Chemical Regulation in the United Kingdom Blends Country-Specific Rules with European Union Directives

Industrial regulations focus on all aspects of the chemical manufacturing and distribution process, ranging from labeling and packaging, to transport and accident prevention and mitigation. Employees are also protected from dangerous substances in the work environment. As European Union directives are transitioned into effect, they frequently overlap with national laws, creating a complex regulatory environment. For example, under the European Regulation on Classification Labelling, and Packaging of Substances and Mixtures (CLP), there are two timelines for regulating substances and preparations. Each describes how portions of CLP and the Chemicals (Hazardous Information and Packaging for Supply) Regulations must be simultaneously enforced for a certain period of time.

Agricultural regulation focuses primarily on pesticide manufacture and usage. United Kingdom-specific regulations will eventually be superseded by European Union directives related to the registration of pesticides and growth regulating products, as well as related to the sustainable use of pesticides. In contrast, consumer-focused regulation relates to biocides and domestic laundry cleaning products. Impending restrictions on pesticides and biocides are generating concern about the development of resistant pests, molds, and fungi. The EU Directive on the Sustainable Use of Pesticides will not be implemented in the United Kingdom until November 25, 2011. Government officials launched a consultation on February 9, 2010, during which industry experts have weighed in with their views about the Directive’s potential impact.

Watch List

- The Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 will gradually be replaced by the European Regulation on Classification Labelling, and Packaging of Substances and Mixtures (CLP).
- When the transition to CLP is complete on June 1, 2015, the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 will be fully repealed.
- Until all existing European Community plant protection products are reviewed and added to the Plant Protection Products Regulations “positive list,” the Control of Pesticides Regulations 1986 will continue to be enforced in the United Kingdom.
- Small and medium sized companies should consider using the COSHH Essentials tool to comply with the Control of Substances Hazardous to Health regulations.

Executive Summary

In the United Kingdom, chemical regulations are enforced primarily by two agencies: The Health and Safety Executive (HSE) and the Department of the Environment, Food and Rural Affairs (Defra). The regulatory landscape is a mix of national laws, regulations designed to support European Union directives, and European Union directives that do not need translation into nation-specific regulations.
Industrial Chemical Legislation & Regulation

Registration, Evaluation, Authorisation & Restriction of Chemicals (REACH)

REACH is a European Union (EU) regulation that came into force on June 1, 2007. It applies to chemicals that are manufactured or imported into the European Union in quantities of one ton or more per year. It includes individual chemicals on their own, in preparations, or in articles. The regulation excludes, however, radioactive substances, substances under customs supervision, the transport of chemicals, non-isolated intermediates, waste, and some low-hazard substances that are naturally occurring.

Under REACH, chemical manufacturers and importers must register substances with the Central European Chemicals Agency (ECHA). Registration packages include a standard set of data on each chemical, however the amount of required data is proportionate to the amount of chemical that is manufactured or supplied. The registration process for existing chemicals will occur in three phases that are distributed over an 11 year period. In the event that a manufacturer or importer does not register their chemicals, they will no longer be able to legally manufacture or supply them.

Within the United Kingdom, the government has developed the REACH Enforcement Regulations 2008. Individuals who breach a REACH provision can be tried summarily or on indictment. The same potential maximum penalty applies for each provision. Following a summary conviction, an individual may pay a fine of up to £5000 and/or up to three months imprisonment. Following conviction on indictment, an individual may pay an unlimited fine and/or up to two years in prison. The regulations also cover many other criminal offenses, such as obstruction of inspectors, providing false statements, failing to comply with enforcement, and others.

Chemicals (Hazard Information & Packaging for Supply) Regulations 2009 (CHIP)

The CHIP regulations came into force on April 6, 2009. These regulations apply to suppliers of dangerous chemicals. The objective of CHIP is to protect both people and the environment from dangerous chemicals by requiring suppliers to provide information about their risks and to package them safely. There are three ways that suppliers are required to comply with the regulations. First, they must identify the hazards associated with a chemical. This process is called classification. Second, they are required to provide information about the hazards, typically through labeling on the package. Third, suppliers must package chemicals in a safe way.

CHIP will gradually be replaced by the European Regulation on Classification, Labelling, and Packaging of Substances and Mixtures. This regulation is also referred to as the CLP Regulation. Safety data sheets (SDS) are no longer part of the CHIP regulations. However, they still must be provided to people who use chemicals in a professional capacity. During the transition period between CHIP and CLP, chemical suppliers must understand what classification and labeling information should or may be included in an SDS.

European Regulation on Classification, Labelling, & Packaging of Substances and Mixtures (CLP)

The European Regulation on Classification, Labelling, and Packaging of Substances and Mixtures (CLP) entered legal effect on January 20, 2009, subject to a long transitional period. Because the regulation is “direct-acting,” EU member states do
not need to transpose the regulation into national laws. The provisions will be phased in over a period of seven and a half years, up to June 1, 2015. When CLP is fully implemented in 2015, the United Kingdom’s CHIP regulations will be fully repealed.

Under CLP, there are two different sets of timelines for regulating substances and preparations/mixtures. The table below provides additional information:

### Timelines for Substances

<table>
<thead>
<tr>
<th>Timeline</th>
<th>Requirements</th>
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<tr>
<td>January 20, 2009 through December 1, 2010</td>
<td>Suppliers must classify substances according to CHIP. They may continue to label and package according to Regulations 6 to 11 of CHIP. As an alternative, suppliers may choose to classify, label, and package substances according to CLP. In this case, they must continue to classify under Regulation 4 of CHIP, but the CHIP labeling and packaging requirements (Regulations 6 to 11) no longer apply.</td>
</tr>
<tr>
<td>December 1, 2010 to June 1, 2015</td>
<td>Suppliers must classify substances according to both CHIP and CLP requirements. Labeling and packaging must conform to CLP regulations.</td>
</tr>
<tr>
<td>June 1, 2015 onward</td>
<td>Suppliers must conform to CLP for classification, labeling, and packaging.</td>
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### Timelines for Preparations (Mixtures)

<table>
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<th>Requirements</th>
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<tbody>
<tr>
<td>January 20, 2009 to June 1, 2015</td>
<td>Suppliers must classify preparations according to CHIP and may continue to label and package them according to Regulations 6 to 11 of CHIP. As an alternative, suppliers may choose to classify, label, and package preparations according to CLP. In this case, they must continue to classify under Regulation 4 of CHIP, but the CHIP labeling and packaging requirements (Regulations 6 to 11) no longer apply.</td>
</tr>
<tr>
<td>June 1, 2015 onward</td>
<td>Suppliers must conform to CLP for classification, labeling, and packaging.</td>
</tr>
</tbody>
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dangerous substances which are identified in the regulations are kept or used. The objective of the regulation is to prevent and mitigate the effects of major accidentsthat involved dangerous substances like chlorines, liquefied petroleum, explosives, and arsenic pentoxide.

The 2005 amendments broadened the scope of COMAH by adding new named substances; changing existing named substances and generic categories of substances; revising qualifying quantities; changing the aggregation rule where several dangerous substances may be present; and broadening the scope at mines, quarries, boreholes, and landfills.

COMAH distinguishes between requirements for “lower tier sites” (sites that hold smaller amounts of dangerous substances) and “top tier sites” (sites that hold larger amounts of dangerous substances). Lower tier site operators must provide basic details about the site to the government. They must also prepare a document called a major accident prevention policy (MAPP). This plan outlines the operator’s policy for preventing major accidents.

Top tier site operators are required to create safety reports. These documents must include information that lower tier operators include in their MAPPs. Safety reports demonstrate that all measures necessary for the prevention and mitigation of major accidents have been taken. Safety reports include methods for identifying major accidents, measures to prevent and mitigate major accidents, and information on the safety precautions built into the plant and equipment when it was designed and constructed. Top tier operators must also create and test an on-site emergency plan and provide information to the public about site operations.

**Control of Substances Hazardous to Health (COSHH)**

The Control of Substances Hazardous to Health regulation requires employers in the United Kingdom to control substances that could endanger employees’ health. It covers chemicals, products containing chemicals, fumes, dusts, vapors, mists, and gases, and biological agents. It also applies to asphyxiating gases, germs that cause diseases, and germs in laboratories.

Under COSHH, employers are required to control exposure to substance through site and process specific measures. If exposure cannot be prevented, then employers must attempt to control the substances adequately by applying the principles of good control practices.

**Prior Informed Consent Regulation (PIC)**

European Union Regulation (EC) 689/2008 is also referred to as the Prior Informed Consent (PIC) Regulation. In 1999, the United Kingdom signed the Rotterdam Convention on the Prior Informed Consent. This agreement allowed signatories to monitor and control the international trade of certain dangerous chemicals. The EU Regulations incorporate the provisions of the Rotterdam Convention. The objective of the regulation is to share information on dangerous chemicals, including their storage, transport, use, and safe disposal. It applies to all European Union based companies involved in the export or import of chemicals or articles containing chemicals and has tiered requirements for exporters.

The United Kingdom’s Export and Import of Dangerous Chemicals Regulations 2008 No 2108 establishes the Health and Safety Executive as the Designated National Authority for the country. In this role, HSE is responsible for the administrative functions related to PIC. It also controls imports and exports of covered chemicals.

**Carriage of Dangerous Goods & Use of Transportable Pressure Equipment Regulations 2009**

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 came into force on July 1, 2009. Enforcement
focuses on public safety-related requirements, such as integrity of packages and tanks, equipment such as fire extinguishers, insecure loads, driver training, vehicle signage, and package labeling.

**Agricultural Chemical Legislation & Regulation**

**The Control of Pesticides Regulations 1986 (COPR)**

The Control of Pesticides Regulations 1986 were created under the Food and Environment Protection Act 1985 (FEPA). These regulations identify which pesticides are subject to government control and define the approvals that are required before any pesticide may be sold, stored, supplied, used, or advertised. It applies to manufacturers, retailers, and users of pesticides, including homeowners and home gardeners.

**The Plant Protection Products Regulations (PPPR)**

The Plant Protection Products Regulations are more recent than COPR. PPPR implements European Directive 91/414/EEC, which regulates plant protection products including agricultural pesticides and growth regulators. The goal of the EU Directive is to harmonize the registration of plant protection products throughout EU member states. PPPR is based on a two tier registration system. Active ingredients are assessed at the European Union Community level for inclusion on a “positive list” and products are subsequently registered by Member States.

Until all existing European Community active ingredients are reviewed and added to the positive list, COPR will continue to be enforced in the United Kingdom. PPPR applies to new active ingredients that are entering the United Kingdom market and existing European Community reviewed ingredients that are on the positive list.

**The EU Directive on the Sustainable Use of Pesticides**

The EU Directive on the Sustainable Use of Pesticides is intended to provide a framework for promoting good and best practices related to the storage, usage, and disposal of pesticides. Under the Directive, member states are required to develop national action plans to support the Directive’s goals. The United Kingdom must implement the Directive by November 25, 2011. In anticipation of this event, government ministers launched a consultation on February 9, 2010 to gather input.

**Consumer Chemical Legislation & Regulation**

**The Biocidal Products Directive (BPD) & Biocidal Products Regulation (BPR)**

The Biocidal Products Directive (BPD) is a European Union Directive. Each member state is responsible for implementing it through national legislation. In the United Kingdom, the Biocidal Products Regulation 2001 has been implemented to accomplish this goal. A biocidal product can be used to control insects, bacteria, molds, and fungus. However, the biocide product category does not include weed killers or chemicals that protect plants from pests. BPD covers four main categories, which contain 23 different product types. The four groups include: Disinfectants for home and industrial use; preservatives for manufactured and natural products; pest control products; and other biocidal products such as vertebrate control and specialized products.

The Biocidal Products Directive provided a ten year period to transition from existing regulatory systems to the new system. However, it became evident that this time period was insufficient. On June 12, 2009, the EU Commission adopted and released a draft regulation proposal for the revision of the BPD. This will be subjected to the EU comitology procedure before it is voted on and finalized. The revised version of BPD
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is currently scheduled to enter force as of January 1, 2013.

**Detergents Regulations 2010 SI 740**

The Detergents Regulations 2010 SI 740 is legislation in the United Kingdom that places a ban on inorganic phosphates in domestic laundry cleaning products (DLCPs). Beginning on January 1, 2015, it will be illegal for companies to market a DLCP that contains more than 0.4% of its weight in inorganic phosphates. The implementation date for the regulation was delayed in order to give the detergents industry sufficient time to switch to compliant ingredients and to change marketing and packaging.

**Applications to Business Strategy/Success**

**Industrial Sector**

**European Regulation on Classification, Labelling, & Packaging of Substances & Mixtures (CLP)**

The CLP regulation has three key implications for chemical suppliers and users in the United Kingdom. First, new scientific criteria will be used to determine the hazardous properties of chemicals. Second, existing hazard symbols used on packaging will be redesigned. Lastly, the existing risk and safety phrases used on labels will be replaced by new harmonized warning and precautionary statements. At this time, government agencies in the United Kingdom do not plan to provide guidance on CLP. Instead, chemical suppliers should use the Central European Chemicals Agency (ECHA) guidance. The regulation does require each member state to establish a national Helpdesk to assist chemical suppliers.

**Biocidal Products Directive & Regulation**

The Biocidal Products Directive and Regulation could have a negative impact on manufacturers of paints and coatings. Manufacturers will be required to discontinue production of non-compliant products. In addition, retailers are legally bound to ensure that existing stocks which do not meet the legal requirements are removed from sale. Many retailers will ask suppliers to provide confirmation that non-compliant products will be withdrawn in time to shift remaining stock.

Chemical industry experts believe that the BPD and BPR may stifle innovation in the biocide sector. Since the introduction of BPD, few new products have been authorized. Chemical companies are trying to rationalize their product lines. As a result, innovation is more likely to come from new product combinations and delivery systems than from the development of new biocidal products. Some feel that incentives should be provided to produce new, innovative biocides. If this does not occur, the number of products available for purchase will become more limited as active substances are phased out. One danger is that organisms will develop resistance to existing disinfectants, especially those disinfectants that are critical to food safety.

Biocides that are not currently covered by EU pesticide regulations must be tested and registered under BPD. As manufacturers pass testing costs on to consumers, the cost of biocides is likely to increase. Manufacturers have indicated that testing could cost as much as £4 million (“Ensure you stay...,” 2009).

**Control of Major Accident Hazards Regulation**

To comply with COMAH, top tier operators must prepare safety reports. This can be a time consuming process, since the regulation focuses on the entire manufacturing operation, rather than isolated areas of manufacturing plants. Even though a significant time investment is needed, safety reports are more than a bureaucratic exercise. The process of creating safety reports helps operators make important decisions related to major accident safety.

Under COMAH, safety reports must be reviewed at least every five years. However, formal reviews of the
one of the industry sectors concerned about the Plant Protection Products Regulations is nursery operators who may lose access to commonly used insecticides and fungicides. This could be an issue, since the alternative products can lead to pest and fungus resistance problems. Farmers are also worried about the financial and practical impact of notifying residential neighbors in advance of spraying.

PPPR could have a significant impact on data collection. Pesticide producers, suppliers, and distributors may be required to keep records of products produced, stored, used, or sold for at least five years. Professional users must also keep records of applications for three years, including the product used, the time of the application, the amount of chemical applied, and the area and crop on which it was used.

The burden is on industry to demonstrate to the maximum extent possible that the scope of PPPR is already covered by existing practice. Where it is not, industry must offer solutions that are both workable and cost-effective.

EU Sustainable Use of Pesticides Directive

The EU Sustainable Use of Pesticides Directive will affect many aspects of the agricultural industry in the United Kingdom. To bring the country into compliance, rules on training and certification will need to be changed. Specific areas that need attention include providing non-agricultural pesticide training, requiring compulsory continuous training systems for operators and advisers, and building a mechanism for withdrawing certification as a penalty for failing to use reasonable precautions.

The Directive also requires member states to ensure that pesticide retailers have sufficient staff to give point of sale advice to amateur users. In the case of professional products, member states must ensure that they
are only sold to individuals who are certified to use them.

Equipment testing is another area of focus. Spray equipment must be tested initially after five years, and thereafter at three year intervals. Although the United Kingdom has an existing voluntary annual testing program, it may be augmented by mandatory testing.

**Acronyms**

- BPD: Biocidal Products Directive
- BPR: Biocidal Products Regulation
- CHIP: Chemicals (Hazard Information and Packaging for Supply) Regulations
- CLP: European Regulation on Classification, Labelling, and Packaging of Substances and Mixtures
- COMAH: Control of Major Accident Hazards Regulation
- COPR: Control of Pesticides Regulations
- COSHH: Control of Substances Hazardous to Health Regulation
- Defra: Department of the Environment, Food and Rural Affairs
- DLCP: Domestic Laundry Cleaning Product
- ECHA: Central European Chemicals Agency
- EU: European Union
- FEPA: Food and Environment Protection Act
- HSE: Health and Safety Executive
- MAPP: Major Accident Prevention Policy
- PIC: Prior Informed Consent Regulation
- PPPR: Plant Protection Products Regulations
- REACH: Registration, Evaluation, Authorisation & Restriction of Chemicals
- SDS: Safety Data Sheet

**Links to the Laws**

**Industrial Laws & Regulation**


Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (CHIP) (http://www.opsi.gov.uk/si/si2009/uksi_20090716_en_1)


Control of Major Accident Hazards Regulation 1999 (COMAH) (http://www.opsi.gov.uk/si/si1999/19990743.htm)

Control of Major Accident Hazards (Amendment) Regulations 2005 (http://www.opsi.gov.uk/si/si2005/20051088.htm)


The Export and Import of Dangerous Chemicals Regulations 2008 (http://www.opsi.gov.uk/si/si2008/uksi_20082108_en_1)

Carriage of Dangerous Goods and Use of Portable Pressure Equipment Regulations 2009 (http://www.opsi.gov.uk/si/si2009/uksi_20091348_en_1)

**Agricultural Laws & Regulation**


Consumer Laws & Regulations


References


Health and Safety Executive. (2010, January 3).