



An Roinn Fiontar, Trádála agus Nuálaíochta
Department of Enterprise, Trade and Innovation

REGULATORY IMPACT ANALYSIS

of the

DRAFT CHEMICALS AMENDMENT BILL 2010

Prepared by the Department of Enterprise, Trade and Innovation

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1. EXECUTIVE SUMMARY

Summary of Regulatory Impact Analysis (RIA)			
Department/Office: Enterprise, Trade and Innovation		Title of Legislation: Chemicals (Amendment) Bill 2010	
Stage: draft Memo with Text of Bill		Date: 25-06-10	
Related Publications : Screening Regulatory Impact Analysis of the Chemicals Bill 2008			
Available to view or download at: http://www.deti.ie			
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What policy options have been considered? Please summarise the costs, benefits and impacts relating to each of the option below and indicate whether a preferred option has been identified.			
1. Baseline/Do-Nothing Option			
2. Amend the Chemicals Act 2008			
3. Amend the Chemicals Act 2008 and the Safety, Health and Welfare at Work Act 2005			
Preferred Option: 3			
OPTIONS			
	COSTS	BENEFITS	IMPACTS
1	High costs for industry and State for non-compliance. Ireland would be subject to penalties from EU Commission.	None	Legal action against Ireland, which would have reputational damage. Lack of clarity in legislative provisions (and consequential fall of enforcement measures with associated costs).
2	None. Reduced administrative costs for business.	Allow Ireland to meet EU obligations. More streamlined enforcement framework for chemicals. High levels of compliance and reduced administrative costs to business.	No negative impacts. Positive longer term environmental impact. Benefit to national competitiveness from improved regulatory efficiency.
3	None. Reduced administrative costs for business.	Allow Ireland to meet EU obligations. More streamlined enforcement framework for chemicals. High levels of compliance and reduced administrative costs to business.	No negative impacts. Positive longer term environmental impact. Benefit to national competitiveness from improved regulatory efficiency.

2. POLICY CONTEXT AND OBJECTIVES

2.1 Existing Regulatory Framework

2.1.1 Chemicals Act 2008 (No. 13 of 2008)

The Chemicals Act 2008 came into effect on 15 July 2008. The purpose of the Act is to provide for the implementation and enforcement of the following EU Regulations:

- ❖ REACH Regulation (EC No. 1907/2006)
- ❖ Detergents Regulation (EC No. 648/2004)
- ❖ Rotterdam Regulation on the Import and Export of Dangerous Chemicals (EC No. 304/2003),

And, by regulations under the Act, to provide for the transposition of certain chemicals related directives, including the “Seveso” Directive on the Control of Major Accident Hazards Involving Dangerous Substances (Council Directive 96/82/EC, as amended by Directive 2003/105/EC).

2.1.2 Classification, Labelling and Packaging of Chemicals Legislation

The EU CLP Regulation (EC No. 1272/2008) on classification, labelling and packaging of substances and mixtures, introduced into EU law on 20 January 2009 the UN Globally Harmonised System, and amends and repeals [with effect from 1 June 2015] the existing body of EU law in this area (Council Directives 67/548/EEC and 1999/45/EC¹). It also amends the EU REACH Regulation.

2.1.3. Rotterdam Import/Export

The Chemicals Act 2008 provides for the implementation and enforcement of the EU Rotterdam Regulation (EC No. 304/2003), among others (see Section 2.1.1 above). The new Rotterdam Regulation (EC No. 689/2008) replaces this. This Regulation implements the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for certain hazardous chemicals and pesticides in international trade. It aims to promote shared responsibility and cooperative efforts in the international movement of hazardous chemicals in order to protect human health and the environment from potential harm, and to contribute to the environmentally sound use of hazardous chemicals.

2.1.4 Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005)

The Safety, Health and Welfare at Work Act 2005 is the regulatory framework aimed at the prevention of workplace accidents, illnesses and dangerous occurrences and at ensuring that workplace safety and health laws are observed.

¹ See Annex I for list of statutory instruments that transpose these Directives into Irish law.

2.2 Necessity of Policy Intervention

A number of amendments to the Chemicals Act 2008 and the Safety, Health and Welfare at Work Act 2005 are necessary in order to meet EU obligations and to take account of legal judgements.

1. Provide the Necessary Legal Mechanism to allow for the Enforcement of Various Directly Applicable EU Chemicals Regulations

This is required in order to meet our obligations as a Member State under the EU Regulations. The chemicals sector is an important economic sector for Ireland, and it is vital that the regulatory framework is up-to-date. By its nature, this sector includes within it highly dangerous chemicals which have the potential to cause serious and widespread damage to human and environmental health. The EU legal framework has been enhanced and will be subject to ongoing and frequent adaptations to technical progress that need to be reflected in the legislation. Intervention is needed to fulfil the obligations placed on Member States in the directly applicable EU Regulations.

The Chemicals Amendment Bill 2010 will bring enforcement measures for the EU Classification, Labelling and Packaging (CLP) Regulation (EC No. 1272/2008) and the Rotterdam Import/Export Regulation (EC No. 689/2008) within the enforcement framework of the Chemicals Act. It will also bring within the enforcement framework all adaptations to technical progress associated with the directly applicable EU Regulations.

2. Amendment to Section 14 (Directions for Improvement Plan) and to Section 15 (Contravention Notice).

The proposed amendments are aimed at making it clear that an improvement plan or a revised improvement plan must be considered to be adequate and must be implemented. These amendments are necessary in order to clarify the legislation on foot of a legal judgement.²

3. Amendments to the Safety, Health and Welfare at Work Act 2005.

Amendment of the Chemicals Act 2008 also provides the opportunity to make some technical amendments to the Safety, Health and Welfare at Work Act 2005 which is the fundamental piece of legislation governing occupational health and safety in Ireland. These are as follows

- Correction of an error in the transposition of Article 6 of Directive 91/383/EEC of 25 June 1991 (Supplementing the Measures to encourage improvements in the safety and health at work of Workers with a Fixed-duration Employment Relationship or a Temporary Employment Relationship);

² Mr Justice Hedigan's High Court Judgement of 7 October 2008 in the case stated "Cork County Council (Appellant) and the Health and Safety Authority (Respondents).

- It became necessary to consider the existing language in the Act around the Minister's obligations to consult prior to making regulations to see if it might require clarification. Having considered the relevant provisions, it is being recommended that the Act be amended to remove the legal obligation on the Minister to consult with the Health and Safety Authority (HSA) before making regulations in situations where the proposals do not emanate from the Authority; and
- Clarifying and strengthening certain provisions of the Act relating to Improvement Plans and revised Improvement Plans on foot of the judgement of Mr Justice Hedigan (7 October 2008) in a High Court case-stated involving the HSA and Cork County Council.

2.3 Objectives

2.3.1 Ultimate Objective

To comply with EU obligations through a streamlined legal enforcement framework for chemicals, that minimises the administrative cost to industry of demonstrating compliance with European Chemicals legislation and encourages co-operation between competent authorities in implementing the EU legislation.

2.3.2 Immediate Objectives

To comply with EU obligations in putting in place arrangements for competent authorities and an enforcement framework including offences and penalties. To clarify the legislation, informed by legal judgement, so that it is made comprehensible to those who must comply with it.

3. POLICY OPTIONS

Option 1 – Baseline/Do-nothing option

Making no policy intervention or change at national level.

Option 2 – Amend the Chemicals Act 2008

This option will provide the necessary legal mechanism to allow for the enforcement of various directly applicable EU Chemicals Regulations. Enforcement measures for the EU Classification, Labelling and Packaging (CLP) Regulation (EC No. 1272/2008) and the Rotterdam Import/Export Regulation (EC No. 689/2008) will be brought within the enforcement framework of the Chemicals Act. It will also bring within the enforcement framework all adaptations to technical progress associated with the directly applicable EU Regulations. Amendments to Sections 14 and 15 of the Act will clarify the text on foot of a legal judgement.

This option will give a solid legal base to national enforcement of directly applicable EU Regulations, will fulfil our obligations under the EU Regulations, will bring clarity to some enforcement provisions, and will further the Better Regulation agenda by further streamlining the legal enforcement framework for chemicals.

Option 3 – Amend the Chemicals Act 2008 and the Safety, Health and Welfare at Work Act 2005

This option will provide the necessary legal mechanism to allow for the enforcement of various directly applicable EU Chemicals Regulations. Enforcement measures for the EU Classification, Labelling and Packaging (CLP) Regulation (EC No. 1272/2008) and the Rotterdam Import/Export Regulation (EC No. 689/2008) will be brought within the enforcement framework of the Chemicals Act. It will also bring within the enforcement framework all adaptations to technical progress associated with the directly applicable EU Regulations. Amendments to Sections 14 and 15 of the Act will clarify the text on foot of a legal judgement.

This option will give a solid legal base to national enforcement of directly applicable EU Regulations, will fulfil our obligations under the EU Regulations, will bring clarity to some enforcement provisions, and will further the Better Regulation agenda by further streamlining the legal enforcement framework for chemicals.

Furthermore, it provides the opportunity to make technical amendments to the Safety, Health and Welfare at Work Act 2005, outlined at paragraph 2.2.3 above, namely,

- Correcting an error in the transposition of Article 6 of Directive 91/383/EEC of 25 June 1991
- Clarifying the situation around the Minister's obligations to consult in relation to the making of certain Regulations.
- Clarifying and strengthening certain provisions of the Act relating to Improvement Plans and revised Improvement Plans on foot of the judgement of Mr Justice Hedigan (7 October 2008) in a High Court case-stated involving the HSA and Cork County Council.

4. COSTS, BENEFITS AND IMPACTS OF EACH OPTION

4.1 Option 1 – Baseline/Do-nothing option

Doing nothing is not considered a viable option, as there must be appropriate sanction for non-compliance in this area. It is likely that the cost of this option would be very high for both industry and the State. The EU Regulations have direct affect in all Member States and non-compliance is not a legal option. It would leave Ireland in breach of its EU obligations to provide for appropriate sanction for non-compliance in this area. In addition, it would mean that the necessary changes identified on foot of legal judgements could not be made.

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 enforce the Regulations or to assist industry in complying with 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 EU Regulations.

If the amendments to Sections 14 and 15 of the Chemicals Act 2008 are not made, an enforcement measure could fall and there would be consequent enforcement costs and court costs. This equally applies in the case of the proposed amendments to Sections 65 and 66 of the Safety, Health and Welfare at Work Act 2005. A key issue here is that, if the Health and Safety Authority cannot use the enforcement instruments in question, it may have to move, more rapidly to more stringent enforcement measures.

4.2 Option 2 - Amend the Chemicals Act 2008

This option would allow us to meet our EU obligations and to clarify certain provisions of the Act on foot of the Hedigan legal judgement.

The Chemicals Act 2008 and the directly applicable EU Chemicals Regulations to be brought within the enforcement framework 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, have obligations as do 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 also have obligations.

Making the regulatory system for business more efficient is an important element in the agenda to improve the competitiveness of our economy. The principal benefits arising from this option should be high levels of compliance, reduced administrative costs to business and to furthering the better regulation agenda. Industry will benefit from having a clear regulatory framework in which to operate. Enforcing a number of different pieces of legislation under the Chemicals Act has the potential to minimise administrative costs and therefore to be of benefit to industry. National authorities, in the course of inspections, can check compliance with all of the pieces of legislation that are within the scope of the Chemicals Act at the same time, thereby saving industry time and money. The policy objective is to minimise the administrative cost to industry. It is assumed that any additional administrative costs to the State arising from the introduction of this legislation would be addressed in the context of annual budgetary allocations to the relevant Departments and Agencies.

There is no negative impact arising from the amendments proposed to Sections 14 and 15 of the Chemicals Act 2008. These amendments are required in order to clarify the legislative provisions. Clearer and more coherent legislation can reduce the need for prosecution.

4.3 Option 3 – Amend the Chemicals Act 2008 and the Safety, Health and Welfare at Work Act 2005

This option would allow us to meet our EU obligations and to clarify certain provisions of the Act on foot of a High Court judgement.

The Chemicals Act 2008 and the directly applicable EU Chemicals Regulations to be brought within the enforcement framework 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 have obligations as do 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 also have obligations.

Making the regulatory system for business more efficient is an important element in the agenda to improve the competitiveness of our economy. The principal benefits arising from this option should be high levels of compliance, reduced administrative costs to business and to furthering the better regulation agenda. Industry will benefit from having a clear regulatory framework in which to operate. Enforcing a number of different pieces of legislation under the Chemicals Act has the potential to minimise administrative costs and therefore to be of benefit to industry. National Authorities, in the course of inspections, can check compliance with all of the pieces of legislation, that are with the scope of the Chemicals Act, at the same time, thereby saving time and money. The policy objective is to minimise the administrative costs both to the Exchequer and industry. It is assumed that any additional administrative costs to the State, arising from the introduction of this legislation, would be addressed in the context of annual budgetary allocations to the relevant Departments and Agencies.

There is no negative impact arising from the amendments proposed to Sections 14 and 15 of the Chemicals Act 2008. These amendments are required in order to clarify the legislative provisions. Clearer and more coherent legislation can reduce the need for prosecution. This equally applies in the case of the proposed amendments to Sections 65 and 66 of the Safety, Health and Welfare at Work Act 2005.

In order to fully meet the requirements of Article 6 of Directive 91/383/EEC of 25 June 1991 (supplementing the measures to encourage improvements in the safety and health at work of Workers with a Fixed-duration Employment Relationship or a Temporary Employment Relationship), and to avoid legal action by the EU Commission for non transposition, it is necessary to make the appropriate amendment to the Safety, Health and Welfare at Work Act 2005.

Option 3 is the preferred Option.

4.4 Impacts

a) Impacts on National Competitiveness

The Chemicals (Amendment) Bill 2010 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.

c) Impacts on the Environment

Compliance with the 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

No impact is expected.

e) North-South, East-West Relations

No impact is expected.

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. National authorities, in the course of inspections can check compliance with all of the pieces of legislation that are within the scope of the Chemicals Act at the same time, thereby saving industry time and money. The policy objective is to minimise the administrative cost to industry.

5. CONSULTATION

A public consultation on the inclusion of these EU Regulations within the scope of the Chemicals Act, as part of the overall policy to streamline the regulatory framework for enforcement of certain EU chemicals legislation was undertaken in late 2007, the outcome of which was positive and remains relevant to this proposed amendment.

6. ENFORCEMENT and COMPLIANCE

The relevant provisions of the Chemicals Act 2008 and the Safety, Health and Welfare at Work Act 2005 will apply.

The following are to be designated as competent authorities for the purposes of the CLP Regulation – the Health and Safety Authority, the Minister for Agriculture, Fisheries and Food in respect of pesticides, and the Minister for Health and Children for the purposes only of Article 45 of that Regulation. This reflects the competent authority functions under the current legislation governing the classification, packaging and labelling. The national authorities for the purposes of the new Rotterdam Regulation will be

- the Health and Safety Authority,
- the Revenue Commissioners (for the purposes of Article 17 of the Regulation), and
- the Minister for Agriculture, Fisheries and Food in respect of pesticides (other than for the purposes of Article 17 of the Regulation).

The Bill provides a statutory basis for these authorities to carry out their respective functions under the legislation to which the Bill will apply. The enforcement provisions of the Chemicals Act 2008 will apply to the EU CLP Regulation and to the Rotterdam Import/Export Regulation.

7. REVIEW

The EU Regulations currently enforced under the Chemicals Act 2008 and the EU CLP Regulation and Rotterdam Import/Export Regulation to be included in the enforcement framework by the Chemicals (Amendment) Bill 2010 require Member States to report on implementation to the European Commission at specified intervals. Section 8 of the Chemicals Act 2008 provides for reporting to the Health and Safety Authority by other national authorities with information on the performance of functions under the Act. The HSA also reports on the operation of the legislation in its Annual Report, taking account of the information from other national authorities. This provides an opportunity to keep the operation of the legislation under review.

Continuing consultation with Government Departments and Agencies will also be a useful tool in assessing the extent to which the Chemicals Act 2008 (and its amending Bill) is achieving its objectives. An Interdepartmental/Agency Group chaired by the Department of Enterprise, Trade and Innovation meets regularly on implementation and policy issues arising in the context of the regulatory framework related to the Chemicals Act.

8. PUBLICATION

This RIA will be published on the Department of Enterprise, Trade and Innovation website (www.deti.ie).

Annex I

Transposition of Directives 67/548/EEC and 1999/45/EC into Irish law

Substances (67/548/EC)

- European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) Regulations 2003 (S.I. No. 116 of 2003).
- European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) Regulations 2006 (S.I. No. 25 of 2006).
- European Communities (Classification, Packaging, Labelling and Notification of Dangerous Substances) (Amendment) Regulations 2008 (S.I. No. 272 of 2008).

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 2007 (S.I. No. 76 of 2007).
- European Communities (Classification, Packaging and Labelling of Dangerous Preparations) (Amendment) Regulations 2008 (S.I. No. 271 of 2008).

Classification, Labelling and Packaging of Pesticides (1999/45/EC)

- European Communities (Classification, Packaging and Labelling of Plant Protection Products and Biocide Products) Regulations 2001.