STATUTORY INSTRUMENTS.

S.I. No. 427 of 2013

EUROPEAN UNION (BIOCIDAL PRODUCTS) REGULATIONS 2013

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I, SIMON COVENEY, Minister for Agriculture, Food and the Marine, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), for the purpose of giving effect to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012[1], Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013[2], Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013[3], Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013[4], Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013[5], Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013[6] and Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009[7] as amended by Commission Regulation (EU) No 656/2011 of 7 July 2011[8] hereby make the following regulations:

Part 1

Preliminary and General

Citation

1. These Regulations may be cited as the European Union (Biocidal Products) Regulations 2013.

Interpretation

2. (1) In these Regulations—

"authorised officer" means—

(*a*) a person who immediately before the making of these Regulations was an authorised officer under the European Communities (Authorisation, Placing on the Market, Use and control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001),

(*b*) a person appointed under Regulation 27,

(*c*) a member of the Garda Síochána, or

(*d*) an officer of Customs and Excise;

[1]OJ No. L 167, 27.6.2012, p.1
[2]OJ No. L 109, 19.4.2013, p. 4
[3]OJ No. L 125, 7.5.2013, p. 4
[4]OJ No. L 204, 31.7.2013, p.25
[5]OJ No. L 167, 19.6.2013, p.17
[6]OJ No. L 234, 3.9.2013, p.1
[7]OJ No. L 324, 10.12.2009, p.1
[8]OJ No. L 180, 8.7.2011, p.3

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 15*th November*, 2013.

"Biocidal Products Regulation" means Regulation (EC) No 528/2012 of the European Parliament and of the Council of 22 May 2012 as amended by Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013, Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013, Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013, Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 and Commission Delegated Regulation (EU) No 837/2013 of 25 June 2013;

"Minister" means the Minister for Agriculture, Food and the Marine;

"notification holder" means the person who is responsible for the notification to the Minister that a biocidal product is placed on the market for sale and use in accordance with Regulations 9, 10 and 11;

"premises" includes land (including land under water) with or without buildings, a vehicle (including a boat, ship, hovercraft, aircraft or offshore installation) (being an offshore installation, within the meaning of the Safety, Health and Welfare (Offshore Installations) Act 1987 (No. 18 of 1987)), railway wagon, container or other thing used in connection with, or ancillary to, a thing aforementioned.

(2) A word or expression that is used in the Biocidal Products Regulation and is also used in these Regulations has, in these Regulations, the same meaning as it has in the Biocidal Products Regulations.

Part 2

Active Substances

Active substances

3. A person shall not use an active substance in a biocidal product unless it is approved in accordance with Chapter II or Chapter III of the Biocidal Products Regulation.

Part 3

Biocidal Products

Application for authorisation of a biocidal product

4. (1) A person shall not place on the market, make available or use a biocidal product unless it is authorised by the Agency or the Minister in accordance with Chapters IV, V, VI, VII and VIII of the Biocidal Products Regulation and Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013.

(2) A person seeking an authorisation to place on the market, make available or use a biocidal product under Chapter IV, V, VI or VII shall apply in a format determined in accordance with Article 79 of the Biocidal Products Regulation with the appropriate fees as determined under Regulation 25.

(3) A person making an application under paragraph (2) shall submit such other information as the Minister considers necessary.

(4) The Minister may attach such conditions to an authorisation as the Minister considers appropriate.

Certificate of authorisation

5. Where a biocidal product has been authorised by the Minister under Regulation 4, the Minister may issue a certificate of authorisation containing—

(*a*) an authorisation number to be known as an IE/BPA number,

(*b*) where appropriate, a suffix to the authorisation number denoting the biocidal product family,

(*c*) a summary of the biocidal product characteristics in accordance with Article 22.2 of the Biocidal Products Regulation, and

(*d*) details of conditions attached by the Minister.

Cancellation or amendment of authorisation

6. (1) An authorisation holder may apply to the Minister to cancel or amend an authorisation of a biocidal product in accordance with Articles 49, 50, 51, 71 and 79 of the Biocidal Products Regulation and Commission Implementing Regulation (EU) 354/2013 of 18 April 2013.

(2) The Minister may cancel or amend an authorisation—

(*a*) in accordance with Article 27, 48 or 88 of the Biocidal Products Regulation,

(*b*) where no application for renewal of an authorisation is received, or

(*c*) where it appears to the Minister to be expedient for the public good to do so.

(3) Where an authorisation for a product is cancelled, the Minister may determine the grace period for disposal, making available on the market or use of existing stock in accordance with Article 52 of the Biocidal Products Regulation.

Notification under Article 17.6 of Biocidal Products Regulation

7. (1) A person wishing to place on the market, make available or use a biocidal product in accordance with Article 17.6 of the Biocidal Products Regulation shall apply to the Minister in writing in a format determined by the Minister with the appropriate fee as determined under Regulation 25.

(2) A person making a notification under paragraph (1) shall submit such other information as the Minister considers necessary.

(3) The Minister may attach such conditions to the authorisation for a product notified under Article 17.6 of the Biocidal Products Regulation as the Minister considers appropriate.

Notification under Article 27 of Biocidal Products Regulation

8. (1) A person wishing to place on the market, make available and use a biocidal product in accordance with Article 27 of the Biocidal Products Regulation shall apply to the Minister in writing in a format determined by the Minister with the appropriate fee as determined under Regulation 25.

(2) A person making a notification under paragraph (1) shall submit such other information as the Minister considers necessary.

(3) The Minister may attach such conditions to the authorisation for a product notified under Article 27 of the Biocidal Products Regulation as the Minister considers appropriate.

Notification under national measures

9. (1) A person wishing to place on the market, make available or use a biocidal product containing an existing active substance or substances that have not yet been approved for that product-type based on evaluation under Commission Regulation (EC) No 1451/2007 of 4 December 2007 and where the provisions of Chapters IV, V, VI, VII and VIII of the Biocidal Products Regulation are not yet applicable, shall apply to the Minister in a format determined by the Minister with such information as the Minister requires and an appropriate fee as determined under Regulation 25.

(2) A person making an application under paragraph (1) shall—

(*a*) submit an application for notification before placing on the market, making available or using the biocidal product, and

(*b*) submit such other information as the Minister considers necessary.

(3) The Minister may attach such conditions to a notification as the Minister considers appropriate.

Notification of biocidal products outside scope of Directive 98/8/EC

10. (1) A person wishing to place on the market, make available or use a biocidal product not covered by the scope of Directive 98/8/EC and where the provisions of Chapters IV, V, VI, VII and VIII of the Biocidal Products Regulation are not yet applicable, shall apply to the Minister in a format determined by the Minister with such information as the Minister requires and an appropriate fee as determined under Regulation 25.

(2) A person making an application under paragraph (1) shall—

(*a*) submit an application for notification of a biocidal product in accordance with the timelines stipulated under Article 93 of the Biocidal Products Regulation, and

(*b*) submit such other information as the Minister considers necessary.

(3) The Minister may attach such conditions to a notification as the Minister considers appropriate.

Cancellation or amendment of notification under national measures

11. (1) A notification holder who wishes to cancel or amend a notification of a biocidal product notified under Regulation 9 or 10 shall apply to the Minister to do so.

(2) A person making an application under paragraph (1) shall apply to the Minister in a format determined by the Minister with such information as the Minister requires and an appropriate fee as determined under Regulation 25.

(3) The Minister may withdraw or amend a notification issued under Regulation 9 or 10 where it appears to the Minister that a condition of the notification is not being adhered to or it is in the public interest to do so.

(4) Where a notification for a product is cancelled, the Minister may determine the grace period for disposal, making available on the market or use of existing stock.

Part 4

Biocidal Product Permits

Application for parallel trade permit

12. (1) A person shall not place on the market, make available or use a biocidal product unless that person has a permit issued in accordance with Chapter X of the Biocidal Products Regulation (referred to as "parallel trade permit").

(2) A person seeking a parallel trade permit under Chapter X of the Biocidal Products Regulation shall apply to the Minister for a parallel trade permit in a format determined by the Minister with the appropriate fee as determined under Regulation 25.

(3) A person making an application under paragraph (2) shall comply with Article 53.4 of the Biocidal Products Regulation and shall submit such other information as the Minister considers necessary.

(4) The Minister may attach such conditions to a permit as the Minister considers appropriate.

Parallel trade permit

13. (1) Where a parallel trade permit has been issued for a biocidal product by the Minister under Regulation 12, the Minister may issue a permit containing—

(*a*) a number to be known as an IE/BPA number, and

(*b*) details of conditions attached by the Minister.

Withdrawal, cancellation or amendment of parallel trade permit

14. (1) The Minister, where it appears to him or her that a condition of the parallel trade permit is not being adhered to or it is in the public interest to do so, may—

(*a*) withdraw a parallel trade permit in accordance with Article 53 of the Biocidal Products Regulation, or

(*b*) cancel or amend a parallel trade permit in accordance with Chapter IX of the Biocidal Products Regulation.

(2) The Minister may, on withdrawal or amendment of a parallel trade permit, determine the grace period for disposal, making available on the market or use of existing stock.

Application for trial permit

15. (1) A person shall not undertake an experiment, test, trial or a programme of experiments, tests or trials unless that person has a trial permit issued in accordance with Article 56 of the Biocidal Products Regulation.

(2) A person seeking a trial permit under Article 56 shall apply to the Minister in writing in a format determined by the Minister with the appropriate fee as determined under Regulation 25.

(3) A person making an application under paragraph (2) shall comply with Article 56 of the Biocidal Products Regulation and shall submit such other information as the Minister considers necessary.

(4) The Minister may attach such conditions to a permit as the Minister considers appropriate.

Trial permit

16. Where a trial permit has been issued by the Minister under Regulation 15, the Minister may issue a permit containing—

(*a*) a trial permit number, and

(*b*) details of conditions attached by the Minister.

Withdrawal, cancellation or amendment of trial permit

17. The Minister may withdraw, cancel or amend a trial permit issued under Regulation 15 where it appears to the Minister that a condition of the trial permit is not being adhered to or it is in the public interest to do so.

Part 5

Registers

Register of users and manufacturers of biocidal products

18. (1) The Minister may establish a register of users of professional biocidal products for the purposes of Article 17.5 of the Biocidal Products Regulation.

(2) The Minister may establish a register of manufacturers or persons who make available biocidal products for the purposes of Article 65 of the Biocidal Products Regulation.

Product Register

19. (1) The Minister may establish a register of authorised, notified and permitted biocidal products to be known as the "Biocidal Products Register" (hereinafter referred to as the "Product Register").

(2) The Minister may enter an authorised, notified or permitted biocidal product in the Product Register.

(3) The Minister may publish the Product Register in a manner as he or she determines appropriate.

(4) Subject to paragraph (5), the Minister may remove a biocidal product from the Product Register when—

(*a*) the product is no longer authorised, notified or permitted,

(*b*) the fees for maintaining the Register are not paid, or

(*c*) it appears to the Minister to be expedient to do so.

(5) The Minister may, in respect of any biocidal product removed from the Product Register in accordance with paragraph (4), determine a grace period for disposal, making available on the market or use of existing stock.

Placing on market, making available or use of biocidal products in Product Register

20. (1) A person shall not place on the market, make available or use a biocidal product unless that product is entered in the Product Register or is subject to a grace period determined under Regulation 19 (5).

(2) A person shall not use a biocidal product unless it has been placed on the market or made available on the market in accordance with paragraph (1) or it has been granted a trial permit in accordance with Regulation 15.

Part 6

Biocidal Products Ancillary Rules

Advertising

21. A person shall not advertise biocidal products other than—

(*a*) authorised, notified or permitted under Regulations 4, 7, 8, 9, 10 or 12,

(*b*) in accordance with Article 72 of the Biocidal Products Regulation, and

(*c*) in accordance with any guidelines issued by the Minister.

Records

22. (1) A person referred to in Article 65.2 and Article 68.1 of the Biocidal Products Regulation shall maintain records in accordance with those Articles and such other records as the Minister may determine.

(2) A person on the register established under Regulation 18 and 19 shall maintain such records as determined by the Minister.

Statistics

23. A person, who—

(*a*) manufactures, or

(*b*) moves in or out of the State

a biocidal product, shall when requested, complete a statistical return on his or her activities in any particular year in a format determined by the Minister.

Part 7

Articles treated with Biocidal Products

Placing on the market of treated articles

24. (1) A person wishing to place on the market a treated article shall do so in accordance with Article 58 and 94 of the Biocidal Products Regulation.

(2) The Minister may establish further procedures and labelling requirements for the application of Article 58 of the Biocidal Products Regulation.

(3) A person placing a treated article on the market under paragraph (1) shall submit such other information as the Minister considers necessary.

Part 8

Fees

Fees

25. (1) The Minister shall charge a fee for a service or act undertaken for the purposes of these Regulations or the Biocidal Products Regulation as the Minister may, from time to time, determine based on the principles set out in Article 80 of the Biocidal Products Regulation.

(2) The Minister may not consider an application for a service or act under these Regulations or the Biocidal Products Regulation unless the appropriate fee is paid in accordance with this Regulation or Commission Implementing Regulation (EU) No 564/2013 as the case may be.

(3) The Minister may charge a fee to place and maintain a biocidal product on the Product Register.

(4) A fee, as determined by the Minister, for maintaining a biocidal product on the Product Register shall be paid for all biocidal products no later than 31st December in the year prior to the year in respect of which the payment is made or by such other date as the Minister may from time to time determine (in this Regulation referred to as "the due date").

(5) The Minister may remove a biocidal product from the Product Register where a fee due under paragraph (4) is not paid by the due date.

(6) The Minister may reinstate a biocidal product on the Product Register if the fee due under paragraph (4) is paid to the Minister with such other costs as the Minister considers appropriate.

(7) The Minister may waive a fee in whole or in part where the Minister is of the view that it is appropriate to do so.

(8) An application for a waiver of a fee shall be in such form and contain such particulars as the Minister may require.

Part 9

Exceptional authorisations

Authorisations of biocidal products under Article 55 of Biocidal Products Regulation

26. (1) The Minister may permit the making available on the market or use of a biocidal product if it is necessary for public health, animal health or the environment in accordance with Article 55.1 of the Biocidal Products Regulation.

(2) The Minister may permit a provisional authorisation of a biocidal product containing a new active substance in accordance with Article 55.2 of the Biocidal Products Regulation.

Part 10

Authorised Officers

Appointment of authorised officers

27. (1) The Minister may appoint such and so many persons as he or she thinks fit to be authorised officers for the purpose of these Regulations.

(2) A warrant of appointment as an authorised officer shall be issued to every person appointed under this Regulation and when exercising a function conferred on that person as an authorised officer such person shall, if requested by a person affected, produce the warrant or evidence that he or she is such an officer or person.

(3) The Minister may terminate the appointment of an authorised officer appointed by him or her, whether or not the appointment was for a fixed period.

(4) An appointment as an authorised officer ceases—

(*a*) if it is terminated pursuant to paragraph (3),

(*b*) if it is for a fixed period, on the expiry of that period, or

(*c*) if the person appointed is an officer of the Minister, on the person ceasing to be such an officer.

(5) Nothing in paragraph (4) shall be construed so as to prevent the Minister from reappointing as an authorised officer a person to whom that paragraph related.

Functions of authorised officer

28. (1) For the purposes of these Regulations or the Biocidal Products Regulation, an authorised officer may—

(*a*) enter and inspect, at all reasonable times, a premises of which he or she has reasonable grounds for believing that—

(i) a biocidal product or treated article is, may be or has been present,

(ii) a record relating to a biocidal product or treated article is, may be or has been present,

(iii) equipment or machinery used in connection with a biocidal product or treated article is, may be or has been present, or

(iv) take, without making a payment, a sample from or of a biocidal product, treated article, production batch sample or other thing as he or she may reasonably require and carry out or cause to be carried out on the sample such tests, analyses, examinations or inspections as he or she considers necessary or expedient,

(*b*) examine a biocidal product or treated article,

(*c*) inspect a vehicle, vessel, aircraft, container, equipment, machinery or other thing used in connection with a biocidal product or treated article and require a person in charge or control of such a thing to refrain from moving it,

(*d*) require the owner or person in charge of a premises to produce to the officer such records (and in the case of a record stored in non-legible form, produce to him or her a copy in a legible form) that are in the person's possession or procurement, or under the person's control, as the officer may reasonably require,

(*e*) require the name and address of a person, including the owner or person in possession or control of a biocidal product, treated article or other thing, or

(*f*) inspect and take copies of any record (including a legible reproduction of one stored in non-legible form) or extracts from the record that the officer finds or is produced to him or her during an inspection.

(2) Where an authorised officer has reasonable grounds for believing that—

(*a*) there is a risk from a biocidal product, treated article or a product represented as such a product,

(*b*) an offence is being or has been committed under these Regulations or the Biocidal Products Regulation, or

(*c*) evidence of a matter referred to in subparagraphs (*a*) or (*b*), or an offence or contravention to which subparagraphs (*a*) or (*b*) relates may be, is or has been on a premises,

the officer may, in addition to the functions exercisable by him or her under paragraph (1), do one or more of the following:

(i) search the premises;

(ii) if necessary, cause to have stopped, a vehicle, vessel, aircraft, container, equipment, machinery or other thing used in connection with a biocidal product, treated article or a product represented as such a product, and may require it to be moved for inspection to such places he or she directs;

(iii) stop and, where he or she believes there is or may be evidence on a person of an offence referred to in paragraph (*c*), if the officer is not a member of the Garda Síochána or an officer of Customs and Excise, cause the search of the person in accordance with paragraph (6);

(iv) give such direction to a person who has a biocidal product, treated article or a product represented as such a product, a vehicle, vessel, container, equipment, machinery or other thing used in connection with a biocidal product or treated article in his or her possession or under his or her control or information relating to such, as the authorised officer may reasonably consider necessary for the purposes of these Regulations and the Biocidal Products Regulation;

(v) seize and detain a biocidal product, treated article or a product represented as such a product, vehicle, container, equipment, machinery, record or other thing;

(vi) mark or otherwise identify a biocidal product, treated article or a product represented as such a product, vessel, vehicle, machinery, equipment or other thing used in connection with a biocidal product or treated article or a sample taken under paragraph (2).

(3) An authorised officer may enter, at all reasonable times, a premises to carry out surveys or programmes relating to biocidal products or treated articles.

(4) An authorised officer shall not enter, except with the consent of the occupier, a private dwelling unless he or she has obtained a search warrant under paragraph (14).

(5) Where a member of the Garda Síochána or an officer of Customs and Excise has reasonable grounds for believing that there is evidence on a person of an offence referred to in paragraph (2)(*b*), or upon the request of an authorised officer, the member or officer may without warrant—

(*a*) search or cause to be searched by such a member or officer the person and, if the member or officer considers it necessary for that purpose, detain the person for such time as is reasonably necessary to carry out the search,

(*b*) search or cause to be searched by such a member or officer any vehicle in which the member or officer suspects that such substance may be found and for the purpose of carrying out the search, if any such member or officer thinks fit, require the person who is, for the time being, in charge or control of the vehicle to bring it to a stop and when stopped to refrain from moving it or, in case the vehicle is already stationary, to refrain from moving it, or

(*c*) seize and detain, or cause to be seized and detained by such a member or officer, anything found in the course of a search under this section, which any such member or officer reasonably suspects to be something which might be required as evidence in proceedings for an offence referred to in paragraph (2)(*b*).

(6) Where a member of the Garda Síochána or an officer of Customs and Excise (as the case may be) decides to search or cause to be searched a person under paragraph (5) the member or officer may require the person to accompany that member or officer to either a Garda Síochána station or a customs office for the purpose of being so searched at that station or office.

(7) An authorised officer, when exercising a function under this Regulation, may be accompanied by other persons and may take with him or her, or those persons may take with them, any equipment or materials to assist the officer in the performance of the functions.

(8) An authorised officer may use reasonable force, if necessary, in the exercise of his or her functions under this Regulation.

(9) An authorised officer is not liable in any proceedings for an offence for anything done in the purported exercise of his or her functions under this Regulation if the court is satisfied that the act was done in good faith and that there were reasonable grounds for so doing it.

(10) If, in the course of exercising a function under this Regulation, an authorised officer finds or comes into possession of anything that the officer has reasonable grounds for believing to be evidence of an offence or suspected offence under these Regulations or the Biocidal Products Regulation, it may be seized and retained for use in evidence in criminal proceedings for an offence under these Regulations or the Biocidal Products Regulation.

(11) An authorised officer who is not a member of the Garda Síochána or an officer of Customs and Excise in uniform, shall not stop a vehicle in a public place for the purposes of paragraph (2), unless he or she is accompanied by such a member.

(12) Nothing in these Regulations shall be construed as affecting a power conferred by another enactment to search, or to stop, seize or detain property, which may be exercised by a member of the Garda Síochána or an officer of Customs and Excise.

(13) Nothing in section 17 of the Industrial and Provident Societies Act 1893 prevents an authorised officer from exercising a function conferred on him or her by these Regulations.

(14) If a judge of the District Court is satisfied by information on oath of an authorised officer that there are reasonable grounds for suspecting-

(*a*) an offence is being or has been committed under these Regulations or the Biocidal Products Regulation,

(*b*) evidence of an offence or contravention or intended contravention to which paragraph (*a*) relates may be, is or has been on a premises,

(*c*) there is or was a biocidal product, treated article or a product represented as such a product, document or other record relating to a biocidal product, treated article, equipment or other thing made, used or adapted for use (including manufacture and transport) in connection with a biocidal product or treated article, or

(*d*) a document or other record related to a thing to which subparagraph (*a*), (*b*) or (*c*) refers is or may be on the premises,

the judge may issue a search warrant.

(15) A search warrant under this Regulation shall be expressed and operate to authorise a named authorised officer, accompanied by such authorised officers or other persons as the named authorised officer thinks necessary, at any time, within one month from the date of issue of the warrant, on production if so requested of the warrant, to enter (if necessary by use of reasonable force) the premises, vehicle, vessel or aircraft named in the warrant.

(16) If a premises is entered under a warrant issued under this Regulation, an authorised officer so entering may exercise all or any of the functions conferred on an authorised officer under these Regulations.

Part 11

Compliance Notices

Compliance Notice

29. (1) Without prejudice to Regulation 28, if an authorised officer has reasonable grounds to suspect that—

(*a*) an act of the institutions of the European Communities relating to biocidal products or treated articles is not being or has not been complied with or there are reasons to believe that such an act of the institutions of the European Communities, will not be complied with,

(*b*) it is necessary for the protection of human health, animal health or welfare, plant health or the environment,

(*c*) it is necessary, ancillary or supplementary for an act of the institutions of the European Communities in relation to biocidal products and treated articles to have full effect,

(*d*) an article, material, substance or mixture, animal, animal product, food or feed is or may be contaminated with a biocidal product, treated article or active substance, or

(*e*) an offence has been committed under these Regulations or the Biocidal Products Regulation,

the authorised officer may serve or cause to be served on the owner or person who appears to be in charge, possession or control of a biocidal product, treated article, material, substance, mixture, premises, vehicle, vessel, animal, animal product, feed or food a notice ("compliance notice") stating that opinion and directing that—

(i) an animal, animal product, feed or food be dealt with in a manner specified in the notice,

(ii) a biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product be dealt with in a manner specified in the notice, including its removal from the market,

(iii) an animal, animal product, feed or food be disposed of or destroyed in a manner (if any) specified in the notice,

(iv) a biocidal product, treated article, material, substance or mixture be disposed of or destroyed in a manner (if any) specified in the notice,

(v) a specified operation or activity cease on a premises, vessel or vehicle,

(vi) a specified operation or activity take place only in a manner specified in the notice,

(vii) a specified operation or activity may only be carried out under and in accordance with such terms and conditions as are specified in the compliance notice, or

(viii) records in relation to the aforementioned activities be maintained and submitted to an authorised officer on request.

(2) A person shall comply with a compliance notice or a requirement of a compliance notice unless and until the notice is annulled under paragraphs (4) or (9) as the case may be.

(3) A requirement contained in a compliance notice may specify a time limit within which the notice is to be complied with.

(4) A requirement specified in a compliance notice (in this paragraph referred to as "the earlier compliance notice") may be amended or withdrawn by a further notice in writing and the earlier compliance notice has effect subject to such amendment or withdrawal.

(5) A compliance notice, whether amended under paragraph (4) or not, may require the owner or person in charge of a premises, vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product to choose between one or more of the requirements specified in the compliance notice and that person shall comply with the alternative requirement that he or she chooses.

(6) A person affected by a compliance notice may, within 7 days of service of the compliance notice, apply to the Judge of the District Court having jurisdiction in the District Court District where—

(*a*) the business is situated, or

(*b*) the person ordinarily resides

on the grounds that the compliance notice or any term of the compliance notice is not reasonable, having regard to the objectives of the Biocidal Products Regulation or these Regulations (in this Regulation referred to as "an appeal").

(7) An appeal may be heard at any sitting of the District Court within the appropriate District Court Area.

(8) A person making an appeal shall serve notice of the appeal, which shall contain a statement of the grounds upon which it is alleged that the compliance notice or any term of the compliance notice is unreasonable having regard to the objectives of Biocidal Products Regulation or these Regulations, on the Minister at least 2 working days prior to the hearing of the appeal and a copy of the notice of appeal shall be lodged with the appropriate District Court Clerk.

(9) On the hearing of an appeal, a Judge of the District Court may confirm, with or without modification, or annul a compliance notice.

(10) A person, including a person on whom a compliance notice is served, shall not-

(*a*) pending the determination of an appeal, deal with a premises, vehicle, vessel, animal, animal product, plant, plant product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product to which a compliance notice relates other than under and in accordance with the notice, or

(*b*) after the appeal, deal with a premises, vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product to which a compliance notice relates other than under and in accordance with the compliance notice or compliance notice as modified.

(11) If—

(*a*) a person, by act or omission, fails to comply, whether within the time specified or otherwise, with a compliance notice (including a compliance notice modified in accordance with paragraphs (4) or (9) as the case may be), or

(*b*) an authorised officer has reasonable cause to suspect—

(i) that a compliance notice (including a compliance notice modified in accordance with paragraph (4) or (9) as the case may be), is not or will not be complied with, or

(ii) pending the determination of an appeal, a biocidal product, treated article, material, substance, mixture, premises, vessel, vehicle, animal, feed, a feed additive or food to which the compliance notice relates is or will not be dealt with other than in accordance with paragraph (10),

an authorised officer may seize, detain or remove a vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product in a manner that he or she thinks fit and sell or dispose of it in a manner as the authorised officer considers appropriate.

(12) Subject to paragraph (13), the proceeds of the sale or disposal of a vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product under paragraph (11) shall be paid to the owner of a vehicle, vessel, animal, animal product, plant, plant product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product as soon as may be after such sale or disposal and after a person has satisfied the Minister that he or she is the owner or otherwise entitled to the proceeds of the sale or

disposal of the vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product.

(13) The costs of seizure, sale or disposal of a vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product under this Regulation shall be recoverable by the Minister—

(*a*) as a simple contract debt in a court of competent jurisdiction, or

(*b*) by deducting the costs from any sum due by the Minister to a person on whom a notice has been served.

(14) The costs of any action required by a compliance notice shall be borne by the owner of a premises, vehicle, vessel, animal, animal product, feed, food, biocidal product, treated article, material, substance, mixture or ingredient for a biocidal product to which the notice relates.

Service of compliance notice

30. (1) Subject to paragraph (2), a compliance notice shall be addressed to the person concerned by name and may be served on or given to the person—

(*a*) by giving a copy to the person, his or her employee, servant or agent, or in the case of a partnership by delivery to any of the partners,

(*b*) by leaving a copy at the address at which the person ordinarily resides, where he or she carries out business, or, where an address for service has been furnished, at that address,

(*c*) by sending a copy by post in a prepaid registered letter to the address at which the person ordinarily resides, carries out business, in the case of a body corporate or unincorporated body the registered office of the body or, where an address for service has been furnished, at that address,

(*d*) by electronic communication,

(*e*) if the address at which the person ordinarily resides cannot be ascertained by reasonable enquiry and the compliance notice relates to a premises, by delivering a copy to the premises or by affixing a copy in a conspicuous position on or near the premises, or

(*f*) if the Minister or an authorised officer considers that the immediate giving of a compliance notice is required, by sending a copy, by means of a facsimile machine, to a device or facility for the reception of facsimiles located at the address at which the person ordinarily resides or carries on business or, if an address for the service of notices has been furnished by the person, that address, provided that the sender's facsimile machine generates a message confirming successful transmission of the total number of pages of the notice.

(2) If a compliance notice is to be served on or given to a person who is the owner or occupier of a premises and the name of the person cannot be ascertained by reasonable enquiry, it may be addressed to the person by using the words 'the owner' or 'the occupier'.

(3) A person shall not, at any time within 6 months after a compliance notice is affixed under paragraph (2), remove, damage or deface the notice without lawful authority.

(4) For the purposes of this Regulation, a company within the meaning of the Companies Acts is considered to be ordinarily resident at its registered office and every other body corporate or unincorporated body is considered to be ordinarily resident at its principal office or place of business.

Part 12

Offences, Prosecutions etc.

Obstruction

31. (1) A person shall not-

(*a*) obstruct or impede an authorised officer in the exercise of his or her functions under Regulation 28,

(*b*) fail, without reasonable cause, to comply with a requirement or direction of an authorised officer under Regulation 28,

(*c*) in purporting to give information required by an authorised officer for the performance of the officer's functions under these Regulations-

(i) make a statement which he or she knows to be false in a material particular or recklessly make a statement which is false in a material particular, or

(ii) fail to disclose any material particular, or

(*d*) aid or abet a contravention of these Regulations or the Biocidal Products Regulation.

Offences

32. (1) A person commits an offence if he or she fails to comply with the Biocidal Products Regulation and in particular—

(*a*) Chapter II and III of the Biocidal Products Regulation in relation to active substances;

(*b*) Articles 17, 19, 20, 25, 26, 27, 29, 32, 33, 34, 39, 42 and 43 of the Biocidal Products Regulation, regarding authorisation of a biocidal product;

(*c*) Articles 31, 45, 48 and Chapter IX of the Biocidal Products Regulation, regarding renewal, withdrawal and amendment of authorisation of a biocidal product;

(*d*) Chapter XII of the Biocidal Products Regulation regarding derogations or special cases for authorisation of a biocidal product;

(*e*) Article 27, 28, 55 and 56 of the Biocidal Products Regulation, regarding specific conditions for authorisation of a biocidal product;

(*f*) Articles 17.5, 37, 47 and Chapter XV of the Biocidal Products Regulation regarding use and information;

(*g*) Chapter XIII of the Biocidal Products Regulation regarding treated articles;

(*h*) Chapter XIV of the Biocidal Products Regulation regarding data protection and data sharing;

(*i*) Articles 69 and 72 of the Biocidal Products Regulation regarding classification, packaging, labelling and advertising of biocidal products;

(*j*) Articles 65.2 and 68 of the Biocidal Products Regulation regarding record keeping;

(*k*) Chapter XI of the Biocidal Products Regulation regarding technical equivalence;

(*l*) Chapter X of the Biocidal Products Regulation regarding parallel trade.

(2) A person commits an offence if he or she fails to comply with Regulation 3, 4, 6, 7, 8, 9, 10, 11, 12, 15, 20, 21, 22, 23, 24, 28, 29, 30 or 31.

(3) A person commits an offence if he or she fails to comply with a condition of—

(*a*) an authorisation under Regulation 4,

(*b*) a notification under Regulation 7, 8, 9 or 10, or

(*c*) a permit under Regulation 12 or 15.

(4) A person commits an offence if he or she-

(*a*) tampers with any biocidal product or treated article so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the biocidal product or treated article, or

(*b*) tampers with any product or thing so as to procure that any sample of it taken pursuant to these Regulations does not correctly represent the product sampled, or

(*c*) tampers or interferes with any sample taken pursuant to these Regulations.

(4) A person found guilty of an offence under these Regulations or the Biocidal Products Regulation is liable on conviction to a Class A fine.

Prosecutions and specific rules of evidence

33. (1) Proceedings for an offence under these Regulations may be brought summarily by the Minister.

(2) In proceedings for an offence under these Regulations, evidence that claims have been made that a product—

(*a*) protects public health, animal health, drinking water, substances, mixtures, materials, articles, equipment, structures, vehicles, products against harmful organisms or prevents the action of such organisms,

(*b*) influences or exerts a controlling effect on the life processes of target organisms,

(*c*) preserves articles, substances, mixtures, films or coatings, wood or timber, fibre, masonry or other construction materials, working or cutting fluids, leather, rubber, polymerised materials, liquids used for cooling and processing systems, equipment, structures, human and animal corpses or parts thereof,

(*d*) destroys all or parts of undesired target organisms or checks, prevents, deters or renders harmless an undesired target organism, or

(*e*) fulfils one or more of the definitions or descriptions in accordance with Annex V of the Biocidal Products Regulation

shall, until the contrary is shown, be sufficient evidence that it is a biocidal product.

(3) In proceedings for an offence under these Regulations, evidence that claims have been made that a treated article that has been treated with or intentionally incorporates one or more biocidal products—

(*a*) protects an article, substance or mixture against harmful organisms or prevents the action of such organisms,

(*b*) influences the life processes of target organisms,

(*c*) preserves an article, substance or mixture,

(*d*) destroys all or parts of undesired target organisms or checks or prevents undesired target organisms in an article, substance or mixture, or

(*e*) is a treated article within the meaning of Article 58 of the Biocidal Products Regulation

shall, until the contrary is shown, be sufficient evidence that it is a treated article.

(4) In any proceedings for an offence under these Regulations—

(*a*) the result of any test, examination or analysis of, or any report on, a sample taken shall not be adduced unless, before the proceedings were instituted, one of the parts into which the sample was divided was left with, delivered to, or sent by registered post to the defendant or his or her agent,

(*b*) evidence of the presence of a substance contained in a biocidal product or treated article in or on equipment capable of use for application of the biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the owner or person in possession of the equipment,

(*c*) evidence of the presence of a residue of a substance contained in a biocidal product on agricultural produce, in soil or compost or in or on surfaces or other materials which may have been treated with or exposed to the biocidal product, shall be evidence, until the contrary is proved, of the use of the biocidal product by the owner, occupier or person in possession, as the case may be,

(*d*) a certificate showing the results of analysis shall, until the contrary is shown, be sufficient evidence of the facts certified to therein in relation to—

(i) the presence in a biocidal product of any active substance, impurity or formulating ingredient and the level of any such presence, or

(ii) the presence of a residue of a biocidal product or substance contained in a biocidal product and the level of such residues in any controlled product or thing, and

a document purporting to be such a certificate shall be such a certificate, or

(*e*) the presence of a biocidal product or treated article on any premises (including any stores), shall, until the contrary is shown, be sufficient evidence that the biocidal product or treated article in question is or was being placed on the market or used by the owner and by the occupier of such premises.

Fixed Payment Notice

34. (1) If the Minister has reasonable grounds for suspecting that a person is committing or has committed an offence under these Regulations or the Biocidal Products Regulation, he or she may serve a notice in writing ("fixed payment notice") on that person stating that—

(*a*) the person is alleged to have committed the offence,

(*b*) the person may during the period of 28 days from the date of the notice make to the Minister a payment of €250 accompanied by the notice, and

(*c*) a prosecution in respect of the alleged offence will not be instituted during the period specified in the fixed payment notice and, if the payment specified in the notice is made during that period, no prosecution in respect of the alleged offence will be instituted.

(2) If a fixed payment notice is given—

(*a*) a person to whom the notice applies may, during the period specified in the notice, make to the Minister at the address specified in the notice the payment specified in the notice accompanied by the notice,

(*b*) the Minister may receive the payment, issue a receipt for it and retain the money so paid, and any payment so received shall not be recoverable in any circumstances by the person who made it, and

(*c*) a prosecution in respect of the alleged offence shall not be instituted in the period specified in the notice, and if the payment so specified is made during that period, no prosecution in respect of the alleged offence will be instituted.

(3) In a prosecution for an offence under these Regulations or the Biocidal Products Regulations, the onus of proving that a payment pursuant to a notice under this Regulation has been made lies on the defendant.

Part 13

Revocation

Application and Saver

35. (1) The European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 (S.I. No. 625 of 2001) are revoked.

(2) A biocidal product authorised, registered, notified or permitted to be marketed or to be used under the European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 shall continue to be so authorised, notified or permitted under the same terms and conditions until other wise determined under Articles 89.2 and 89.3 of the Biocidal Products Regulation.

(3) Any notice issued under Regulation 38 of the European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 shall continue in force as though issued under Regulation 29.

(4) Any proceedings issued under Regulation 39 of the European Communities (Authorization, Placing on the Market, Use and Control of Biocidal Products) Regulations 2001 shall continue as if initiated under Regulation 33.

L.S.

GIVEN under my Official Seal,
5 November 2013.

SIMON COVENEY,
Minister for Agriculture, Food and the Marine.

EXPLANATORY NOTE

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

These Regulations set down the requirements and conditions relating to the authorisation and registration of biocidal products, which must be complied with in relation to the placing of such products on the market and their usage, in accordance with European Parliament and Council Regulation (EU) No. 528/2012.

In addition, these Regulations set down the requirements which must be met for articles treated with biocidal products that are intended to be placed on the market, together with associated enforcement and financial provisions.

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