
STATUTORY INSTRUMENTS

2015 No. 821

ENVIRONMENTAL PROTECTION

The Nagoya Protocol (Compliance) Regulations 2015

Made - - - - *17th March 2015*

Laid before Parliament *23rd March 2015*

Coming into force in accordance with regulation 1

The Secretary of State, who is designated for the purposes of section 2(2) of the European Communities Act 1972⁽¹⁾ in relation to the environment⁽²⁾, makes these Regulations in exercise of the powers conferred by that section of that Act.

PART 1

Introduction

Citation and commencement

- 1.—(1) These Regulations may be cited as the Nagoya Protocol (Compliance) Regulations 2015.
(2) Parts 1 and 2 come into force on 9th July 2015.
(3) Parts 3 to 6 and the Schedule come into force on 12th October 2015.

Interpretation

- 2.—(1) In these Regulations—
“body corporate” includes a limited liability partnership;
“civil sanction” has the meaning given by regulation 7;
“compliance notice” has the meaning given by paragraph 1 of the Schedule;

(1) 1972 c. 68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c. 51), section 27(1)(a), and the European Union (Amendment) Act 2008 (c. 7), Part 1 of the Schedule. Under section 57 of the Scotland Act 1998 (c. 46), despite the transfer to the Scottish Ministers of functions in relation to implementing obligations under EU law in respect of devolved matters, the function of the Secretary of State in relation to implementing those obligations continues to be exercisable as regards Scotland. Under paragraph 5 of Schedule 3 to the Government of Wales Act 2006 (c. 32), despite the transfer to the Welsh Ministers of functions in relation to implementing obligations under EU law in relation to devolved matters, the Secretary of State retains power to exercise such functions as regards Wales.

(2) S.I. 2008/301.

“the EU Regulation” means Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union⁽³⁾;

“inspector” has the meaning given by regulation 9;

“the Nagoya Protocol” means the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity adopted at the tenth meeting of the Conference of the Parties to the Convention on Biological Diversity on 29th October 2010⁽⁴⁾;

“non-compliance penalty” has the meaning given by paragraph 23 of the Schedule;

“officer” in relation to a body corporate, means any director, secretary or other similar officer of the body corporate;

“partnership” does not include a limited liability partnership;

“premises” includes any vehicle, vessel, aircraft, hovercraft, tent or moveable structure;

“stop notice” has the meaning given by paragraph 12 of the Schedule;

“unincorporated association” does not include a partnership;

“variable monetary penalty” has the meaning given by paragraph 2 of the Schedule.

(2) In paragraph (1), “director”, in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(3) Subject to paragraph (4), terms used in these Regulations that are used in the EU Regulation have the meaning they bear in that Regulation.

(4) For the purposes of these Regulations, the EU Regulation is to be read as though references to “traditional knowledge associated with genetic resources” include traditional knowledge described in paragraph (5).

(5) These Regulations also apply to traditional knowledge associated with genetic resources held by an indigenous or local community that is described as such in mutually agreed terms applying to the utilisation of traditional knowledge.

PART 2

Competent authority and other functions

Competent authority

3. The Secretary of State is the competent authority for the purposes of the EU Regulation.

Register of collections

4. The Secretary of State must carry out the functions of the member State under Article 5 of the EU Regulation.

Monitoring user compliance

5. The Secretary of State must make the request referred to in Article 7(1) of the EU Regulation.

(3) OJ No L 150, 20.5.2014, p. 59.

(4) Miscellaneous series No. 5/2014: Cm 8856. ISBN 9781474102919.

Complementary functions

6. The Secretary of State must—
- (a) carry out the functions of the member State under Article 13 of the EU Regulation;
 - (b) take any other appropriate, effective and proportionate administrative or policy measures necessary to provide that genetic resources or traditional knowledge associated with genetic resources are utilised in accordance with the Nagoya Protocol.

PART 3

Civil sanctions

Power to impose civil sanctions

7.—(1) The Secretary of State may impose a requirement upon a person to comply with a compliance notice, a stop notice or to pay a variable monetary or a non-compliance penalty (a “civil sanction”) as set out in the Schedule.

- (2) The Schedule (which provides for civil sanctions) has effect.

Due diligence obligations of the EU Regulation which are subject to civil sanctions

8.—(1) Subject to paragraphs (2) and (3), civil sanctions may be imposed in relation to a failure to comply with any of the following provisions—

- (a) Article 4(1) of the EU Regulation (obligation to exercise due diligence);
- (b) Article 4(3) of the EU Regulation (obligation to seek, keep and transfer information and documentation to subsequent users);
- (c) Article 7(2) of the EU Regulation (obligation to make a declaration of due diligence).

(2) There is no failure to comply with the provisions referred to in paragraph (1) if the Secretary of State is satisfied that the user has shown that they have effectively implemented best practice recognised under Article 8(2) of the EU Regulation.

(3) There is no failure to comply with Article 4(3) of the EU Regulation if the Secretary of State is satisfied that—

- (a) the user is considered to have exercised due diligence under Article 4(4) of the EU Regulation (use of the Plant Treaty’s Standard Material Transfer Agreement for material not listed in Annex 1 to that Treaty);
- (b) the user is considered to have exercised due diligence under Article 4(7) of the EU Regulation (users obtaining material from a registered collection); or
- (c) the use is in accordance with Article 4(8) of the EU Regulation (use of pathogen for the purpose of public health emergency preparedness).

PART 4

Enforcement

Inspectors

9. The Secretary of State may authorise in writing a person (an “inspector”) to carry out inspections for the purpose of enforcing the EU Regulation.

Powers of entry

10.—(1) An inspector may, on serving reasonable notice, enter premises at any reasonable hour for the purpose of enforcing the EU Regulation, except premises used wholly or mainly as a private dwelling house.

(2) The requirement to serve a notice does not apply—

- (a) where reasonable efforts to agree an appointment have failed;
- (b) where an inspector reasonably believes that serving a notice would defeat the object of the entry;
- (c) where an inspector has a reasonable suspicion that an offence has been committed under regulation 13; or
- (d) in an emergency.

(3) An inspector must, if requested, produce a duly authenticated authorisation document.

(4) Paragraph (1) does not affect any right of entry conferred by a warrant issued in accordance with paragraph (5).

(5) A justice of the peace may by signed warrant permit an inspector to enter premises, if necessary by reasonable force, if the justice, on sworn information in writing, is satisfied that—

- (a) there are reasonable grounds for an inspector to enter those premises for the purpose of enforcing the EU Regulation; and
- (b) one of the conditions in paragraph (6) is met.

(6) The conditions are that—

- (a) entry to the premises without warrant has been refused or is likely to be refused, and notice of the intention to apply for a warrant has been served on the occupier;
- (b) asking for admission to the premises, or serving notice of entry, would defeat the object of the entry;
- (c) entry is urgently required;
- (d) the premises are unoccupied or the occupier is temporarily absent.

(7) But the power in paragraph (5) does not extend to premises used wholly or mainly as a dwelling house.

(8) A warrant is valid for three months.

(9) An inspector entering premises under this regulation may—

- (a) be accompanied by such other persons as the inspector considers necessary;
- (b) bring onto the premises such equipment as the inspector considers necessary.

(10) Where an inspector enters premises which are unoccupied or from which the occupier is temporarily absent, the inspector must leave them as effectively secured against unauthorised entry as they were before the inspector's entry.

(11) An inspector may require a vehicle, vessel, aircraft or hovercraft that the inspector has reasonable grounds to believe is transporting evidence to stop to allow the inspector to exercise the powers conferred by these Regulations.

(12) In paragraph (5)—

- (a) in relation to Scotland, a reference to a justice of the peace is a reference to a sheriff, and the reference to “sworn information in writing” is a reference to evidence on oath;
- (b) in relation Northern Ireland, a reference to a justice of the peace is a reference to a lay magistrate, and the reference to “sworn information in writing” is a reference to a sworn complaint in writing.

Powers of inspection

- 11.**—(1) An inspector who has entered premises in exercise of a power under regulation 10 may—
- (a) inspect the premises and any products, goods or biological material found on the premises;
 - (b) search the premises;
 - (c) have access to, inspect and copy documents, records or other information, in whatever form they are held, and remove them to enable them to be copied;
 - (d) require the production of, and inspect and check the data on, and operation of, any computer and any associated apparatus used in connection with such documents, records or other information, and require computer records to be produced in a form in which they may be easily accessed and taken away by the inspector;
 - (e) take samples of products, goods or biological material;
 - (f) carry out any examination, investigation or test; and
 - (g) take photographs, measurements or recordings.
- (2) An inspector may require any person to provide as may be necessary for the purpose of enforcing the EU Regulation any—
- (a) assistance;
 - (b) documents, records or other information.

Restrictions on enforcement powers

- 12.** Nothing in these Regulations must be taken as—
- (a) requiring a person to produce any document which that person would be entitled to refuse to produce in any proceedings in any court on the grounds that it is the subject of legal professional privilege or, in Scotland, that it contains a confidential communication made by or to an advocate or solicitor in that capacity; or
 - (b) authorising a person to take possession of any document which is in the possession of a person who would be so entitled.

PART 5

Offences and penalties

Offences

- 13.** It is an offence to fail to comply with—
- (a) a compliance notice;
 - (b) a stop notice within the time limit specified in the notice;
 - (c) Article 4(6) of the EU Regulation (obligation to keep information for 20 years after utilisation).

Obstruction of an inspector

- 14.** Where an inspector exercises a power under these Regulations, it is an offence for any person to—
- (a) intentionally obstruct the inspector;

- (b) without reasonable excuse, fail to give the inspector any information or assistance that the inspector may reasonably require;
- (c) knowingly give false or misleading information to the inspector;
- (d) without reasonable excuse, fail to produce a record or document when reasonably required to do so by the inspector.

Offences by bodies corporate, partnerships and unincorporated associations

15.—(1) Proceedings for an offence under these Regulations alleged to have been committed by a partnership or unincorporated association may be brought against the partnership or association in the name of the partnership or association.

(2) For the purposes of such proceedings—

- (a) rules of court relating to the service of documents have effect as if the partnership or unincorporated association were a body corporate; and
- (b) the following provisions apply as they apply in relation to a body corporate—
 - (i) section 33 of the Criminal Justice Act 1925⁽⁵⁾ (procedure on charge of offence against corporation) and Schedule 3 to the Magistrates' Courts Act 1980⁽⁶⁾ (corporations); and
 - (ii) section 18 of the Criminal Justice Act (Northern Ireland) 1945⁽⁷⁾ (procedure on charge) and Schedule 4 to the Magistrates Courts' (Northern Ireland) Order 1981⁽⁸⁾ (corporations).

(3) A fine imposed on a partnership or unincorporated association on its conviction of an offence under these Regulations is to be paid out of the funds of the partnership or association.

(4) If an offence under these Regulations committed by a body corporate is proved—

- (a) to have been committed with the consent or connivance of an officer, or
- (b) to be attributable to the negligence of an officer,

that officer, as well as the body corporate, is guilty of the offence and liable to be proceeded against and punished accordingly.

(5) If an offence under these Regulations committed by a partnership is proved—

- (a) to have been committed with the consent or connivance of a partner, or
- (b) to be attributable to the negligence of a partner,

that partner, as well as the partnership, is guilty of the offence and liable to be proceeded against and punished accordingly.

(6) If an offence under these Regulations committed by an unincorporated association is proved—

- (a) to have been committed with the consent or connivance of an officer of the association or member of its governing body, or
- (b) to be attributable to the negligence of that officer or member,

(5) 1925 c. 86; subsections (1), (2) and (5) of section 33 were repealed by the Magistrates' Courts Act 1952 (c. 55), Schedule 6; subsection (3) was amended by the Courts Act 1971 (c. 23), Schedule 8, Part 2; subsection (4) was amended by the Courts Act 2003 (c. 39), Schedule 8, paragraph 71, and Schedule 10.

(6) 1980 c. 43; paragraph 2(a) of Schedule 3 was repealed by the Criminal Justice Act 2003 (c. 44), Schedule 3, Part 2, paragraph 51(13)(a), and Schedule 37, Part 4; paragraph 5 was repealed by the Criminal Justice Act 1991 (c. 53), section 25(2) and Schedule 13; paragraph 6 was amended by the Criminal Justice Act 2003, Schedule 3, Part 2, paragraph 51(13)(b).

(7) 1945 c. 15 (N.I.); section 18 was amended by the Magistrates' Courts Act (Northern Ireland) 1964 (c. 21) and by the Justice (Northern Ireland) Act 2002 (c. 26), Schedule 12.

(8) S.I. 1981/1675 (N.I. 26).

that officer or member, as well as the association, is guilty of the offence and liable to be proceeded against and punished accordingly.

(7) In paragraphs (4), (5) and (6), any reference to an officer, partner or member, as the case may be, includes any person purporting to act in such a capacity.

Penalties

16.—(1) A person guilty of an offence under paragraph (a) or (b) of regulation 13 is liable—

- (a) on summary conviction to a fine not exceeding £5,000 or to a term of imprisonment not exceeding three months, or to both;
- (b) on conviction on indictment, to a fine or to a term of imprisonment not exceeding two years, or to both.

(2) A person guilty of an offence under paragraph (c) of regulation 13 is liable on summary conviction to a fine not exceeding £5,000.

(3) For the purposes of paragraph (1), the reference to £5,000 in relation to a fine in Northern Ireland shall be read as meaning the statutory maximum.

(4) For the purposes of paragraph (2), the reference to £5,000 in relation to a fine in Scotland or Northern Ireland shall be read as meaning level 5 on the standard scale.

(5) Notwithstanding section 127 of the Magistrates Court Act 1980⁽⁹⁾ (limitation of time) or article 19 of the Magistrates Court (Northern Ireland) Order 1981⁽¹⁰⁾ (time within which complaint charging offence must be made to give jurisdiction), if the relevant condition in paragraph (6) is met in respect of an offence under regulation 13—

- (a) a magistrates' court in England and Wales, may try an information;
- (b) a magistrates' court in Northern Ireland, may try a complaint.

(6) The condition is that, within three years of the date of the offence or within one year from the discovery of the offence by the prosecutor, whichever is earlier—

- (a) in the case of England and Wales, the information is laid;
- (b) in the case of Northern Ireland, the complaint is made.

(7) In Scotland, summary proceedings for an offence under regulation 13 may be commenced within three years of the date of the offence or within one year of the discovery of the offence by the prosecutor, whichever is earlier.

(8) For the purposes of paragraph (7), section 136(3) of the Criminal Procedure (Scotland) Act 1995⁽¹¹⁾ will apply as it applies for the purposes of that section.

(9) For the purposes of this regulation—

- (a) a certificate signed by or on behalf of the prosecutor and stating the date on which the prosecutor first knew of evidence sufficient to justify the proceedings is conclusive evidence of that fact; and
- (b) a certificate stating that matter and purporting to be so signed is deemed to be so signed unless the contrary is proved.

Recovery of expenses of enforcement

17.—(1) This regulation applies where a court convicts a person of an offence under regulation 13.

⁽⁹⁾ 1980 c. 43.

⁽¹⁰⁾ S.I. 1981/1675.

⁽¹¹⁾ 1995 c. 46.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person convicted to reimburse the Secretary of State for any expenditure the Secretary of State or any inspector has reasonably incurred in investigating the offence, including expenditure incurred in the exercise of any power conferred by regulation 10 or 11.

PART 6

Miscellaneous provisions

Service of notices

18.—(1) Any notice served under these Regulations must be in writing and may be amended, suspended or revoked in writing at any time.

(2) A notice may be served on a person by—

- (a) personal delivery;
- (b) leaving it at the person's proper address; or
- (c) sending it by post or by electronic means to person's proper address.

(3) In the case of a body corporate, a notice may be served on an officer of that body.

(4) In the case of a partnership, a notice may be served on a partner or person who has control or management of the partnership business.

(5) In the case of an unincorporated association, a notice may be served on an officer of the association or a member of its governing body.

(6) For the purposes of this regulation and section 7 of the Interpretation Act 1978(12) (which relates to service of documents by post) so far as it applies to this regulation, "proper address" means—

- (a) in the case of a body corporate or an officer of that body—
 - (i) the registered or principal office of the body; or
 - (ii) the email address of the officer.
- (b) in the case of a partnership or a partner or person who has control or management of the partnership business—
 - (i) the principal office of the partnership; or
 - (ii) the email address of the partner or person who has that control or management.
- (c) in the case of an unincorporated association or an officer of the association or member of its governing body—
 - (i) the principal office of the association; or
 - (ii) the email address of the officer or member;
- (d) in any other case, a person's last known address, which includes an email address.

(7) For the purposes of paragraph (6), the principal office of a company registered outside the United Kingdom or a partnership or unincorporated association carrying on business outside the United Kingdom is its principal office in the United Kingdom.

(8) If the name or address of any occupier of premises on whom a notice is to be served under these Regulations cannot, after reasonable inquiry, be ascertained, the notice may be served by leaving it conspicuously affixed to a building or object on the premises.

(12) 1978 c. 30.

Review

- 19.**—(1) The Secretary of State must from time to time—
- (a) carry out a review of these Regulations;
 - (b) set out the conclusions of the review in a report; and
 - (c) publish the report.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to the how the EU Regulation is enforced in other member States.
- (3) The report must in particular—
- (a) set out the objectives intended to be achieved by these Regulations;
 - (b) assess the extent to which those objectives are achieved; and
 - (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved in a less burdensome way.
- (4) The first report under this regulation must be published before the end of the period of five years beginning on the date this regulation comes into force.
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

17th March 2015

de Mauley
Parliamentary Under Secretary of State
Department for Environment, Food and Rural
Affairs

SCHEDULE

Regulation 7

Civil sanctions

PART 1

Compliance notices and variable monetary penalties

Imposition of a compliance notice

1.—(1) The Secretary of State may by notice (“a compliance notice”) impose on any person, in relation to a failure to comply with any provision referred to in regulation 8(1), a requirement to take such steps as the Secretary of State may specify, within such periods as may be specified, to secure that the non-compliance does not continue or recur.

(2) Before doing so, the Secretary of State must be satisfied beyond reasonable doubt that a person has failed to comply with the provision.

(3) A compliance notice may not be imposed on more than one occasion in relation to the same act or omission.

Imposition of a variable monetary penalty

2.—(1) The Secretary of State may by notice impose on any person, in relation to a failure to comply with any provision referred to in regulation 8(1) or an offence committed under regulation 13(c) or 14, a requirement to pay a monetary penalty to the Secretary of State in such amount as the notice may determine (“a variable monetary penalty”).

(2) Before doing so, the Secretary of State must be satisfied beyond reasonable doubt that the person has failed to comply with the provision or committed the offence.

(3) A variable monetary penalty may not be imposed on more than one occasion in relation to the same act or omission.

(4) There is no limit to the amount of a variable monetary penalty.

(5) Before serving a notice relating to a variable monetary penalty, the Secretary of State may require the person on whom it is to be served to provide such information as is reasonable to establish the amount of any financial benefit arising as a result of the non-compliance or the offence.

(6) The Secretary of State may recover any variable monetary penalty imposed under this paragraph as if payable under order of the court.

Notice of intent

3.—(1) If the Secretary of State proposes to serve a compliance notice or a variable monetary penalty on a person under this Part, the Secretary of State must serve on that person a notice of what is proposed (“a notice of intent”).

(2) The notice of intent must include—

(a) the grounds for the proposed notice or penalty;

(b) the requirements of the notice and, in the case of a penalty, the amount to be paid;

(c) information as to—

(i) the right to make representations and objections within 28 days beginning with the day on which the notice of intent was received;

(ii) the circumstances in which the Secretary of State may not impose the notice.

Making representations and objections

4. A person on whom a notice of intent is served may, within 28 days beginning with the day on which the notice was received, make written representations and objections to the Secretary of State in relation to the proposed imposition of a compliance notice or variable monetary penalty.

Third party undertakings

5.—(1) A person on whom a notice of intent is served may offer an undertaking as to action to be taken by that person (including payment of a sum of money) to benefit any third party affected by non-compliance or the offence (“a third party undertaking”).

(2) The Secretary of State may accept or reject such a third party undertaking.

(3) The Secretary of State must take into account any third party undertaking that is accepted in its decision whether or not to serve a final notice and, if a notice is served imposing a variable monetary penalty, the amount of the penalty.

Final notice

6.—(1) After the end of the period for making representations and objections, the Secretary of State must decide whether to impose the requirements in the notice of intent, with or without modifications.

(2) Where the Secretary of State decides to impose a requirement, the notice imposing it (“the final notice”) must comply with paragraph 7 or 8.

Contents of final notice – compliance notice

7. A final notice relating to a compliance notice must include information as to—

- (a) the grounds for imposing the notice;
- (b) what compliance is required and the period within which it must be completed;
- (c) rights of appeal; and
- (d) the consequences of failing to comply with the notice.

Contents of final notice – variable monetary penalty

8. A final notice relating to a variable monetary penalty must include information as to—

- (a) the grounds for imposing the penalty;
- (b) the amount to be paid;
- (c) how payment may be made;
- (d) the period within which payment must be made, which must be not less than 28 days;
- (e) rights of appeal; and
- (f) the consequences of failing to comply with the notice.

Appeals against a final notice

9.—(1) The person receiving the final notice may appeal against it.

(2) The grounds for appeal are—

- (a) that the decision was based on an error of fact;
- (b) that the decision was wrong in law;

Status: This is the original version (as it was originally made).

- (c) in the case of a non-monetary penalty, that the nature of the requirement is unreasonable;
- (d) in the case of a variable monetary penalty, that the amount of the penalty is unreasonable;
- (e) that the decision was unreasonable for any other reason;
- (f) that the decision was wrong for any other reason.

Criminal proceedings

10. If, in relation to an offence under regulation 13(c) or 14—

- (a) a variable monetary penalty is imposed on any person, or
- (b) a third party undertaking is accepted from any person,

that person may not at any time be convicted of the offence in respect of the act or omission giving rise to the variable monetary penalty or third party undertaking except in a case to which paragraph 11(1)(b) applies.

Non-compliance with a third party undertaking

11.—(1) If a person does not comply with a third party undertaking, the Secretary of State may—

- (a) in the case of failure to comply with any provision in regulation 8(1), serve a compliance notice or variable monetary penalty;
- (b) in the case of an offence committed under regulation 13(c) or 14, bring criminal proceedings.

(2) If a person has complied partly but not fully with an undertaking, that partial compliance must be taken into account in the imposition of any criminal or other sanction on the person.

(3) Criminal proceedings for offences to which a third party undertaking relates may be instituted at any time up to six months from the date when the Secretary of State notifies the person that they have failed to comply with that undertaking.

PART 2

Stop notices

Stop notice

12.—(1) The Secretary of State may serve a notice (“a stop notice”) on any person—

- (a) in relation to a failure to comply with any provision referred to in regulation 8(1), prohibiting that person from carrying on an activity specified in the notice until the person has taken the steps specified in the notice;
- (b) where a person is likely to make available on the market a product developed by means of the utilisation of genetic resources or traditional knowledge associated with genetic resources for which the obligations under the EU Regulation have not been met, requiring that person to take such steps and, within such period as the notice may specify, to secure that its being made available on the market is prohibited or restricted.

(2) A stop notice may only be served where—

- (a) the person is carrying on the activity, and
- (b) the Secretary of State reasonably believes that—

- (i) the activity carried on by that person involves or is likely to involve a failure to comply with any provision referred to in regulation 8(1); or

- (ii) that person is likely to make available on the market a product developed by means of the utilisation of genetic resources or traditional knowledge associated with genetic resources for which the obligations under the EU Regulation have not been met.

Contents of a stop notice

- 13.** A stop notice must include information as to—
- (a) the grounds for serving the stop notice and the activity which is prohibited;
 - (b) the steps the person must take to comply with the stop notice;
 - (c) the period within which the activity must stop;
 - (d) rights of appeal; and
 - (e) the consequences of failing to comply with the notice.

Appeals

- 14.—**(1) The person on whom a stop notice is served may appeal against the decision to serve it.
- (2) The grounds for the appeal are—
- (a) that the decision was based on an error of fact;
 - (b) that the decision was wrong in law;
 - (c) that the decision was unreasonable;
 - (d) that any step specified in the notice is unreasonable;
 - (e) that the person has not failed to comply and would not have failed to comply had the stop notice not been served;
 - (f) that the person is not likely to make available on the market a product developed by means of the utilisation of genetic resources or traditional knowledge associated with genetic resources for which the obligations under the EU Regulation have not been met;
 - (g) that the person would not, by reason of any defence, have been liable to be convicted of the offence had the stop notice not been served;
 - (h) that the decision was wrong for any other reason.

Completion certificates

15.—(1) The Secretary of State must issue a certificate (a “completion certificate”) if, after service of a stop notice, the Secretary of State is satisfied that the person has taken the steps specified in the notice.

(2) A stop notice ceases to have effect on the issue of a completion certificate.

(3) A person on whom a stop notice is served may at any time apply for a completion certificate.

(4) The Secretary of State must decide whether to issue a completion certificate within 14 days of the application.

(5) A person on whom the stop notice was served may appeal against a decision not to issue a completion certificate on the grounds that—

- (a) the decision was based on an error of fact;
- (b) the decision was wrong in law;
- (c) the decision was unfair or unreasonable;
- (d) the decision was wrong for any other reason.

Compensation

16.—(1) The Secretary of State must compensate a person for loss suffered as the result of the service of a stop notice or the refusal of a completion certificate if a person has suffered loss as a result of the notice or refusal and—

- (a) a stop notice is subsequently withdrawn or amended by the Secretary of State because the decision to serve it was unreasonable or any step specified in the notice was unreasonable;
- (b) a person successfully appeals against the stop notice and the First-tier Tribunal finds that the service of the notice was unreasonable; or
- (c) a person successfully appeals against the refusal of a completion certificate and the First-tier Tribunal finds that the refusal was unreasonable.

(2) A person may appeal against a decision not to award compensation or the amount of compensation on the grounds that—

- (a) the Secretary of State’s decision was unreasonable;
- (b) the amount offered was based on incorrect facts;
- (c) the decision was wrong for any other reason.

PART 3

Enforcement undertakings

Enforcement undertakings

17. The Secretary of State may accept a written undertaking (an “enforcement undertaking”) given by a person to the Secretary of State to take such action as may be specified in the undertaking within such period as may be specified, where the Secretary of State has reasonable grounds to suspect that the person has failed to comply with any provision referred to in regulation 8(1) or has committed an offence under regulation 13(c) or 14.

Contents of an enforcement undertaking

18.—(1) An enforcement undertaking must specify—

- (a) action to be taken by the person to secure that the non-compliance or commission of the offence does not continue or recur;
- (b) action to secure that the position is, so far as possible, restored to what it would have been if the non-compliance had not occurred or the offence had not been committed; or
- (c) action (including the payment of a sum of money) to be taken by the person to benefit any person affected by the non-compliance or commission of the offence.

(2) It must specify the period within which the action must be completed.

(3) It must include—

- (a) a statement that the undertaking is made in accordance with this Schedule;
- (b) the terms of the undertaking;
- (c) information as to how and when a person is considered to have discharged the undertaking.

(4) The enforcement undertaking may be varied, or the period within which the action must be completed may be extended, if both parties agree in writing.

Acceptance of an enforcement undertaking

19. If the Secretary of State has accepted an enforcement undertaking then, unless the person from whom the undertaking is accepted has failed to comply with the undertaking or any part of it—

- (a) that person may not at any time be convicted of the offence in respect of the act or omission to which the undertaking relates; and
- (b) the Secretary of State may not impose on that person a compliance notice, stop notice or variable monetary penalty in respect of that act or omission.

Discharge of an enforcement undertaking

20.—(1) If the Secretary of State is satisfied that an enforcement undertaking has been complied with, the Secretary of State must issue a certificate to that effect.

(2) The Secretary of State may require the person who has given the undertaking to provide sufficient information to determine that the undertaking has been complied with.

(3) The person who gave the undertaking may at any time apply for such a certificate.

(4) The Secretary of State must decide whether to issue such a certificate, and give written notice of the decision to the applicant, within 14 days of such an application.

(5) The person to whom the notice is given may appeal against a decision not to issue a certificate on the grounds that the decision was—

- (a) based on an error of fact;
- (b) wrong in law;
- (c) unfair or unreasonable;
- (d) wrong for any other reason.

Inaccurate, incomplete or misleading information

21.—(1) A person who has given inaccurate, misleading or incomplete information in relation to an enforcement undertaking is regarded as not having complied with it.

(2) The Secretary of State may by notice in writing revoke a certificate issued under paragraph 20(1) if it was issued on the basis of inaccurate, incomplete or misleading information.

Non-compliance with an enforcement undertaking

22.—(1) If a person does not comply with an enforcement undertaking, the Secretary of State may—

- (a) in the case of failure to comply with any provision referred to in regulation 8(1), serve a compliance notice, stop notice or variable monetary penalty;
- (b) in the case of an offence committed under regulation 13(c) or 14, bring criminal proceedings.

(2) If a person has complied partly but not fully with an undertaking, that partial compliance must be taken into account in the imposition of any criminal or other sanction on the person.

(3) Criminal proceedings for offences to which an enforcement undertaking relates may be instituted at any time up to six months from the date when the Secretary of State notifies the person that they have failed to comply with that undertaking.

PART 4

Non-compliance penalties

Non-compliance penalties

23.—(1) If a person fails to comply with a compliance notice, stop notice, third party undertaking or enforcement undertaking, irrespective of whether a variable monetary penalty was also imposed, the Secretary of State may serve a notice on that person imposing a monetary penalty (“a non-compliance penalty”).

(2) The amount of the non-compliance penalty must be determined by the Secretary of State, and must be a percentage of the costs of fulfilling the remaining requirements of the notice, third party undertaking or enforcement undertaking.

(3) The percentage must be determined by the Secretary of State having regard to all the circumstances of the case and may, if appropriate, be 100%.

(4) The notice must include information as to—

- (a) the grounds for imposing the non-compliance penalty;
- (b) the amount to be paid;
- (c) how payment must be made;
- (d) the period within which payment must be made, which must not be less than 28 days;
- (e) rights of appeal;
- (f) the consequences of failure to make payment in the specified period;
- (g) any circumstances in which the Secretary of State may reduce the amount of the penalty.

(5) If the requirements of the compliance notice, stop notice, third party undertaking or enforcement undertaking are fulfilled before the time set for payment of the non-compliance penalty, the penalty is not payable.

(6) The person on whom the notice imposing the non-compliance penalty is served may appeal against it.

(7) The grounds of appeal are—

- (a) that the decision to serve the notice was based on an error of fact;
- (b) that the decision was wrong in law;
- (c) that the decision was unfair or unreasonable for any reason;
- (d) that the amount of the penalty was unreasonable;
- (e) that the decision was wrong for any other reason.

(8) The Secretary of State may recover any non-compliance penalty imposed under this paragraph as if payable under order of the court.

PART 5

Withdrawal and amendment of notices

Withdrawing or amending a notice

24. The Secretary of State may at any time in writing—

- (a) withdraw a notice imposing a variable monetary penalty or a notice imposing a non-compliance penalty notice or reduce the amount specified in the notice;
- (b) withdraw a compliance notice or stop notice or amend the steps in order to reduce the amount of work necessary to comply with the notice.

PART 6

Appeals

Appeals

25.—(1) Any appeal under this Schedule must be made to the First-tier Tribunal**(13)**.

(2) In any appeal where the commission of an offence is an issue requiring determination, the Secretary of State must prove that offence according to the same burden and standard of proof as in a criminal prosecution.

(3) In any other case the Tribunal must determine the standard of proof.

(4) All notices (other than stop notices) are suspended pending determination or withdrawal of the appeal.

(5) The Tribunal may suspend or vary a stop notice.

(6) The Tribunal may, in relation to the imposition of a requirement or service of a notice—

- (a) withdraw the requirement or notice;
- (b) confirm the requirement or notice;
- (c) vary the requirement or notice;
- (d) take such steps as the Secretary of State could take in relation to the act or omission giving rise to the requirement or notice;
- (e) remit the decision to confirm the requirement or notice, or any matter relating to that decision, to the Secretary of State.

PART 7

Guidance and publicity

Guidance as to use of civil sanctions

26.—(1) The Secretary of State must publish guidance about the use of civil sanctions under these Regulations.

(2) The Secretary of State must revise and update the guidance where appropriate.

(3) The Secretary of State must have regard to the guidance or revised and updated guidance in exercising functions under these Regulations.

(4) In the case of guidance about compliance notices, stop notices, variable monetary penalties and non-compliance penalties, the guidance must contain information as to—

- (a) the circumstances in which the civil sanction is likely to be imposed; and
- (b) the circumstances in which it is not likely to be imposed.

(13) The Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 (S.I. 2009/1976) govern the practice and procedure to be followed by the First-tier Tribunal in proceedings allocated to the Tribunal's General Regulatory Chamber.

Status: This is the original version (as it was originally made).

(5) In the case of guidance about variable monetary penalties and non-compliance penalties, the guidance must contain information about—

- (a) the matters likely to be taken into account by the Secretary of State in determining the amount of penalty (including voluntary reporting by a person of their own non-compliance); and
- (b) rights to make representations and objections and rights of appeal.

(6) In the case of guidance about enforcement undertakings, the guidance must contain information as to—

- (a) the circumstances in which the Secretary of State is likely to accept an enforcement undertaking; and
- (b) the circumstances in which the Secretary of State is not likely to accept an enforcement undertaking.

Consultation on guidance

27. The Secretary of State must consult such persons as the Secretary of State considers appropriate before publishing any guidance or revised guidance.

Publication of enforcement action

28.—(1) The Secretary of State must from time to time publish—

- (a) the cases in which civil sanctions have been imposed;
- (b) where the civil sanction is a compliance notice, stop notice or variable monetary penalty, the cases in which a third party undertaking has been accepted;
- (c) cases in which an enforcement undertaking has been accepted.

(2) In sub-paragraph (1)(a), the reference to cases in which civil sanctions have been imposed does not include cases where a sanction has been imposed but overturned on appeal.

(3) This paragraph does not apply in cases where the Secretary of State considers publication would be inappropriate.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement, within the United Kingdom, compliance measures for users of genetic resources or traditional knowledge associated with genetic resources resulting from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (“the Protocol”). The Protocol aims to promote the conservation and sustainable use of biodiversity by ensuring the benefits from the use of genetic resources and traditional knowledge associated with genetic resources are shared fairly. Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (OJ No L 150, 20.5.2014, p 59) (“the EU Regulation”) requires users to exercise due diligence that they only utilise genetic

resources or traditional knowledge associated with genetic resources that have been accessed in accordance with the Protocol. Users are also required to make a declaration confirming due diligence at the final stage of development of a product.

Part 2 deals with the allocation of functions to the Secretary of State as competent authority for the EU Regulation and as member State under Articles 5, 7(1) and 13 of the EU Regulation. Regulation 6 provides that the Secretary of State must take any other administrative or policy measures that are necessary to provide that genetic resources or traditional knowledge associated with genetic resources are utilised in accordance with the Protocol.

Part 3 and the Schedule enable the Secretary of State to impose civil sanctions. Compliance with requirements to exercise due diligence under, or to fail to make a declaration of due diligence in accordance with, the EU Regulation is made subject to civil sanctions, but will not directly be made an offence. Variable monetary penalties may be imposed in relation to offences under the Regulations.

Part 4 deals with enforcement. Regulations 9, 10 and 11 confer entry, inspection and seizure powers on inspectors. Regulation 12 makes provision for documents which are the subject of legal professional privilege or its equivalent in Scotland.

Part 5 sets out offences and penalties. Regulation 13 provides for offences for failure to comply with compliance or stop notices, as well as requirements to keep information under the EU Regulation. Regulation 14 makes it an offence to obstruct an inspector.

Part 6 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years of the enforcement and penalty provisions coming into force.

An impact assessment **has** not been produced for these Regulations as no significant impact on the costs of business or the voluntary sector is foreseen as a result of them. The Explanatory Memorandum is published alongside the instrument on www.legislation.gov.uk.