

SCHEDULES

SCHEDULE 31

Regulation 328(3)

Sampling

Introductory

1.—(1) This Schedule has effect where a person authorised by an enforcement authority (in this Schedule referred to as a “sampling officer”) obtains a sample of a substance or article—

- (a) in order to determine whether there has been a contravention of any provision of these Regulations which the enforcement authority (“the relevant enforcement authority”) must or may enforce by virtue of regulations 323 and 324; or
- (b) otherwise for a purpose connected with the performance of the relevant enforcement authority of its functions under these Regulations.

(2) This Schedule has effect whether the sample is obtained by purchase or in exercise of a power conferred by regulation 327.

(3) In this Schedule “medicines control laboratory” means a laboratory that is—

- (a) designated by the licensing authority in accordance with Article 111(1) of the 2001 Directive for the purpose of the analysis of samples of one or more types of medicinal product; and
- (b) is so designated in relation to a particular medicinal product that is submitted to it for analysis.

Division of sample

2. The sampling officer must as soon as practicable—

- (a) divide the sample into three parts;
- (b) mark each part;
- (c) seal or fasten each part; and
- (d) deal with the parts in accordance with paragraphs 3 to 10.

3. If the sample was purchased by the sampling officer otherwise than from a vending machine the officer must supply one part of the sample to the seller.

4. If the sampling officer obtained the sample from a vending machine—

- (a) if a person’s name and an address in the United Kingdom are stated on the machine as being the name and address of the owner of the machine, the sampling officer must supply one part of the sample to that person; and
- (b) in any other case, the sampling officer must supply one part of the sample to the occupier of the premises on which the machine stands or to which it is affixed.

5. If the sample is a sample of goods consigned from outside the United Kingdom, and was taken by the sampling officer before delivery to the consignee, the sampling officer must supply one part of the sample to the consignee.

Status: This is the original version (as it was originally made).

6. If, in a case not falling within any of paragraphs 3 to 5 of this Schedule, the sample was obtained by the sampling officer at the request or with the consent of a purchaser, the sampling officer must supply one part of the sample to the seller.

7. If, in a case not falling within any of paragraphs 3 to 6 of this Schedule, the sample was taken in transit, the sampling officer must supply one part of the sample to the consignor.

8. In any case not falling within any of paragraphs 3 to 7 of this Schedule, the sampling officer must supply one part of the sample to the person appearing to the sampling officer to be the owner of the substance or article from which the sample was taken.

9. In every case falling within any of paragraphs 3 to 8 of this Schedule, the sampling officer must inform the person to whom the part of the sample in question is supplied that the sample has been obtained for the purpose of analysis or other examination.

10. Unless the sampling officer decides not to submit the sample for analysis or other examination the sampling officer must—

- (a) retain one of the two remaining parts for future comparison; and
- (b) submit the other part for analysis or examination in accordance with the following provisions of this Schedule.

11. If a sample consists of substances or articles in unopened containers, the sampling officer may divide the sample into parts by dividing the containers into three lots without opening them if it appears to the sampling officer that—

- (a) it is not reasonably practicable to open the containers and divide the contents into parts; or
- (b) opening the containers and dividing the contents into parts might affect the composition or impede the analysis or other examination of the contents.

12. Regulation 343(1)(a) to (d) has effect in relation to supplying a part of a sample in pursuance of the preceding paragraphs as it has effect in relation to the service of a document.

13. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom, or the address at which, a part of a sample should be supplied, the sampling officer may retain that part of the sample.

Notice to person named on container

14.—(1) This paragraph applies where the sampling officer has obtained a sample of a substance or article and it appears to the sampling officer that—

- (a) the substance or article was manufactured in the United Kingdom by a person (“M”) whose name and address in the United Kingdom are stated on its container or packaging; and
- (b) M is not a person to whom a part of the sample must be supplied under the preceding provisions of this Schedule.

(2) Unless the sampling officer decides not to submit the sample for analysis or other examination, the sampling officer must give notice to M—

- (a) stating that the sample has been obtained; and
- (b) specifying the person from whom the sampling officer purchased it or, if it was obtained otherwise than by purchase, the place from which the sampling officer obtained it.

(3) Notice under sub-paragraph (2) must be given to M within the period of three days beginning immediately after the day on which the sample was obtained.

Analysis or other examination

15. Where the enforcing authority that authorises the sampling officer is the Secretary of State or the Minister for Health, Social Services and Public Safety, if the sampling officer decides to submit the sample for analysis the officer must do so—

- (a) to a medicines control laboratory; or
- (b) to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

16. Where any other enforcing authority authorises the sampling officer, if the sampling officer decides to submit the sample for analysis the officer must do so to a laboratory available for the purpose in accordance with any arrangements made by the enforcing authority in question.

17.—(1) Arrangements of the kind mentioned in paragraphs 15(b) and 16 made by an enforcement authority in England, Wales or Scotland other than the Secretary of State must be approved by the Secretary of State.

(2) Arrangements of the kind mentioned in paragraph 15(b) made by a district council in Northern Ireland must be approved by the Minister for Health, Social Services and Public Safety.

18. A laboratory to which a sample is submitted under paragraph 15 or 16 must analyse or examine the sample as soon as practicable,

19. A laboratory that has analysed or examined a sample submitted under the preceding provisions of this Schedule must issue and send to the sampling officer a certificate specifying the result of the analysis or examination.

20. A person to whom a part of the sample is to be supplied in accordance with paragraphs 2 to 8 is entitled, on payment of the required fee, to be given a copy of any certificate as to the result of an analysis or examination which is sent to the sampling officer under paragraph 19.

Provisions as to evidence

21.—(1) In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings and purporting to be a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document unless sub-paragraph (2) applies.

(2) A party to proceedings, other than the party who produced the document mentioned in paragraph (1), may require that the person who issued the certificate be called as a witness.

(3) In proceedings in Scotland, if the person who issued the certificate is called as a witness, that person's evidence is to be sufficient evidence of the facts stated in the certificate.

22. In proceedings for an offence under these Regulations, a document produced by one of the parties to the proceedings which has been supplied by another party to the proceedings as a copy of a certificate issued under paragraph 19 is to be sufficient evidence of the facts stated in the document.

23.—(1) If, in proceedings before a magistrates' court for an offence under these Regulations, a defendant intends to produce a certificate issued under paragraph 19, or to require that the person by whom a certificate was issued be called as a witness, the defendant must give notice of that intention and (where a certificate is to be produced) a copy of the certificate to the other party at least three clear days before the day on which the summons is returnable.

(2) If sub-paragraph (1) is not complied with the court may adjourn the hearing on such terms as it thinks fit.

(3) In Scotland, if in proceedings in the sheriff court for an offence under these Regulations the accused intends to produce a certificate under paragraph 19, or to require that the person by whom

a certificate was issued be called as a witness, the accused must give notice of that intention and (where a certificate is to be produced) a copy of the certificate to the procurator fiscal at least three clear days before the day on which the case proceeds to trial.

(4) If sub-paragraph (3) is not complied with the sheriff may adjourn the diet on such terms as the sheriff thinks fit.

Analysis under direction of court

24.—(1) This paragraph applies where proceedings for an offence under these Regulations relate to a substance or article of which a sample has been taken as mentioned in paragraph 1 of this Schedule.

(2) Where this paragraph applies, the part of the sample retained in pursuance of paragraph 10(a) is to be produced as evidence.

(3) The court must, if requested by a party to the proceedings, and may, in the absence of such a request, cause that part of the sample to be sent for analysis to the Government Chemist (or, in Northern Ireland, to the Government Chemist in Northern Ireland) or to be sent for other examination to a laboratory specified by the court.

(4) If, in a case where an appeal is brought, no action has been taken under sub-paragraph (3), that sub-paragraph applies to the court by which the appeal is heard.

(5) A person or laboratory to whom or to which a part of a sample is sent under this paragraph for analysis or other examination must—

(a) analyse or examine it; and

(b) issue and give to the court a certificate specifying the results of the analysis or examination.

(6) A certificate under sub-paragraph (5)(b) is to be evidence (and, in Scotland, is to be sufficient evidence) of the facts stated in the certificate unless a party to the proceedings requires that the person by whom it was issued be called as a witness.

(7) In Scotland, if the person by whom a certificate is issued is called as a witness that person's evidence is sufficient evidence of the facts stated in the certificate.

25. The costs of analysis or examination under paragraph 24 are to be paid by the prosecutor or the defendant (or, in Scotland, the accused) as the court may order.

Proof by written statement

26.—(1) In relation to England and Wales section 9 of the Criminal Justice Act 1967⁽¹⁾ does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

(2) In relation to Northern Ireland any enactment corresponding to section 9 of the Criminal Justice Act 1967 does not have effect with respect to a document produced as mentioned in paragraph 21 or 22, or with respect to any certificate transmitted to a court under paragraph 24.

Payment for sample taken under compulsory powers

27.—(1) Where a sampling officer takes a sample in the exercise of a power conferred by regulation 327, the officer must, if payment is required, pay the value of the sample to the person to whom a part of the sample is required to be supplied under paragraph 5, 7 or 8 (as the case may be) of this Schedule.

(1) 1967 c.80.

(2) If the sampling officer and the person mentioned in sub-paragraph (1) are unable to agree, the value of the sample is to be determined—

- (a) by the arbitration of a single arbitrator appointed by the sampling officer and the other person in question; or
- (b) if they are unable to agree on an arbitrator, by the county court for the district (or in Northern Ireland the division) in which the sample was taken.

(3) In the application of this paragraph to Scotland for references to the county court there is to be substituted a reference to the sheriff.