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Draft

REGULATORY IMPACT ANALYSIS

Safety, Health and Welfare at Work (Biological Agents) Regulations 2010 (S.I. No. XXX of 2010)

&

Code of Practice for Safety, Health and Welfare at Work (Biological Agents) Regulations 2009 (S.I. No. XXX of 2010)

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Foreword

The Health and Safety Authority has prepared this Regulatory Impact Analysis (RIA) of the potential impact of the proposed draft of the Safety, Health and Welfare at Work (Biological Agents) Regulations 2010 and the Code of Practice for Safety, Health and Welfare at Work (Biological Agents) Regulations 2010.

The proposed Regulations will transpose fully into Irish legislation the requirements of Directive 2000/54/EC of the European Parliament and of the Council (hereafter referred to as the Biological Agents Directive). Biological agent classification anomalies will be removed and the opportunity will be taken to up-date the Regulations in line with the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005) and the Safety Health and Welfare at Work (General Applications) Regulations 2007 (S.I. No. 299 of 2007) as amended by the by the Safety, Health and Welfare at Work (General Application)(Amendment) Regulations 2007 (S.I. No. 732 of 2007).

The proposed new Regulations will repeal and replace the Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 (S.I. No. 146 of 1994) and the Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations 1998 (S.I. No. 248 of 1998).

The purpose of this RIA is to support the development of an effective and proportionate national regulation and Code of Practice by providing a thorough examination of the nature and extent of the potential impacts on the range of stakeholders and customers.

Robert Roe
Assistant Chief Executive Officer and Secretary to the Board

1.0 BACKGROUND INFORMATION

The purpose of the Biological Agents Directive and the Regulations transposing it into Irish law is to protect workers from the risks related to exposure to biological agents at work. The Directive and Biological Agents Regulations apply to activities in which workers are or potentially are exposed to biological agents as a result of their work.

The current Biological Agents Directive 2000/54/EC consolidates the previous relevant Directives by replacing and repealing Council Directive 90/679/EEC and its successive amendments and adaptations to technical progress in Council Directive 93/88/EEC and Commission Directives 95/30/EC, 97/59/EC and 97/63/EC.

The Safety Health and Welfare (Biological Agents) Regulations 1994 (S.I. No. 146 of 1994) as amended by the Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations 1998 (S.I. No. 248 of 1998) transposed into Irish legislation the requirements of Directive 90/679/EEC and its amending Directives.

2.0 OBJECTIVES OF THE PROPOSED REGULATIONS

The objective is to replace both sets of existing Regulations with one set of Regulations which will:

1. Transpose in full the requirements of the Biological Agents Directive and remove a current classification anomaly.
2. With reference to 1 above, allow the employer, having completed a risk assessment, to dispense with certain group 3 containment measures for specific agents identified in a relevant code of practice. and allow the Authority to publish guidelines, as deemed necessary, specifying minimum containment measures which shall be applied..
3. Enable by regulation, the publication of the Schedule of the Safety Health and Welfare at Work (Biological Agents) (Amendment) Regulations 1998 as a Code of Practice. It is proposed, in the interest of the safety of the relevant workforce, to regularly update the Code of Practice, having regard to the latest and most up to date scientific information.
4. Simplify and improve on the existing Regulations by reference to the Safety, Health and Welfare at Work Act 2005 and the General Application Regulations 2007.
5. Clarify the notification process and clearly align the Regulation with the requirements of the Directive.

3.0 OPTIONS

3.1 Options

(a) Maintain the existing Regulations unchanged

(b) Issue a Code of Practice (CoP)

(c) Update and restructure the Regulations so that they are aligned with the 2005 Act and the General Applications Regulations, so that the anomalies are removed and the notification process is clarified.

(d) Update and restructure the Regulations so that they are aligned with the 2005 Act and the General Applications Regulations 2007, so that the anomalies are removed and the notification process is clarified. Based on up-to-date best practice issue separately a Code of Pactice which will include the list of biological agents, their classification and related containment measures.

4.0 IMPACT ANALYSIS

4.1 Option (a)

4.1.1 Health and safety benefits

There will be no new health and safety benefits from continuing with existing legislation. There will be no mechanism to utilize new scientific data and resulting best practice will not be reflected.

4.1.2 Business benefits

The current Regulations do not allow for the re-classification of certain biological agents as listed in the Directive. This anomaly will effect extra unnecessary cost in that it obliges the employer in some circumstances to install group 3 control measures where lesser measures will suffice.

4.1.3 National competitiveness benefits

No benefit

4.2 Option (b)

4.2.1 Health and safety benefits

Issuing a Code of Practice would lead to confusion and error in that it would be up-dating information such as classifications and control measures and would be at odds with existing information in the Regulations.

4.2.2 Business benefits

There would be no business benefit and possible interpretation errors vis a vis the Regulations might incur unnecessary expense.

4.2.3 National competitiveness benefits

No benefit

4.3 Option (c)

4.3.1 Health and safety benefits

- Improved safety and health performance should be facilitated by employers having access to up-to-date information and classification options.
- The restructuring of the Regulations in line with the 2005 Act will bring clarity to the requirements in the Regulations and remove any ambiguity.

    - Proposed Regulation 6 will be expanded to clearly catalogue and reference in one Regulation the employer's duties that are currently enshrined in a number of Regulations.

    - Proposed Regulation 5 will allow the Authority to prohibit a specific use or request that additional control measures are put in place.

4.3.2 Business benefits

By removing the classification anomaly, the requirement to apply level 3 containment measures will be diminished and level 2 containment will suffice in relevant instances. As level 2 containment measures are less stringent, it is anticipated that facility installation, operational and maintenance costs will be less in these cases.

The classification anomaly will be removed and the client will be allowed to apply for a dispensation on appropriate containment measures. This dispensation measure will now be included in proposed Regulation 16, aligning more fully the requirement of the Regulations with the Biological Agents Directive.

Clarification of the notification process will lead to simpler and less frequent notification requirements.

The number of regulatory instruments which business will need to consult to establish their duties in relation to safe use of biological agents will be reduced. Previously, employers were required to read and cross-reference two sets of Regulations. Option 2 will see all the relevant provisions in a single instrument.

4.3.3 National competitiveness benefits

Reducing costs as outlined in paragraph 4.2.2 above should contribute positively to the national competitiveness benefits. As the proposed Regulations transpose the EU Directive, no disadvantage is likely.

4.4 Option (d)

4.4.1 Health and safety benefits

See paragraph 4.2.1 above.

Additionally, regularly issuing/updating a separate Code of Practice will facilitate the timely transposition of future adaptations to technical progress (ATPs) of the Biological Agents Directive and also ensure the Code of Practice(CoP) is based on all available and up-to-date scientific knowledge. For example, since the publication of the 2000 Directive and its Annex of agents, the UK HSE Advisory Committee on Dangerous Pathogens has up-dated its list in 2004 and added a number of new agents – one example being the causative agent of Severe Acute Respiratory Syndrome (SARS) has been added in Hazard Group 3. This will ensure employers have access to up-to-date information and classification.

4.4.2 Business benefits

See paragraph 4.3.2 above.

Additionally, the revised structure of the proposed Regulations and accompanying Code of Practice means that when it is necessary to update the list of agents, their classification or associated control measures, option 3 will allow for completing such updates by revising the approved Code of Practice only. Thus, employers will not need to familiarise themselves with amended Regulations on every occasion.

4.4.3 National competitiveness benefits

See paragraph 4.3.3 above

4.5 Recommended Option

Based on points put forward above the Authority recommends adopting option (d), i.e. update and replace the existing Regulations and publish a supporting Code of Practice.

5.0 COMPLIANCE COSTS FOR BUSINESS

The Authority does not expect that the proposed Regulations will impose further costs on employers who are already applying the requirements of the existing Regulations. These employers will need to familiarise themselves with the new Regulations and Code of Practice and respond accordingly. Since in some specific cases the notification and or the containment requirements are likely to be less onerous, it is anticipated that ongoing costs will be reduced.

5.1 Familiarisation & training

Irish businesses that use biological agents will need to familiarise themselves with the proposed Regualtion and Code of Practice and provide training for their staff on the new

provisions. It is difficult to estimate the costs involved given that there are no available data on the number of businesses that use biological agents in Ireland. However, there are a number of factors that will support familiarisation and training:

a) the substantive changes are minimal (See Appendix),

b) the public consultation process will bring these changes to the attention of the relevant trade associations and employers,

c) in conjunction with the publication of the new Regulations and Code of Practice, the Authority. proposes to publish related guidelines,

d) the documents will be published on the HSA website, making them widely available to all relevant employers/employees with access to the internet.

5.2 Control measures

Control or containment measures which will now be published in the proposed Code of Practice have not been changed and where indicated certain group 3 agents, depending on an assessment, may have some of the level 3 containment levels dispensed with. Therefore, the proposed Regulations are likely to be cost neutral and some employers may achieve cost savings in relation to their controls.

5.3 Compliance cost for a typical business

Compliance costs to a typical enterprise are considered minimal. Some expense will be incurred in training and familiarisation but given the scale of the changes these costs are not expected to be significant.

6.0 ENFORCEMENT COSTS

The proposed Regulations and Code of Practice will be administered and enforced by the Health and Safety Authority. The Authority does not expect enforcement of these Regulations to require significant additional resources. Some re-allocation of resources will be necessary in relation to inspector training, inspection targets and the production of guidance documents, but it is anticipated that these changes can be accommodated within existing budgets.

7.0 ENVIRONMENT COST

The Authority does not foresee that the proposed Regulations will have any environmental impacts.

8.0 ADMINISTRATIVE BURDEN

The proposed Regulations and Code of Practice will not require employers to keep any additional records beyond those in place under the current Regulations and, in fact, the clarification of the reporting process will reduce the reporting requirements.

9.0 CONSULTATION

The proposed Regulations, Code of Practice and the associated RIA will be made available for public consultation on the Authority's website for a one month period in 2010, in accordance with the Authority's standard public consultation policy. Selected stakeholders may be contacted directly by the Authority and invited to make submissions.

The submissions from the public consultation will be collated by the Authority and relevant additions or amendments will be considered. Any changes to the proposed Regulations and Code of Practice will be reflected in this Regulatory Impact Analysis. The revised documents will be submitted to the Legislation and Guidance Sub-Committee of the Board and the Board of the Authority for consideration and approval. The proposals as approved will be submitted to the Minister for Labour Affairs at the Department of Enterprise, Trade and Employment for his consideration with a view to formal legal settlement by the Office of the Parliamentary Counsel to the Government.

10.0 REVIEW

The Authority will regularly review the Code of Practice and update it in line with any adaptation to technical progress (ATP), any relevant amending Directive or on the basis of best available scientific data.

REFERENCES

Towards 2016 - Ten Year Framework Social Partnership Agreement 2006-2015, Department of the Taoiseach, June 2006
http://www.taoiseach.gov.ie/attached_files/Pdf%20files/Towards2016PartnershipAgreement.pdf

RIA Guidelines - How to conduct a Regulatory Impact Analysis, Department of the Taoiseach, October 2005,
http://www.betterregulation.ie/attached_files/Pdfs/RIAguidelines.pdf

Safety, Health and Welfare at Work (Biological Agents) Regulations 1994 (S.I. No. 146 of 1994)

Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations (1998, S.I. No. 248 of 1998)

UK HSE Advisory Committee on Dangerous Pathogens – Approved List of Dangerous Pathogens, 2004.

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

APPENDIX

LIST OF PROPOSED CHANGES IN 2010 DRAFT BIOLOGICAL AGENTS REGULATIONS COMPARED WITH THE BIOLOGICAL AGENTS REGUALTIONS 1994 AND 1998.

- The proposed Regulations have been fundamentally restructured to align them with the structure and content of the Safety, Health and Welfare at Work Act 2005 and the Safety, Health and Welfare at Work (General Applications) Regulations 2007.

- The Safety, Health and Welfare at Work (Biological Agents) (Amendment) Regulations 1998 (S.I. No 248 of 1998) (list of Biological Agents and their classification) and Schedules 7 & 8 (containment measures and levels) are now placed in a separate associated Code of Practice. The Authority plans to review and update the Code of Practice regularly. The List of Agents in the Code of Practice has been updated in line with Directive 200/54/EC and also the Approved List of Dangerous Pathogens 2004 – UK Advisory Committee on Dangerous Pathogens.

- Proposed Regulation 8 on risk assessment includes a requirement where an employer may, having first completed a risk assessment, consider dispensing with some of the group 3 containment requirements where there is a limited risk of infection for employees because the specified agents are not normally infectious by the airborne route. Such agents are marked with an asterix in the Code of Practice. **An employer will notify the Authority of his/her intention to dispense with such measures as per Schedule 4 in the relevant Code of Practice**

- Proposed Regulation 5 allows for the Authority, on receipt of a notification as per proposed Regulation 15, to prohibit the use of an agent(s) or require the application of additional controls.

- Proposed Regulation 15(f) is restructured to state the notification to the Authority requirements as laid down in Directive 2000/54/EC.

  The Authority must be notified **of:**

  - **The first time use of group 2, 3 and 4 agents**

  - **Use for the first time of each subsequent group 4 agent**

  - **Each subsequent use of a new group 3 agent where the** employer provisionally classifies the agent

  - In diagnostic use only the first time use of a group 4 agent.

  - The employer's intention to consider dispensing with some of the group 3 containment requirements where there is a limited risk of infection for employees because the specified agents are not normally infectious by the airborne route. Such agents are marked with an asterisk in the Code of Practice.

- In any case where there are substantial changes

This will be further clarified in the proposed guidelines.

- Proposed Regulation 6 on the duties of employers has been restructured and expanded to bring clarity and focus in one Regulation on an employer's duties under various Regulations.

- Proposed Regulation 4 (application) provides that the Regulations do not apply to Group 1 agents where there is no identifiable health risk but the principles of good occupational safety and hygiene are applied.

- An additional point has been added to proposed Regulation 8 on risk assessment, to include the risk assessment of potential exposure to a biological agent, where the activity does not involve a deliberate intention to work with or use a biological agent.

- Regulations on hygiene and individual protection have been structured so that they refer to the General Applications Regulations 2007 and avoid duplication.

- Proposed Regulation 15(c) requires employers to provide information to their employees on the risk assessment, when requested.

- Record keeping time requirements in proposed Regulation 13 - health surveillance - have been aligned with proposed Regulation 17 - occupational exposure registers.

- Although Group 1 Biological Agents are, in general, outside the remit of the Regulations, proposed Regulation 4 requires that good occupational safety and hygiene measures are observed when handling group 1 agents.