

An Roinn Fiontar, Trádála agus Fostaíochta Department of Enterprise, Trade and Employment

SCREENING

REGULATORY IMPACT ANALYSIS

OF THE

CHEMICALS BILL 2008

Department of Enterprise, Trade and Employment

March 2008

14

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1 POLICY CONTEXT, OBJECTIVES AND OPTIONS

1.1 Policy Context

1.1.1 Introduction

The aim of this Regulatory Impact Analysis [RIA] is to consider the costs and benefits that are likely to arise from a number of options considered regarding the enforcement of current and pending EU chemicals-related legislation. The EU legislation that it is envisaged will require enforcement includes:

- The REACH [Registration, Evaluation, Authorisation and Restriction of Chemicals]
 Regulation [EC No. 1907/2006], which entered into force on 1 June 2007;
- Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28
 January 2003 concerning the export and import of dangerous chemicals implements
 the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for
 certain hazardous chemicals and pesticides in international trade in the Community.;
- Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31
 March 2004 on detergents;
- The proposed GHS Regulation [Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006];
- The Seveso Directive on Control of Major Accident Hazards involving Dangerous Substances [<u>Directive 96/82/EC</u> as amended by <u>Directive 2003/15/EC</u>].

This RIA does not consider the impact of the EU legislation but is restricted to considering how best to enforce it and to ensure that compliance is maximised. The European Commission has already carried out impact assessments at EU level. At national level, Forfás engaged consultants to carry out a <u>national Impact Assessment on the REACH Regulation</u>. A separate screening RIA is being undertaken at national level on the proposed GHS Regulation to inform the negotiations as they continue.

1.1.2 Background

In the Programme for Government 2007, the Government commits to implement the new EU chemicals regime as a matter of priority in a way which does not impact on the competitiveness of our economy.

The REACH Regulation will, when it becomes operationally effective from 1 June 2008, require manufacturers and importers to gather comprehensive information on the properties of all substances produced or imported in quantities higher than one tonne per year and to submit the necessary information to demonstrate their safe use in a registration dossier to the <u>European Chemicals Agency</u>. Failure to register will mean the substance cannot be manufactured or imported into the EU market.¹

The Regulation on the import and export of dangerous chemicals implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade. The aim of the Rotterdam Convention is to promote shared responsibility in international trade of dangerous chemicals in order to protect human health and the environment.

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¹ Other legislation regulating chemicals (e.g. on cosmetics, pesticides, biocides) or related legislation (e.g. on health and safety of workers handling chemicals, product safety, construction products) not replaced by REACH will continue to apply. REACH has been designed not to overlap or conflict with the other chemical legislation.

GHS is an acronym for the Globally Harmonised System of classification, packaging and labelling of chemicals, the aim of which is to have one system worldwide. The objective of this proposal for an EU Regulation is to introduce this global system into the EU. It is set to replace the two existing European Classification, Packaging and Labelling Directives 67/548/EEC (substances) and 99/45/EC (preparations), with one Regulation covering both substances and mixtures. Adoption of the draft Regulation is expected before the end of 2008. Pending the adoption of the GHS Regulation, Directive 2006/121/EC of 18 December 2006 introduces technical amendments to Directive 67/548/EEC in order to adapt it to the REACH Regulation, and these technical amendments will be transposed into Irish law by statutory instrument.

The scope of the EU Detergents Regulation is to harmonise rules relating to the biodegradability of surfactants in detergents, restrictions or bans on surfactants on grounds of biodegradability, additional labelling of detergents, including fragrance allergens, and information that manufacturers must hold at the disposal of the Member States competent authorities and medical personnel.

<u>Directive 96/82/EC on the control of major accident hazards involving dangerous substances</u> (known as Seveso) as amended by <u>Directive 2003/105/EC</u> of the European Parliament and of the Council is transposed into Irish Law by <u>European Communities</u> (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2006 [S.I. No. 74 of 2006]. It is considered appropriate to provide for the enforcement of the Seveso Directives in the context of enforcement of other chemicals legislation.

This legislation will impact on a wide range of businesses in Ireland across many sectors. Those who manufacture substances, or who import them into Ireland from outside the EU will have obligations, as will those who produce or import articles. Additionally, downstream businesses that use and distribute chemicals, such as the ICT, printing and publishing, food and medical devices sectors will also have obligations.

At the end of 2006, the Irish manufacturing sector employed 221,000 people, which represents 11% of the total number in employment at that time. The chemical products and man-made fibres subsector employed 25,000 at end 2006. The manufacturing sector contributed 23.3% of total value added to the economy [compared to 1.7% for agriculture, 9.9% for construction and 63.4% for services]. Within manufacturing, chemical products and man-made fibres contributed 32.5% total value added, which represents an overall total value added of 7.5% to the Irish economy.²

1.1.3 Necessity of policy intervention

Public policy intervention is needed to meet the commitment in the Programme for Government [as outlined above] and to fulfil the obligations placed on Member States in the EU Regulations, which are directly applicable.

1.2 Objectives of the proposal

1.2.1 Ultimate Objective

The ultimate objective of the policy intervention is to support compliance with chemicals legislation by putting in place the administrative and enforcement measures required under current and pending EU chemicals legislation, and in line with the principles of Better Regulation.

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² Source: CSO Quarterly National Household Survey.

1.2.2 Immediate Objectives

The immediate objectives of the proposal are:

- To comply with the obligations that are placed on Member States in the European Regulations³;
- To provide a statutory basis for the national authorities, and their inspectors, that will
 enforce the legislation, and to provide for high levels of co-operation between
 national authorities as regards enforcement;
- To provide necessary measures to allow for cooperation and information exchange with other Member States;
- To minimise the administrative cost to industry of demonstrating compliance with the European legislation;
- To take account of policies regarding simplification, that legislation be made comprehensible to those who must comply with it; and
- To introduce a simple and coherent legal enforcement framework for the regulation of chemicals in Ireland that will not unduly impact on industry and will maintain or enhance national competitiveness.

1.3 Identification of options/choices

Option 1 - Baseline/ Do-nothing option

Making no policy intervention or change at a national level. This is not a viable option, since it will leave Ireland in breach of its EU obligations, but is useful to consider as a benchmark for comparison.

Option 2 - Consideration of policy options other than legislation

Putting in place alternatives to regulation, such as self-regulation.

Option 3 - Provide for enforcement measures under existing legislation

Making regulations under the European Communities Acts, which provides for indictable offences.

Making regulations under the Safety, Health and Welfare at Work Act, 2005, was considered. However the scope of that Act is insufficient to provide for the wider human health and environmental aspects of the EU legislation.

Option 4 - New Primary legislation

Introduction of new primary legislation, in the form of a framework Chemicals Bill. This is the preferred option.

2 IDENTIFICATION OF COSTS, BENEFITS & IMPACTS

2.1 Identify costs of each option

2.1.1 Introduction to cost analysis

When considering costs of the policy intervention, only administrative costs are considered, and not costs related to compliance with the EU Regulations, which are directly applicable.

The Health and Safety Authority [HSA] was designated by Government in 2005 as the interim national competent authority for enforcement of the REACH Regulation in Ireland. The Government also acknowledged the role of the Environmental Protection Agency [EPA]

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³ REACH becomes operationally effective on 1 June 2008 and enforcement will need to begin soon after that date.

on the environmental aspects of REACH. There are cost implications associated with the additional responsibilities for these two bodies.

There will also be roles for other national authorities. Much of the administrative work envisaged for these other bodies will be a continuation of current roles, particularly as regards Seveso and Import/Export, and should therefore not incur additional costs. Some administrative costs may be associated with REACH and GHS enforcement, for example as regards training staff to enforce these new pieces of legislation.

The likely costs of all options are summarised in Table 1.

Option 1 – No policy change

It is likely that the cost of Option 1, doing nothing, would be very high, for both industry and the State. The EU Regulations will have direct effect in all Member States and, to a certain extent, the market should work to encourage a level of compliance with them. For example, the REACH Regulation contains a "no data-no market" provision, which would mean it could be more difficult for a manufacturer to market his or her chemical if that chemical is not registered in accordance with the Regulation. Loss of market share as a result of being unable to market chemicals could also be a potential cost to industry. REACH also encourages increased communication up and down the supply chain, which should encourage a certain level of compliance.

If no policy intervention is made at a national level, there are a number of likely consequences. Firstly, national authorities will not have the required statutory basis to assist industry in complying with the Regulations or to enforce them. Secondly, the absence of proportionate penalties and sanctions would be more likely to lead to non-compliance, the cost of which would far outweigh the cost of compliance. Thirdly, by doing nothing, Ireland would be subject to legal action, and large open-ended penalties, from the European Commission for non-compliance with the Regulations.

Costs to industry would arise from loss of competitiveness compared to other EU Member States associated with Ireland not putting in place the necessary enforcement and administrative regime to assist industry compliance. Assuming non-compliance, high costs would also be incurred as regards human health and the environment.

Option 2 – Alternatives to regulation

The REACH Regulation will have the effect of switching the burden of proof for demonstrating the safety of chemicals from the national authorities to industry. This, along with the market effects of REACH discussed above under option 1, will mean that the REACH Regulation will be self-regulatory to a certain extent. The same will be true for the Import/Export Regulation – industry will need to ensure that chemicals are in compliance with these rules before the chemicals can be marketed. There is less potential for Seveso to be self-regulatory since industry needs to work closely with national authorities, on preparation and testing of emergency plans for example.

This option would incur similar potential high costs as outlined above for option 1, since this option would also incur penalties from the European Commission. In addition, even though the HSA has been designated interim national authority for REACH in Ireland by the Government in 2005, pursuing this option would not give the HSA, or other bodies, a statutory basis for enforcement.

Self-regulation would have additional cost implications for business, including the cost of setting up and managing the regime to check and demonstrate compliance. It is likely that, without the intervention and assistance of enforcement authorities, many companies, particularly SMEs, would not be able to comply.

Option 3 – Existing legislation

There is an opportunity cost associated with the possibility of not achieving the policy objective of increasing co-operation between national authorities.

There would be an opportunity cost of not achieving the objective of introducing a simple and coherent enforcement framework for chemicals.

It is assumed that any additional administrative costs to the State would be addressed in the context of annual budgetary allocations to the relevant Departments and Agencies.

The only compliance burden is the cost associated with resources devoted to facilitating inspections and compliance checks. These are already costs borne by industry in facilitating such inspections and checks under existing health and safety and environmental legislation, for example. The policy objective is to minimise the administrative cost to industry,

Option 4 – New primary legislation

It is assumed that any additional administrative costs to the State arising from the introduction of new primary legislation would be addressed in the context of annual budgetary allocations to the relevant Departments and Agencies.

The only compliance burden associated with the introduction of new primary legislation is the cost associated with resources devoted to facilitating inspections and compliance checks. These are already costs borne by industry in facilitating such inspections and checks under existing health and safety and environmental legislation, for example. The policy objective is to minimise the administrative cost to industry.

2.2 Identify the benefits of each option

Options 1 & 2

Potential benefits of each option are summarised in Table 2. The summary shows that options 1 and 2 (do-nothing or alternatives to regulation) could result in benefits to industry. Individual companies could, by not complying with the European Acts, gain a short-term advantage over EU companies that are in compliance. However, any financial benefits accrued would be short term and would likely be outweighed by loss of competitiveness arising from not having clear administrative structures in place to assist compliance and loss of business from other EU States that would demand/expect compliance.

Financial benefits to the State from these options would accrue from not having to commit resources to enforcement. However, any benefits would be quickly outweighed by sanctions from the European Commission and potential longer-term societal costs of non-compliance.

Option 3

Industry is already familiar with the current regulatory regime. The option of expanding this to provide for the enforcement of new EU Regulations could be seen as a benefit to industry. This benefit however may only be limited to larger industry, given the complexity of this option.

Option 4

The principal benefits arising from option 4, making new primary legislation, should be high levels of compliance, reduced administrative costs to business and to furthering the better

regulation agenda. It should also ensure increased co-operation between the various national authorities that will be involved in enforcement. Industry will benefit by having a clear regulatory framework in which to operate. Providing for increased co-operation between national authorities, and between national authorities and authorities in other Member States, and enforcing a number of different pieces of legislation under the one Bill, has the potential to minimise administrative costs and therefore to be of benefit to industry. National authorities, in the course of inspections, could check compliance with all of the pieces of legislation that are within the scope of the Bill at the same time, thereby saving industry time and money. Increased co-operation between national authorities and agencies, such as the HSA, the EPA, the Pesticide Control Service and the Revenue Commissioners (Customs), should also facilitate a greater level of information exchange and should minimise the need for individual businesses to supply the same information to a number of different bodies.

Assuming the Bill ensures a high level of industry compliance with the chemicals legislation to which it applies, the State should benefit in terms of the contribution of this legislation to future decreases in costs associated with public health and environmental remediation. There should also be a reputational benefit to the State resulting from introducing and maintaining an effective regulatory regime and from resultant high standards in the industry.

The inclusion in the Bill of framework provisions to make replacement regulations for the Seveso/control of major accident hazards regulations should result in a clearer enforcement framework, which, in turn, should result in increased compliance with the regulations and a consequent lower risk of major accidents occurring.

2.3 Impacts

a) Impacts on National Competitiveness

The Chemicals Bill will have no negative impact on national competitiveness. However, there should be a benefit to national competitiveness arising from the improved regulatory efficiency it aims to introduce.

b) Impacts on Socially Excluded or Vulnerable Groups

No impact is expected from any of the options.

c) Impacts on the Environment

Compliance with the new chemicals regime by industry should result in better management of the risks associated with the use of chemicals and therefore a positive longer term environmental impact.

d) Impacts on Consumers and Competition

A positive impact on consumers and competition can be expected since the Chemicals Bill contains provisions to ensure better information on chemicals for consumers.

e) North-South, East-West Relations

There should be benefits arising from co-operation and mutual assistance arrangements between the national authorities under the Bill and competent authorities in Northern Ireland and in the UK, thus having a positive impact on North/South and on East/West relations. The Health and Safety Authority has already taken part in joint awareness raising and training initiatives on REACH with the Health and Safety Executive.

f) Impacts on the Rights of Citizens

No impact is expected.

g) Compliance Burdens

The only compliance burden with this Bill is the cost associated with resources devoted to facilitating inspections and compliance checks. These are already costs borne by industry in facilitating such inspections and checks under existing health and safety and environmental legislation, for example. The policy objective is to minimise the administrative cost to industry.

2.4 Summary of costs, benefits and impacts of each option

Table 1 – Summary of costs of each policy option

| Costs | 1. Do-nothing option | 2. Alternatives to legislation | 3. Provide for enforcement under existing legislation | 4. New primary legislation |
|---|-------------------------|--------------------------------|---|-------------------------------|
| Costs to State | ++++ | ++++ | ++ | + |
| Costs to Industry | +++ | + | + | + |
| Environmental costs | +++ | +++ | ++ | 0 |
| Other Societal costs (e.g. public health) | +++ | +++ | ++ | 0 |

| Key: | |
|------|------------------|
| 0 | no cost |
| + | small cost |
| ++ | medium cost |
| +++ | high cost |
| ++++ | exhorbitant cost |

Table 2 – Summary of benefits of each policy option

| Benefits | 1. Do-nothing option | 2. Alternatives to legislation | 3. Provide for enforcement under existing legislation | New primary legislation |
|-------------------------|-------------------------|--------------------------------|---|---|
| Better Regulation | 0 | 0 | + | +++ |
| Benefits to Industry | + | + | 0 | ++ |
| Benefits to Environment | 0 | 0 | ++ | +++ |
| Public Health Benefits | 0 | 0 | ++ | +++ |
| Benefit to State | 0 | 0 | + | + |

| Key: 0 + ++ | no benefit small benefit medium benefit |
|--------------------|---|
| +++ | high benefit |

Table 3 – Summary of Impacts of each policy option

| Impacts | 1. Do-nothing option | 2. Alternatives to legislation | 3. Provide for enforcement under existing legislation | 4. New primary legislation |
|----------------------------------|-------------------------|--------------------------------|---|-------------------------------|
| National competitiveness | - | - | + | + |
| Socially excluded or vulnerable | 0 | 0 | 0 | 0 |
| Environment | - | - | 0 | + |
| Consumers and competition | - | - | 0 | + |
| North-South, East-West relations | 0 | 0 | 0 | + |
| Rights of citizens | 0 | 0 | 0 | + |
| Compliance burden | + | 0 | - | + |

Key:

means a negative impact
means a positive impact
means little or no impact

2.5 Conclusion & Preferred Option

In conclusion, the analysis of costs, benefits and impacts summarised above shows that the option that would incur the least cost and accrue the most benefit, and would also best meet the policy objectives, is Option 4, introduction of new primary legislation in the form of a Chemicals Bill. This will allow for maximum flexibility in compliance instruments and will allow for the appointment of the relevant national authorities. The Bill is framework and enables both the enforcement of EU Regulations which are directly applicable and the making of regulations to give effect to EU measures in this area which are in the form of Directives.

The Bill should minimise administrative costs to business since it provides for stronger cooperation between national authorities.

It also furthers the Better Regulation agenda by streamlining a number of pieces of existing chemicals legislation into one Act. Making the regulatory system for business more efficient is an important element in the agenda to improve the competitiveness of our economy⁴. More information on the Better Regulation aspect of the Bill is included in section 5 below.

3 CONSULTATION

3.1 Identification of Stakeholders

3.1.1 Government Departments and State Agencies

Consultation has been ongoing with relevant Departments and Agencies during the drafting of the Bill including:

The Health and Safety Authority;

⁴ Report of the Business Regulation Forum, March 2007

- The Department of Environment, Heritage and Local Government;
- The Department of Agriculture and Food and the Pesticide Control Service;
- The Department of Justice, Equality and Law Reform;
- The Department of Health and Children;
- The Environmental Protection Agency;
- Revenue/ Customs:
- National Poisons Information Centre.

3.1.2 Social Partners

3.1.3 Other Stakeholders

The social partners were consulted, and a wider public internet consultation was undertaken over four weeks from 19 October to 16 November 2007. The two responses which were received expressed views relating to the penalties envisaged on summary conviction, sought clarification on certain enforcement powers of inspectors, and on the confidentiality of information. The provisions of the Bill to a great extent already accommodate the views expressed.

4 ENFORCEMENT AND COMPLIANCE

4.1 National Authorities

The HSA was designated interim National Competent Authority for the administration and enforcement of REACH in Ireland by the Government in June 2005. The HSA has already commenced its information campaign to inform industry about obligations under REACH and GHS. A helpdesk has also been set up to answer industry queries, as well as a dedicated website www.reachright.ie.

The HSA has competent authority functions with regard to the current legislation governing the classification, packaging and labelling of chemicals and the export and import of dangerous chemicals. The HSA is also Central Competent Authority under Seveso legislation in Ireland. So, the Bill provides a statutory basis for the HSA to carry out its required functions under the legislation to which the Bill will apply.

The Bill also makes provision for appropriate roles to be taken on by other Government Departments and agencies. These include:

- the Minister for Agriculture, Fisheries and Food as regards pesticides under the REACH Regulation and the Rotterdam Regulation on the export and import of dangerous chemicals.
- the Revenue Commissioners for the purposes of Article 17 of the Rotterdam Regulation on the export and import of dangerous chemicals,
- the Environmental Protection Agency in respect of the prevention of environmental pollution under REACH, and
- the Minister for Health and Children for the purposes of receiving medical information under Article 9.3 of the Detergents Regulation.

4.2 Compliance instruments

The Bill provides for a flexible and proportionate range of instruments to encourage compliance. The approach taken in the Bill balances compliance approaches to enforcement and deterrence approaches.

Compliance approaches, emphasising measures which fall short of prosecution, include:

- serving a direction for an improvement plan. This will require the submission, within one month, of an improvement plan setting out how the company proposes to address the risk that is the subject of the plan:
- Enforcement notices may be served to deal with a failure to comply with the law. A
 Contravention Notice gives a period of time for the matter to be remedied, while a
 Prohibition Notice requires that the activity that has created the risk to human health
 or the environment is stopped immediately;
- Application to the High Court for an order prohibiting or restricting the activity.

Deterrence approaches, which are penal and use prosecutions in order to deter future breaches, include:

- provision for specification in regulations of fixed payment notices for summary offences;
- the prosecution of offences in either the District or Circuit Courts;
- publication of the names and addresses of those subjected to a prohibition notice, High Court order or a penalty following a court conviction.

5 BETTER REGULATION

5.1 EU Legislation to be Enforced/ Given Effect to under the Chemicals Bill

| Name | Full Title |
|---|---|
| REACH Regulation | Regulation EC No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| Import Export of Dangerous Chemicals [Rotterdam convention] | Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade in the Community. |
| Detergents Regulation | Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, as amended by Commission Regulation (EC) No. 907/2006 of 20 June 2006 |
| Seveso Directives on the Control of Major Accident Hazards Involving Dangerous Substances | <u>Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003</u> amending <u>Council Directive 96/82/EC</u> on the control of major accident hazards involving dangerous substances. |

The Chemicals Bill provides for the enforcement of the REACH Regulation, the Detergents Regulation and the Regulation on the Import and Export of Dangerous Chemicals. It also enables the making of Regulations to enforce the Seveso Directives on control of major accident hazards involving dangerous substances [the Seveso Directive is currently transposed in regulations made under the European Communities Act, see 5.2.7 below].

Legal advice indicates that it will not be possible to include the proposed GHS Regulation [(COM(2007) 355 final)] within the scope of the Bill until it is formally adopted at EU level. Adoption of the Regulation is expected before the end of 2008. It will then be possible to bring the GHS Regulation within the scope of the Bill by amending it via regulations made under section 3 of the European Communities Act 1972.

5.2 Current National Legislative Provisions

5.2.1 Introduction

Below is a list of the current national legislation enforcing European chemicals-related legislation. The legislation will be considered for repeal, as appropriate, when the Chemicals Bill has been enacted.

5.2.2 Marketing and use of dangerous substances

The Limitations Directive <u>76/769/EEC</u> restricts or prohibits the use and placing on the market of certain dangerous chemicals in order to protect the environment, workers, consumers and public health. It is transposed into Irish law by the following pieces of legislation:

- European Communities (Dangerous Substances and Preparations) (Marketing and Use) Regulations 2003: S.I No. 220 of 2003
- European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2003: <u>S.I. No. 503 of 2003</u>.
- European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2004: <u>S.I. No. 852 of 2004</u>.
- European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2006: S.I. No. 364 of 2006.
- European Communities (Dangerous Substances and Preparations) (Marketing and Use) (Amendment) Regulations 2007: S.I. No. 746 of 2007.

The Directive will be revoked and replaced as of 1st June 2009 by Title VIII and Annex XVII of the REACH Regulation (No. 1907/2006).

5.2.3 Classification, packaging and labelling of dangerous chemicals

The Classification, Packaging and Labelling Regulations are intended to protect human health and the environment from the harmful effects of dangerous chemicals. When adopted, the GHS Regulation will replace the currently existing EU Directives on classification and labelling, i.e. Directive 67/548/EEC and 1999/45/EC, after a transitional period. These Directives are currently transposed into Irish law as follows:

Substances [67/548/EEC]:

- European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations, 2003. S.I. No. 116 of 2003;
- S.I. No. 25 of 2006 [European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) Regulations 2006].

Preparations [1999/45/EC]:

- European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulations, S.I. No. 62 of 2004.
- European Communities (Classification, Packaging and Labelling of Dangerous Preparations) (Amendment) Regulations 2006 [S.I.No. 76 of 2007].

5.2.4 Classification, packaging and labelling of pesticides [1999/45/EC]:

• <u>S.I. No. 624/2001</u> European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations, 2001.

5.2.5 Import and Export of Dangerous Chemicals

Specific enforcement measures were not put in place in Ireland for The Import/ Export Regulation [EC No. 304/2003]. The EU Regulations which it replaced [(EEC) No. 2455/92 and (EC) No. 41/94] were enforced in Ireland by Regulations made under the European Communities Act. These are:

- for pesticides/ biocides <u>S.I. No. 135 of 1995</u> as amended by <u>S.I. No. 183 of 1995</u> and <u>S.I. No. 88 of 1998</u>; and
- for industrial chemicals S.I. No. 395 of 2002.

5.2.6 The Detergents Regulation

The Detergents Regulation is currently enforced in Ireland by European Communities (Detergents) Regulations 2005, S.I. No. 844 of 2005.

5.2.7 Control of Major Accident Hazards Involving Dangerous Substances [known as "Seveso"]

<u>Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003</u> amending <u>Council Directive 96/82/EC</u> on the control of major accident hazards involving dangerous substances is transposed into Irish law by:

 S.I. No. 74 of 2006 [European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2006]

5.3 Regulation making powers in the Chemicals Bill

The Bill is framework in nature and will provide for the making of regulations under it in a number or areas. Section 5 sets out the regulation making powers.

It is intended that the Seveso Regulations [5.2.7 above] will be remade under the Bill soon after it is enacted. This will enable the higher penalties to be applied and will further encourage compliance. It is not expected that costs will be any higher for Industry and the State than the costs of compliance with the current European Communities Seveso Regulations. In fact, by providing for enhanced cooperation between national authorities, costs may actually be streamlined by enforcing Seveso under the Bill.

It will also be possible to make regulations in respect of methods of serving notices, charging fees for services, and setting the levels of fixed payments ["on-the-spot" fines].

6 REVIEW

Each of the pieces of EU legislation which will be enforced require Member States to report on implementation to the European Commission at specified intervals. Section 5 of the Chemicals Bill provides for reporting to the Health and Safety Authority by other national authorities with information on the performance of functions under the Bill. The HSA will also report on the operation of the legislation in its Annual Report, taking account of the information from other national authorities. This will provide an opportunity to keep the operation of the Bill in practice under review.

A mechanism for ongoing feedback from industry could also be useful and could be considered. This could include customer feedback surveys via the HSA helpdesk for REACH or regular contact with IBEC, who will also provide a REACH helpdesk for industry.

Continuing consultation with Government Departments and Agencies will also be a useful tool in assessing the extent to which the Bill when enacted is achieving its objectives.

7 Sources of Further Information

Listed below are a number of websites that may be consulted for further information on the legislation that it is proposed enforce under the Bill:

- www.reachright.ie HSA's dedicated REACH and GHS website
- European Chemicals Agency [ECHA] http://ec.europa.eu/echa/home_en.html
- DG Enterprise & Industry REACH and GHS
 http://ec.europa.eu/enterprise/reach/ghs_en.htm
- Health and Safety Authority Seveso Frequently Asked Questions http://www.hsa.ie/eng/FAQs/Chemical/Seveso II.html
- Health and Safety Authority Export Import information http://www.hsa.ie/eng/Sectors/Chemicals/Export_Import
- Forfás Report: <u>An Impact Assessment of the Proposed EU Chemical Policy</u> (REACH) on Irish Industry

http://www.forfas.ie/publications/show/pub15.html