 1974 makes the HSE and local authorities responsible for enforcing UK health and safety regulations.[54]

3.3 Legislation

The COSHH Regulations were first introduced in the *Control of Substances Hazardous to Health Regulations 1988*, but have since been updated, with the *Control of Substances Hazardous to Health Regulations 2002*; those currently in force.[55] The Regulations cover and are consistent with multiple European Community (EC) Directives.[56]

Other Regulations that are relevant to, but are not covered by, the *COSHH Regulations 2002*, include: the *Control of asbestos at Work Regulations 2012*, the *Control of Lead at Work Regulations 2002*, the *Control of Major accidents Hazard Regulations 1999*, the *Dangerous Substances and Explosive Atmosphere Regulations 2002* and *the Dangerous Substances (Notification and Marking of Sites) Regulations 1990*.[57]

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52 'Working with substances hazardous to health A brief guide to COSHH', HSE, October 2012
53 Tolley's Health and Safety at Work Handbook, 2016, section H21
54 The *Health and Safety at Work etc. Act 1974*, section 18
55 Tolley's Health and Safety at Work Handbook, 2016, section H21
56 'Explanatory note for the *Control of Substances Hazardous to Health Regulations 2002*', SI 2002/2677
57 Tolley's Health and Safety at Work Handbook, 2016, section H21

4. Cosmetic Products (CP) Regulation

The *Cosmetic Products (CP) Regulation* is responsible for ensuring that chemicals used in cosmetics are safe for consumers. The Regulation requires manufacturers to carry out safety assessments for their products, with specific safety assessments for products that are intended for external intimate hygiene and use on children under 3 years old. Those who place a cosmetic product onto the European Market[58] must notify the European Commission of this.[59]

The CP Regulation defines a cosmetic product:

'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;[60]

4.1 Obligations

Responsible Person

Cosmetic products that are placed on the European Market must have the name and address of a responsible person (RP) recorded on them. A RP must ensure that the product complies with all the requirements of the Regulation. The RP may be an individual (natural person) or a company (legal person) and they can be:

- the manufacturer or a brand owner marketing a cosmetic product under their name or trademark; or
- the importer who is importing a cosmetic product from outside of the Community Market; or
- a person or a company established within the Community mandated to act as the RP by the RP. In this situation, a mandate should exist and there should be acceptance from the designated person in writing.[61]

RP's must also have access to the product information file (PIF) of the cosmetic product they are responsible for.

Product Information File

Every product must have a PIF and these are open to inspection by the competent authority or authorities within each Member State. A PIF must cover the following:

- the product description;
- the Cosmetic Product Safety Report;

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58 European Market means the market of the EU and EEA (EEA 102/98) countries.
59 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
60 OJ L 342/59, 30 November 2009
61 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016

- details of methods of manufacture in accordance with [good manufacturing practice] GMP;
- proof of the effect claimed for the cosmetic product, where justified by the nature or the effect of the cosmetic product; and
- data on animal testing.[62]

Distributors

The CP Regulations define a distributor:

> 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market;[63]

The distributor must also ensure that:

- the name and address of the RP and the batch number and/or the list of ingredients are present;
- the 'off pack ingredient notice' accompanies the product;
- the product complies with the language requirements established by the relevant national law;
- the products have not exceeded their minimum durability date.[64]

Distributors may also be required, in certain circumstances, to notify products on the cosmetic product notification portal (CPNP).[65]

The Cosmetic Product Notification Portal

The CPNP is an online system that enables RPs and, in certain cases, distributors to deposit information about the products they place on the European market. The CPNP is made electronically available to:

- Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information)
- Poison Centres or similar bodies established by [European Union] EU countries (for the purposes of medical treatment).[66]

Safety Assessment

The CP Regulation requires a cosmetic product to be safe when used under normal and foreseeable conditions. Therefore, a safety assessment must be undertaken before a cosmetic product can be placed on the European Market. Specific safety assessments must be carried out for products that are intended for external intimate hygiene and use on children under 3 years old.[67] The safety assessor for any product must be suitably qualified:

> The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a

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62 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
63 OJ L 342/59, 30 November 2009
64 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
65 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
66 'Cosmetic Product Notification Portal', European Commission, Accessed: 29 July 16
67 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016

diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course recognised as equivalent by a Member State.[68]

The safety assessment should cover the following:

- the general toxicological profile of each ingredient used;
- the chemical structure of each ingredient;
- the level of exposure of each ingredient;
- the specific exposure characteristics of the areas on which the cosmetic product will be applied;
- the specific exposure characteristics of the class of individuals for whom the cosmetic product is intended;
- the manufacturing process; and
- the directions for safe use labelled on the product.[69]

Where the composition of the ingredients is unknown, such as where they are confidential, a safety assessment should be obtained from the ingredient supplier.[70]

Ingredients

Annexes II and III of the CP Regulation prohibit certain substances from being incorporated into cosmetic products and the Annexes IV, V and VI list the only preservatives, UV filters and colours that can be used. Otherwise a substance can be used if:

- the substance is not classified as a Carcinogenic, Mutagenic or Reprotoxic (CMR) substances by the Classification, Labelling and Packaging Regulation (CLP); and
- the manufacturer has the appropriate safety data to ensure the ingredient and the final product is safe.[71]

Good Manufacturing Practice

Manufacturers have a responsibility to prevent harm to downstream users by having good practices in place. The most common route for harm is through contamination by microorganisms. In order to comply with the CP Regulation a manufacturer must show they have abided with the International Standard Organisation (ISO) Guidelines on GMPs (ISO 22716) or demonstrate their practices are equivalent.[72]

Serious Undesirable Effects

Any serious undesirable effects (SUEs) and the number of undesirable effects (UEs) per product must be recorded in the PIF and reported by the RP and distributer to the competent authority of the Member State.[73]

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68 OJ L 342/59, 30 November 2009
69 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
70 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
71 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
72 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
73 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016

SUEs and UEs are defined in the CP Regulation:

> 'serious undesirable effect' means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death;
>
> 'undesirable effect' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;[74]

4.2 Enforcement

Each Member State must assign the enforcement of the cosmetic product regulation to a competent authority. In the UK this is undertaken by local Trading Standards Officers (TSOs). Primary Authority Partnerships (PAPs) can be set up when a company operates in more than one area of the UK.[75] These allow the advice of a TSO in one area (usually the area where the company's decisions are made) to be taken into account by other TSOs when carrying out an inspection or dealing with noncompliance.[76]

4.3 Legislation

The CP Regulation (EC Regulation 1223/2009) is the main legislation governing the placing of cosmetics on the European Market. The *Cosmetic Products Enforcement Regulations 2013* defined those responsible for the CP Regulation's enforcement.[77] The Cosmetic Products (Safety) Regulations 2008 have been mostly replaced by the new regulations, but some obligations are applicable if the product was placed on the European Market before 11 July 2013.[78] Cosmetics are also subject to the REACH Regulation, which aim to prevent damage to human health.[79]

74 OJ L 342/59, 30 November 2009
75 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
76 'Primary Authority Partnerships', PAR, 29 July 2016
77 'Supplying Cosmetic Products on the UK Market?', CPTA, March 2016
78 *The Cosmetic Products Enforcement Regulations 2013*, SI 2013/1478
79 'REACH and Cosmetics', Cosmetics Europe, Accessed: 28 July 2016

5. Biocidal Products (BP) Regulation

The *Biocidal Products (BP) Regulation* governs the use of products that contain chemicals, which protect humans, animals, materials or articles against harmful organisms like pests or bacteria. They are in place to ensure these chemicals are safe for humans and the environment, whilst improving the functioning of the biocidal products market.[80]

Examples of biocidal products include: human hygiene, veterinary hygiene, pest control and antifouling products, disinfectants, preservatives and taxidermist fluids.[81]

5.1 Approval

Biocidal products need to be approved before they can be placed on the European Market. However, there are exceptions if:

- the active substance within the product is under review it can be placed on the European Market pending the final decision and for up to 3 years after this;
- a new substance is under assessment it may be placed on the European Market where provisional authorisation is granted.[82]

The active substances are evaluated by a Member State's competent authority; this is the HSE in the UK. The results are forwarded to the European Chemical Association's (ECHA's) Biocidal Products Committee to form an opinion. The European Commission then use this opinion to make their final decision on the approval of the substance. The substance can be approved for up to 10 years, after which it requires renewal.

Exclusions

Generally any substance that meets the following criteria is not approved:

- carcinogens, mutagens and reprotoxic substances categories 1A or 1B according to the CLP Regulation
- endocrine disruptors
- persistent, bioaccumulative and toxic (PBT) substances
- very persistent and very bioaccumulative (vPvB) substances[83]

Substitutions

There are exceptions to the exclusions criteria where the substance is needed to protect public health and there is no other alternative. In this circumstance the substance is approved for a maximum of 5 years.

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80 'Understanding Biocidal Products Regulations', ECHA, Accessed: 29 July 2016
81 'Biocidal product types', HSE, Accessed: 9 August 2016
82 'Approval of active substances', ECHA, Accessed: 29 July 2016
83 'Approval of active substances', ECHA, Accessed: 29 July 2016

Substances can also be designated as candidates for substitution during the approval process; this means they may be suitable for replacement with less hazardous substances in the future. If this occurs, the substances are approved for a maximum of 7 years.[84]

5.2 Authorisation

All biocidal products need authorisation before being placed on the European Market.[85] However, there are different types of authorisation available depending on the circumstances.[86]

Union-Wide Authorisation

Union-wide authorisation should be used when companies wish to make their product available across large portions of or the entirety of the European Market. This type of authorisation must be given by the European Commission, as outlined above.[87]

National Authorisation and Mutual Recognition

National authorisation and mutual recognition should be used where a product is to be placed on the market of a single country or small number of Member States, respectively. In the case of the former, the authority of the single country is sufficient. In the case of the later, the product can be authorised in sequence or in parallel.

Authorising in sequence requires a company to get their product authorised in one country and then apply for recognition by other member states. However, authorising in parallel requires a company to apply for authorisation in one member state and simultaneously ask others to recognise the authorisation once it has been granted.[88]

Renewal of this type of authorisation can be undertaken for more than one of the company's products, making the procedure easier.[89]

Simplified Authorisation

Simplified authorisation can be used where biocidal products meet a special set of criteria, including when:

- all the active substances contained in the biocidal product appear in Annex I of the BPR [BP Regulation] and comply with the specified restrictions;
- the biocidal product does not contain any substance of concern;
- the biocidal product does not contain any nanomaterials;
- the biocidal product is sufficiently effective;
- the handling of the biocidal product and its intended use do not require personal protective equipment.[90]

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84 'Approval of active substances', ECHA, Accessed: 29 July 2016
85 European Market means the market of the EU and EEA (EEA 130/2011) countries.
86 'Authorisation', ECHA Accessed: 1 August 2016
87 'Union authorisation', ECHA Accessed: 1 August 2016
88 'National authorisation and mutual recognition', ECHA Accessed: 1 August 2016
89 'National authorisation and mutual recognition renewal', ECHA Accessed: 1 August 2016
90 'Simplified Authorisation', ECHA Accessed: 1 August 2016

For this type of authorisation an application is made to ECHA and the suitable authority of the Member State evaluates the application. If authorisation is given then the product can placed on the whole European Market, but each member state where the product is to be distributed must be informed 30 days prior to this.[91]

5.3 Data Sharing and Record Keeping

Those who have data on an active substance must share data with each other as well as with prospective applicants. This is to avoid unnecessary costs and animal testing. As an applicant you must enquire to ECHA concerning any previous testing that has been undertaken, in particular any testing on animals.[92]

In the UK data relating to the manufacturer and distributers, physical properties and the potential hazards of the active substance in the biocidal product must be submitted to the National Poisons Information Service (NPIS). The NPIS is a service provided by the Department of Health.[93]

Manufacturers should also make records and document the following:

- safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;
- records of the various manufacturing operations performed;
- results of internal quality controls;
- identification of production batches.

These should be supplied to the competent authorities on request.[94]

5.4 Enforcement

Enforcement of the BP Regulation is undertaken on a Member State level. TSOs are responsible for the enforcement of advertising and retail in the UK, whilst HSE are responsible for investigations relating to their use.[95]

5.5 Legislation

The BP Regulation (EU Regulation 528/2012) governs the placing of biocidal products on the European Market.[96] It is directly applicable to UK law, the *Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013* defined those responsible for enforcing it.[97]

CLP Regulation apply to biocidal products although there are additional criteria that must be followed.[98] The BP Regulation can apply to those

91 'Simplified Authorisation', ECHA Accessed: 1 August 2016
92 'Data Sharing', ECHA Accessed: 1 August 2016
93 'Record Keeping and Reporting', HSE, Accessed: 1 August 2016
94 'Record Keeping and Reporting', HSE, Accessed: 1 August 2016
95 'Enforcement of Biocidal Products', HSE, Accessed: 1 August 2016
96 'Biocidal Products Regulation', HSE, Accessed: 1 August 2016
97 'Enforcement of Biocidal Products', HSE, Accessed: 1 August 2016
98 'Packaging and Labelling for Biocidal Products', HSE, Accessed: 1 August 2016

substances covered by REACH, but some active substances in biocidal products are exempt from REACH Regulations.[99]

There is also UK legislation, the *Control of Pesticides Regulations 1986*, which covers non-agricultural pesticides that are not covered by the BP Regulation: such as wood preservatives, rodenticides and insect repellents.[100] These regulations implemented Part III of the Food and Environment Protection Act 1985 and were amended in 1997.[101] HSE and local TSOs are responsible for enforcing the regulations.[102]

99 OJ L 167, 22 May 2012
100 'Control of Pesticides Regulations', HSE, Accessed: 2 August 2016
101 'Explanatory note for the Control of Pesticides Regulations 1986', SI 1986/1510
102 'Control of Pesticides Regulations', HSE, Accessed: 2 August 2016

6. Regulatory Issues

6.1 Brexit

Pre-EU Legislation

The UK had legislation concerning the regulation of chemicals prior to joining the EU, including:

- The Agriculture (Poisonous Substances) Act 1952 – This was repealed in 1997 by the *Health and Safety (Repeals and Revocations) Regulations 1996*.[103]
- The Health and Safety at Work etc. Act 1974 - This is still the primary piece of UK Health and Safety Legislation, but has been amended many times since 1974 to make it consistent with EU law.[104] In section 6 it states that it is the duty of anyone who manufacturers, imports or supplies substances to ensure that the substance will be safe.[105]
- *The Control of Lead at Work Regulations 1980* – These were revoked and re-enacted with modifications as the *Control of Lead at Work Regulations 1998*, which gave effect to the provisions of the Council Directive 82/605/EEC.[106] The 1998 Regulations were later amended, with the *Control of Lead at Work Regulations 2002* those currently in force.[107]
- *The Asbestos (Licensing) Regulations 1983* – These amended in 1998 and revoked in 2012 by regulations implementing the Council Directive 2009/148/EC.[108]

However, it was not until after joining the EU that more specific legislation was made to control chemicals, such as the REACH, CLP and COSHH Regulations. A useful webpage detailing the history of health and safety legislation in the UK can be found via the Royal Society for the Prevention of Accidents (RoSPA) webpage.

Potential Implications of Brexit

If the UK no longer participated in the EU chemicals regulation systems the burdens applied to industry might be reduced, there might be more flexibility in testing the risks presented by some substances and a reduction in the administrative burden of registering these with the European Agencies. However, some form of safety testing would probably have to take its place. Any benefits would have to be balanced against the inconvenience both to local and international industry caused by a UK withdrawal from these established systems. It is worth considering that a substantial investment has been made by industry during the transition to the new harmonised European systems. Further changes, and in particular any reversal, might well prove unpopular. The

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103 'History of Occupational Safety and Health', RoSPA, Accessed: 2 August 2016
104 'The Health and Safety at Work etc. Act 1974', HSE, Accessed: 2 August 2016
105 The *Health and Safety at Work etc. Act 1974*, section 6
106 'Explanatory note for Control of Lead at Work Regulations 1998', SI 1998/543
107 'Explanatory note for Control of Lead at Work Regulations 2002', SI 2002/2676
108 'Asbestos (Licensing) Regulations 1983', Ai Solutions Ltd, Accessed: 2 August 2016

most realistic result of EU withdrawal would see the UK adopting similar positions to Norway, Iceland and other non-member States which have chosen to adopt EU REACH legislation independently.

Considering health and safety legislation more generally, it is the case that over the last quarter century much of this has originated in the form of EU Directives – Article 118A of the Treaty of Rome gives health and safety prominence in the objectives of the EU. These Directives have built on the pre-existing UK safety systems underpinned by the *Health and Safety at Work etc. Act 1974* and associated secondary legislation. Over the years there have been concerns over the potential for overzealous application of modernised health and safety law, be it the result of "gold-plating" when transposing the Directives into UK law or of misunderstandings as to what the law actually requires. These concerns prompted the establishment of reviews by Lord Young of Graffham and Professor Ragnar Löfstedt and subsequent reforms by the Coalition Government.[109] In his report, Löfstedt commented: "Many of the requirements that originate from the EU would probably exist anyway, and many are contributing to improved health and safety outcomes. There is evidence, however, that a minority impose unnecessary costs on business without obvious benefits."[110]

6.2 Pharmaceutical Substrates

The Chemical Business Association (CBA) were among those consulted when new chemicals legislation is being formulated, in order to avoid undermining the UK chemicals industries profitability and competiveness. The association speaks on behalf of the industry and helps it to implement new legislation when it is passed into law.[111]

Despite this and others input to policy making, some areas of chemicals regulation are still seen to hinder the industry. For example, the active substances found in pharmaceuticals are covered by the *Human Medicines Regulations 2012*, but the chemical substrates that are used to make these substances are covered by the REACH Regulation. This issue was raised by Steve Bates of the Bioindustry Association:

> [REACH] aims to protect from the risks posed by hazardous chemicals. While medicinal products and active pharmaceutical ingredients are exempt from REACH, other substrates … such as processing solvents used in the manufacture of [active pharmaceutical ingredients] are not exempt, so there is chemical regulation in one part of the field and medical regulation in another part of the field. One of the solvents used for stopping viruses getting into product is being treated under the chemical rules rather than the medicine rules, and we think it would be sensible for them to be treated entirely under the medicine rules.[112]

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109 DWP, 2010 to 2015 government policy: health and safety reform, 8 May 2015
110 DWP, Reclaiming health and safety for all: An independent review of health and safety legislation, Cm 8219, November 2011
111 'Regulatory Issues', CBA, Accessed: 2 August 2016
112 *EU regulation of the life sciences*, Science and Technology Committee, 7 June 2016 HC158.

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