STATUTORY INSTRUMENTS.

S.I. No. 572 of 2013

SAFETY, HEALTH AND WELFARE AT WORK (BIOLOGICAL AGENTS) REGULATIONS 2013

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SAFETY, HEALTH AND WELFARE AT WORK (BIOLOGICAL AGENTS) REGULATIONS 2013

I, RICHARD BRUTON, Minister for Jobs, Enterprise and Innovation, in exercise of the powers conferred on me by section 58 of the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005), and for the purpose of giving effect to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000[1] and after consultation with the Health and Safety Authority, hereby make the following regulations:

PART 1

Preliminary and general

Citation and commencement

1. These Regulations may be cited as the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013.

Interpretation

2. In these Regulations, save where the context otherwise requires—

"Act" means the Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005);

"biological agent" means micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity, classified into 4 risk groups according to their level of risk of infection, as follows (if the biological agent to be assessed cannot be classified clearly in one of the following groups, it shall be classified in the highest risk group among the alternatives):

(*a*) a "group 1 biological agent" means one that is unlikely to cause human disease to employees;

(*b*) a "group 2 biological agent" means one that can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available;

(*c*) a "group 3 biological agent" means one that can cause severe human disease and presents a serious hazard to employees and that may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available;

[1]O.J. No. L 262, 17.10.2000, p.21.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 3*rd January*, 2014.

(*d*) a "group 4 biological agent" means one that causes severe human disease and is a serious hazard to employees and that may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available;

"cell culture" means the in-vitro growth of cells derived from multicellular organisms;

"exposure" means exposure of an employee at a place of work to a biological agent;

"hazard" means a potential source of injury or damage to health from exposure;

"incident" means an occurrence which involves the risk of exposure;

"micro-organism" means a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;

"occupational medical adviser" means a person designated under section 63 of the Act;

"relevant code of practice" means a code of practice, relating to these Regulations, published under section 60 of the Act;

"responsible medical practitioner" means a registered medical practitioner employed, or otherwise engaged, by an employer to be responsible for health surveillance of employees under these Regulations.

Application

3. (1) Subject to paragraph (2), these Regulations, and any relevant code of practice, apply to activities in a place of work where existing or potential, whether deliberate or incidental, exposure to a biological agent has occurred or may occur.

(2) Where the results of a risk assessment under Regulation 7 show that there is exposure or potential exposure (or both) to a group 1 biological agent, including attenuated vaccines, with no identifiable health risks to employees, Regulations 5(*b*)(ii) to (iv) and (vi) to (xiv), 6, 7(1)(*c*) and (*f*), 7(2)(*a*) and (*b*), 8, 9, 10, 11, 12, 13, 14(1)(*b*) to (*f*), 14(2) to (4), 15, 16 and 17 shall not apply in relation to such exposure, but the principles of good occupational safety and hygiene shall be observed.

(3) Obligations and duties arising under these Regulations are in addition to obligations and duties arising under any other enactment.

(4) In this Regulation, "enactment" means—

(*a*) an Act of the Oireachtas,

(*b*) a statute that was in force in Saorstát Éireann immediately before the date of the coming into operation of the Constitution and that continues in force by virtue of Article 50 of the Constitution, or

(*c*) an instrument made under—

(i) an Act of the Oireachtas, or

(ii) a statute referred to in subparagraph (*b*).

Prohibitions

4. The Authority, on receipt of a notification referred to in Regulation 14(1)(*e*), may prohibit the use of the biological agent or agents referred to in the notification or require the application of additional controls to safeguard the safety, health and welfare of employees from exposure to the said notified agent or agents.

PART 2

Duties of employers and employees

Duties of employers

5. Where an employee is, or is likely to be, exposed to biological agents as a result of his or her work activities, his or her employer shall—

(*a*) apply these Regulations and any relevant code of practice,

(*b*) without prejudice to paragraph (*a*)—

(i) complete a risk assessment as required under Regulation 7 and apply, if appropriate, the special measures specified in Regulations 16 and 17,

(ii) avoid the use of a harmful biological agent, if the nature of the activity so permits, by replacing it with a biological agent which, under its conditions of use and in the present state of knowledge, is not dangerous or is less dangerous, as the case may be, to the health of employees,

(iii) prevent the exposure of employees to a biological agent at a place of work where the results of the risk assessment under Regulation 7 reveal a risk to employees' health and safety,

(iv) where the results of the risk assessment under Regulation 7 reveal that it is not technically possible to prevent exposure, apply the prevention and risk reduction measures specified in Schedule 2, in order to ensure that, as far as technically practicable, the level of exposure of employees is reduced to as low a level as necessary in order to adequately protect the health and safety of the employees concerned,

(v) where the results of the risk assessment under Regulation 7 show that the exposure or potential exposure (or both) is to a group 1 biological agent, including live attenuated vaccines, with no identifiable health risk to employees, ensure that the principles of good occupational safety and hygiene are applied,

(vi) where a risk assessment under Regulation 7(1)(*f*) shows that the activity may result in exposure to a biological agent, as in the course of the activities for which an indicative list is given in Schedule 1, comply with the provisions of these Regulations, unless the results of such assessment show such compliance to be unnecessary,

(vii) provide information and training and consult with employees as required under Regulation 8,

(viii) make available facilities and put in place procedures as specified in Regulation 9,

(ix) provide for the supply of suitable work clothing, special protective clothing and personal protective equipment as required under Regulation 10,

(x) make effective vaccines available as required under Regulation 11,

(xi) provide, as required under Regulation 12, relevant health surveillance prior to exposure and at such intervals as are necessary,

(xii) establish and maintain safety precautions, emergency procedures and plans as appropriate and required under Regulation 13,

(xiii) provide information and notification to the Authority as specified in Regulation 14, and

(xiv) maintain, as required under Regulation 15, for the purposes of this subparagraph, a list of the employees who have been or may be exposed to any or all of—

(I) a group 2 biological agent specified in a relevant code of practice,

(II) a group 3 biological agent, and

(III) a group 4 biological agent.

Duties of employees

6. An employee shall report immediately to his or her employer, or to the person responsible for safety and health at work in the employer's undertaking, any accident or incident of which he or she becomes aware, involving exposure, or risk of exposure, to, or release of, a biological agent involving, or likely to involve, a risk to the health or safety of an employee.

PART 3

Protective and preventive measures

Risk assessment

7. (1) Subject to Regulations 16 and 17, an employer shall—

(*a*) assess any risk, whether existing or potential, to the health and safety of employees resulting from any activity at that employer's place of work likely to involve a risk of exposure and for that purpose determine the nature, degree and duration of any such risk and apply—

(i) the prevention and risk reduction measures specified in Schedule 2 to be taken, and

(ii) any special protective measures which may be required,

to ensure the safety and health of such employees,

(*b*) keep the risk assessment referred to in subparagraph (*a*) in written form as required by section 19 of the Act,

(*c*) when carrying out the risk assessment required by subparagraph (*a*), assess the risk, in the case of activities involving exposure to biological agents from 2 or more of the risk groups in paragraphs (*b*), (*c*) and (*d*) of the definition of "biological agent" in Regulation 2, on the basis of the hazards presented by all biological agents present,

(*d*) as often as necessary and, in any event, whenever there is a change in conditions at the place of work which may affect any employee's exposure to a biological agent, review and, as appropriate, amend the risk assessment required by subparagraph (*a*),

(*e*) conduct the risk assessment referred to in subparagraph (*a*) on the basis of all available information, including—

(i) the classification of each biological agent which is or may be a hazard to human health as specified in a relevant code of practice,

(ii) information on diseases which may be contracted as a result of the work of the employees,

(iii) potential allergenic or toxigenic effects as a result of the work of the employees,

(iv) knowledge of a disease from which an employee is found to be suffering and which has a direct connection with his or her work, and

(v) any recommendations which have been made by the Authority indicating that a particular biological agent should be controlled in order to protect employees' health where employees are or

may be exposed to such a biological agent as a result of their work,

and

(*f*) where the results of the risk assessment show that the activity does not involve a deliberate intention to work with or use a biological agent but may result in exposure, as in the course of the activities for which an indicative list is given in Schedule 1, comply with the provisions of these Regulations, unless the results of such assessment show such compliance to be unnecessary.

(2) (*a*) Certain biological agents classified as group 3 biological agents which may be specified in a relevant code of practice may present a limited risk of infection for employees because they are not normally infectious by the airborne route. Subject to subparagraph (*b*), an employer may, for biological agents so specified, having completed an appropriate risk assessment and taking account of the nature of specific activities in question and of the quantity of the agent involved, dispense with such group 3 containment measures as may be specified in a relevant code of practice.

(*b*) The Authority may, where necessary, publish in a relevant code of practice the minimum containment measures which shall be applied in cases to which subparagraph (*a*) applies.

Information, training and consultation of employees

8. (1) An employer, in the case of any activity in relation to which there is a risk to the health or safety of an employee due to work with a biological agent, shall take appropriate measures to ensure that each such employee or his or her safety representative (or both) receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions concerning—

(*a*) potential risks to health,

(*b*) precautions to be taken to prevent exposure,

(*c*) hygiene requirements,

(*d*) wearing and use of suitable work clothing, special protective clothing and personal protective equipment, and

(*e*) steps to be taken by employees in the case of incidents and to prevent incidents.

(2) Prior to the commencement of work involving contact with a biological agent, an employer shall give the training referred to in paragraph (1) and ensure that such training is adapted to take account of new or changed risks and is repeated as often as is necessary.

(3) An employer shall provide written instructions at the place of work, and, if appropriate, display notices which shall, at a minimum, include the procedure to be followed in the case of—

(*a*) a serious accident or incident involving the handling of a biological agent, and

(*b*) the handling of a group 4 biological agent.

(4) An employer shall ensure that employees or their safety representative (or both) are or is—

(*a*) informed, immediately, of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection or illness (or both),

(*b*) informed, as quickly as possible, when a serious accident or incident occurs of the causes thereof and of the measures taken or to be taken to rectify the situation, and

(*c*) consulted in relation to the matters referred to in Regulation 7.

(5) An employer shall provide information in accordance with paragraph (1) to—

(*a*) any other employer whose employees, or

(*b*) any self-employed person who,

may be affected by exposure to a biological agent arising from the conduct of the employer's undertaking.

Hygiene

9. In the case of any activity in relation to which there is a risk to the health or safety of employees caused by working with a biological agent, an employer shall take appropriate measures to ensure that—

(*a*) employees do not eat or drink in any location within a place of work where there is a risk of contamination by a biological agent,

(*b*) employees are provided within the place of work with appropriate and adequate washing and toilet facilities, which may include eye washes and skin antiseptics, and

(*c*) procedures are specified for taking, handling and processing samples of human or animal origin.

Individual protection

10. (1) In the case of any activity in relation to which there is a risk to the health or safety of employees caused by working with a biological agent, an employer shall provide all employees so at risk with—

(*a*) suitable work clothing,

(*b*) special protective clothing, and

(*c*) personal protective equipment.

(2) An employer shall ensure that—

(*a*) suitable work clothing, special protective clothing and personal protective equipment, referred to in paragraph (1), which may be contaminated by a biological agent, are removed on leaving the working area and, before taking the measures referred to in subparagraph (*b*), are kept separately from other clothing in a well defined place, and

(*b*) the suitable work clothing, special protective clothing and personal protective equipment referred to in subparagraph (*a*) are checked before and after each use and cleaned and decontaminated or, if necessary, destroyed.

Vaccination

11. In the case of any activity in relation to which there is a risk to the health or safety of employees caused by working with a biological agent, an employer shall—

(*a*) make effective vaccines available, when necessary, to those employees who are not already immune to the biological agent to which they are exposed or are likely to be exposed, and

(*b*) comply with the matters set out in Schedule 4 when making vaccines available to employees.

Health surveillance

12. (1) In the case of any activity in relation to which there is a risk to the health or safety of employees due to work with a biological agent, an employer shall—

(*a*) make provision for appropriate health surveillance as provided for in section 22 of the Act to be made available, and undertaken by a responsible medical practitioner, for each employee for whom the results of a risk assessment under Regulation 7 reveal a risk to his or her health or safety as a result of exposure,

(*b*) ensure that, where appropriate, the health surveillance required under subparagraph (*a*) includes health surveillance made available prior to exposure and at such intervals as are necessary thereafter and that these arrangements are such that it is directly possible to implement appropriate individual and occupational hygiene measures,

(*c*) ensure that, where an employee is found to be suffering from an infection or illness (or both) which is suspected to be the result of exposure, health surveillance is made available to all other employees

who have been similarly exposed, whenever requested by the responsible medical practitioner or by the Authority,

(*d*) ensure that where the health surveillance required under subparagraph (*c*) is undertaken, the risk assessment is reviewed and, as appropriate, amended in accordance with Regulation 7(1)(*d*),

(*e*) ensure that, where an employee receives health surveillance under this Regulation, an individual health record of such matters is kept by such employer for at least 10 years following the end of exposure of that employee, and

(*f*) in the case of an employee referred to in paragraph (*c*) of Regulation 15, keep an individual health record for such employee for an appropriately longer time, not exceeding 40 years, to be determined as provided for in that paragraph, following the last known exposure of the employee concerned.

(2) An employer shall ensure that each employee is provided with information and advice regarding any health surveillance which he or she may undergo following the end of exposure of such employee.

(3) A responsible medical practitioner and an employer, as appropriate, shall give access to an employee to the results of the health surveillance, or review of same, which concern that employee.

(4) A responsible medical practitioner, when carrying out relevant health surveillance under this Regulation, shall—

(*a*) comply with the requirements contained, and take account of the other matters specified, in Schedules 4 and 5,

(*b*) propose any protective or preventive measures to be taken, including any special protective measures which may be required, in respect of any individual employee, as appropriate,

(*c*) allow access to the individual confidential medical record of any individual employee to an occupational medical adviser,

(*d*) make available to the Authority or such person as the Authority directs, each individual confidential medical record of an individual employee held by him or her, in cases where—

(i) the employer's undertaking ceases activity, or

(ii) he or she is ceasing to practice as a registered medical practitioner,

and

(*e*) keep an individual confidential medical record and retain that record for at least 10 years and, taking account of cases referred to in paragraph (*c*) of Regulation 15, keep an individual confidential medical record for an appropriately longer time, not exceeding 40 years, to be determined as provided for in that paragraph, following the last known exposure of the employee.

(5) An employer who becomes aware of, or a registered medical practitioner (including a responsible medical practitioner) who diagnoses, a case of disease or death of an employee resulting from occupational exposure to a biological agent, shall notify such occurrence to the Authority.

(6) An employer may request a review of the results of the health surveillance referred to in subparagraph (*a*) of paragraph (1).

(7) Where an individual confidential medical record of an employee is, pursuant to subparagraph (*d*) of paragraph (4), made available to the Authority or such person as the Authority directs, the Authority or such person, as the case may be, shall retain that record for a period of time equivalent to the length of time not yet elapsed of whichever of the periods referred to in subparagraph (*e*) of paragraph (4) is relevant in relation to the employee concerned.

Emergency plans

13. In the case of any activity in relation to which there is a risk to the health or safety of employees due to work with a biological agent, an employer shall establish and maintain safety precautions, emergency procedures and plans appropriate to the hazards in the place of work.

PART 4

Notification and record keeping

Information and notification to be provided to the Authority

14. (1) An employer shall—

(*a*) provide the Authority, when requested, with the information used for making any risk assessment carried out under Regulation 7 and with the findings of any such assessment,

(*b*) where the results of a risk assessment carried out under Regulation 7 reveal a risk to an employee's health or safety, provide the Authority, when requested, with appropriate information relating to—

(i) the said results,

(ii) the activities in which employees have been exposed or may have been exposed,

(iii) the number of employees exposed,

(iv) the name and competencies of the person responsible for safety and health at work,

(v) the protective, preventive and risk reduction measures, and any special protective measures, taken, including working procedures and methods, and

(vi) an emergency plan for the protection of employees from exposure to a biological agent which might result from a loss of physical containment,

(*c*) provide employees or their safety representatives (or both), at their request, with the information referred to in subparagraph (*b*),

(*d*) immediately notify the Authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection or illness (or both),

(*e*) notify the Authority—

(i) at least 30 days prior to the commencement of work involving the use for the first time of biological agents from the risk groups in paragraphs (*b*), (*c*) and (*d*) of the definition of "biological agent" in Regulation 2,

(ii) subject to subparagraph (iii), at least 30 days prior to the commencement of work involving the use for the first time of each subsequent group 4 biological agent and each subsequent new group 3 biological agent, where the employer provisionally classifies that biological agent,

(iii) in the case of laboratories providing a purely diagnostic service in relation to a group 4 biological agent, only the initial intention to use for the first time the biological agent concerned, and

(iv) in any case where there are substantial changes of importance to safety and health at work to either or both processes and procedures which render the notifications required by clause (i), (ii) or (iii) out of date,

and

(*f*) include in the notification required by subparagraph (*e*)—

(i) the name and address of the employer and, where different, the place of work,

(ii) the name and competencies of the person responsible for safety and health at work,

(iii) the results of the risk assessment under Regulation 7,

(iv) the species of the biological agent, and

(v) the protection and preventive and risk reduction measures that are envisaged.

(2) Where an employer's undertaking is to cease activity, the employer shall, before such cessation, deliver the list required by Regulation 15 and the individual health records required by Regulation 12(1)(*e*) to the Authority.

(3) Where an employer that is a body corporate fails, before the cessation referred to in paragraph (2), to deliver the list required by Regulation 15 and the individual health records as required by that paragraph, any person who was, at the time of such cessation, a director of the said body corporate shall be personally liable to ensure delivery of the said list and the said individual health records to the Authority.

(4) Where either or both a list required by Regulation 15 and the individual health records required by Regulation 12(1)(*e*) are delivered to the Authority, the Authority shall retain that list and those records for a period of time equivalent to the length of time not yet elapsed of whichever of the periods referred to in paragraphs (*b*) and (*c*) of Regulation 15 and subparagraphs (*e*) and (*f*) of Regulation 12(1) is relevant in relation to the employees concerned.

Occupational exposure lists

15. In the case of any activity in relation to which there is a risk to the health or safety of employees due to work with a biological agent, an employer shall—

(*a*) maintain a list (in this Regulation referred to as "the list") of the employees who have been or may be exposed to any or all of—

(i) a group 2 biological agent specified, for the purposes of this paragraph, in a relevant code of practice,

(ii) a group 3 biological agent, and

(iii) a group 4 biological agent,

indicating the type of work done or to be done by each employee, and, whenever possible, the biological agent to which they have been or may be exposed, as well as records of exposures, accidents and incidents, as appropriate,

(*b*) keep the list for at least 10 years following the end of the last known exposure,

(*c*) keep the list for an appropriately longer period not exceeding 40 years following the last known exposure, depending on the likely duration of risk to the health and safety of employees determined during the risk assessment referred to in Regulation 7, following the last known exposure in the case of those exposures which may result in an infection—

(i) with a biological agent known to be capable of establishing persistent or latent infections,

(ii) that in the light of present knowledge is not diagnosable until illness develops many years later,

(iii) that has particularly long incubation periods before illness develops,

(iv) that results in illness that recrudesces at times over a long period despite treatment, or

(v) that results in illness that may have serious long-term sequelae,

(*d*) ensure that each employee has access to the information on the list which relates to him or her, personally,

(*e*) ensure that the employees or their safety representative (or both) have access to collective information from the list which does not identify information relating to any individual employee, and

(*f*) ensure that the list is made available, on request, to the responsible medical practitioner, the Authority or an occupational medical adviser.

PART 5

Special measures

Health care and veterinary care facilities other than diagnostic laboratories

16. In the case of health care and veterinary care facilities other than diagnostic laboratories, an employer shall—

(*a*) when carrying out a risk assessment under Regulation 7 pay particular attention to—

(i) the risks posed by the nature of the work,

(ii) uncertainties about the presence of a biological agent in human patients or animals and the materials and specimens taken from them, and

(iii) the hazard represented by a biological agent known or suspected to be present in human patients or animals and the materials and specimens taken from them,

(*b*) take appropriate measures to protect the health and safety of employees at a place of work which is either a health care facility or veterinary care facility including, in particular, by—

(i) specifying appropriate decontamination and disinfection procedures, and

(ii) implementing procedures enabling contaminated waste to be handled and disposed of without risk,

and

(*c*) apply appropriate containment measures, as specified in a relevant code of practice, in order to minimise the risk of infection at a place of work which is an isolation facility where there are either human patients or animals who are or who are suspected of being infected with—

(i) a group 2 biological agent specified, for the purposes of this paragraph, in a relevant code of practice,

(ii) a group 3 biological agent, or

(iii) a group 4 biological agent.

Laboratories, industrial processes and animal rooms

17. (1) This Regulation applies to an employer at a place of work which is either or both—

(*a*) a laboratory, including a diagnostic laboratory, and

(*b*) a room for laboratory animals, which animals—

(i) have been deliberately infected with—

(I) a group 2 biological agent,

(II) a group 3 biological agent, or

(III) a group 4 biological agent,

or

(ii) are, or are suspected to be, carriers of such an agent.

(2) An employer to whom paragraph (1) applies shall—

(*a*) as part of the risk assessment required by Regulation 7, where work is to be carried out which involves the handling of a biological agent from any of the risk groups in paragraphs (*b*), (*c*) and (*d*) of the definition of "biological agent" in Regulation 2 for research, development, teaching or diagnostic purposes, determine containment levels and implement containment measures, as specified in a relevant code of practice, in order to minimise the risk of infection,

(*b*) carry out activities involving the handling of a biological agent only in working areas corresponding to at least the containment level specified in a relevant code of practice for—

(i) containment level 2 for a group 2 biological agent,

(ii) containment level 3 for a group 3 biological agent, and

(iii) containment level 4 for a group 4 biological agent,

and, in determining the containment level required for the said biological agent, follow the risk assessment required by Regulation 7,

and

(*c*) adopt—

(i) at least containment measures specified for containment level 2 as specified in a relevant code of practice, where handling materials in respect of which there exists uncertainties about the presence of a biological agent which may cause human disease, but which laboratories do not have as their aim working with a biological agent including cultivating or concentrating a biological agent, and

(ii) containment measures specified for containment level 3 or 4, as specified in a relevant code of practice, as and when appropriate, where he or she knows or ought to know that it is necessary, except where a relevant code of practice shows that a lower containment level is appropriate.

(3) At a place of work where industrial processes using a group 2 biological agent, a group 3 biological agent or a group 4 biological agent are carried out, an employer shall—

(*a*) apply the containment measures and containment levels referred to in paragraph (2)(*b*) and take account of containment measures and containment levels for industrial processes specified in a relevant code of practice,

(*b*) apply the measures to be taken which are considered necessary in accordance with the risk assessment required under Regulation 7 linked to the industrial use of a group 2 biological agent, a group 3 biological agent or a group 4 biological agent,

(*c*) apply at least the containment measures for level 3 as specified in a relevant code of practice when carrying out any activity covered by this Regulation, where it has not been possible to carry out a conclusive assessment of a biological agent but where it appears that the use envisaged might involve a serious health risk for employees, and

(*d*) where appropriate, apply combined containment measures and containment levels specified in a relevant code of practice on the basis of the risk assessment required by Regulation 7.

PART 6

Revocations

Revocations

18. 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) are revoked.

SCHEDULE 1

Regulations 5(b)(vi) and 7(1)(f)

Indicative list of activities

1. Work in food production plants.

2. Work in agriculture.

3. Work in biotechnology, including the production of pharmaceutical products.

4. Work activities where there is contact with animals and products of animal origin (or both).

5. Work in health care, including isolation and post mortem units, funeral and cremation undertakings.

6. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.

7. Work in refuse disposal plants.

8. Work in sewage purification installations.

SCHEDULE 2

Regulations 5(b)(iv) and 7(1)(a)(i)

Prevention and risk reduction measures

(Measures to be taken where it is not technically possible to prevent exposure)

1. The keeping as low as possible of the number of employees exposed or likely to be exposed to a biological agent.

2. The design of work processes and engineering control measures so as to avoid or minimise the release of a biological agent into the place of work.

3. The use of both collective protection measures and individual protection measures where exposure cannot be avoided by other means.

4. The use of hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the place of work.

5. The use of the biohazard sign depicted in Schedule 3, and other relevant warning signs which are in compliance with Regulations 158 to 162 of and Schedule 9 to the Safety, Health and Welfare at Work (General Application) Regulations 2007 (S.I. No. 299 of 2007).

6. The drawing up of plans to deal with accidents involving a biological agent.

7. The testing, where necessary and technically possible, for the presence, outside the primary physical confinement, of a biological agent used at work.

8. The use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate.

9. The making of arrangements for the safe handling and transport of a biological agent within the place of work.

SCHEDULE 3

Schedule 2(5)

Biohazard sign

SCHEDULE 4

Regulation 11(b) and Regulation 12(4)(a)

Matters relating to vaccination practice

1. If the risk assessment referred to in Regulation 7 reveals that there is a risk to the health and safety of an employee due to his or her exposure to a biological agent for which effective vaccines exist, the employer shall offer vaccination to each such employee.

2. Vaccination shall be carried out in accordance with any current best medical practice and employees should be informed of the benefits and drawbacks of both vaccination and non-vaccination.

3. Vaccination shall be offered free of charge to employees.

4. A vaccination certificate may be drawn up which shall be made available to the employee concerned and, on request, to the Authority.

SCHEDULE 5

Regulation 12(4)(a)

Matters relating to health surveillance of employees

1. A responsible medical practitioner shall be familiar with the exposure conditions or circumstances of each employee.

2. Health surveillance of employees shall be carried out in accordance with the principles and practices of occupational medicine; it shall include at least the following measures:

(*a*) keeping records of an employee's medical and occupational history;

(*b*) a personalised assessment of the employee's state of health;

(*c*) where appropriate, biological monitoring as well as detection of early and reversible effects.

3. Further tests may be decided upon for each employee, when he or she is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

L.S.

GIVEN under my Official Seal,
20 December 2013.

RICHARD BRUTON,
Minister for Jobs, Enterprise and Innovation.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations transpose 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. This is a codified Directive which repealed and replaced Council Directive 90/679/EEC of 26 November 1990 as amended by Council Directive 93/88/EEC of 12 October 1993, Commission Directive 95/30/EC of 30 June 1995, Commission Directive 97/59/EC of 7 October 1997, and Commission Directive 97/65/EC of 26 November 1997.

These Directives were previously transposed in Ireland through 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 1994 and 1998 Regulations are repealed and replaced by these Regulations which transpose Directive 2000/54/EC.

These Regulations enable the publication of some aspects of the Biological Agents Directive (i.e. the list of biological agents and their classification, together with indications concerning containment measures and levels) in a relevant Code of Practice, rather than in the Regulations themselves.

These Regulations define biological agents and apply to activities in which workers are or potentially are exposed to biological agents as a result of their work. Employers must identify the biological agent to which workers are, or may be, exposed. They must assess the risk, making use of the list of biological agents, their classification, containment levels and measures provided for in the relevant Code of Practice, and proceed in accordance with the remaining Regulations where appropriate.

These Regulations permit the Health and Safety Authority to prohibit a specific use of a Biological Agent or request that additional control measures are put in place (Regulation 4).

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