STATUTORY INSTRUMENTS

2005 No. 1803

The General Product Safety Regulations 2005

PART 4

MISCELLANEOUS

Duty to notify Secretary of State [F1]... E+W+S

33.—**[**[F2](A1) The Secretary of State must establish and operate a database containing information relating to market surveillance and product safety.**]**

[[F3](B1) The database referred to in paragraph (A1) must be designed so as to enable notifications required under paragraph (1), (2) or (4), or under Article 22 of Regulation (EC) 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, to be made to the Secretary of State through the database.**]**

[[F4](1) An enforcement authority which has received a notification of a risk under regulation 9(1) shall immediately notify the Secretary of State of the risk through the database referred to in paragraph (A1).**]**

(2) Where an enforcement authority takes a measure which restricts the placing on the market of a product, or requires its withdrawal or recall, it shall immediately notify the Secretary of State **[**[F5]of the action taken through the database referred to in paragraph (A1)**]**, specifying its reasons for taking the action. It shall also immediately notify the Secretary of State of any modification or lifting of such a measure.

[F6](3) . . . . . .

(4) Where an enforcement authority adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, a measure or action to prevent, restrict or impose specific conditions on the possible marketing or use of a product (other than a **[**[F7]medicinal**]** product) by reason of a serious risk, it shall immediately notify the Secretary of State **[**[F8]of the measure or action taken through the database referred to in paragraph (A1)**]**. It shall also immediately notify the Secretary of State of any modification or withdrawal of any such measure or action **[**[F9]through the database referred to in paragraph (A1)**]**.

[F10](5) . . . . . .

[F10](6) . . . . . .

[F10](7) . . . . . .

[F10](8) . . . . . .

[F10](9) . . . . . .

(10) In this regulation—

(a) references to a product excludes a second hand product supplied as an antique or as a product to be repaired or reconditioned prior to being used, provided the supplier clearly informs the person to whom he supplies the product to that effect;

[[F11](b) "medicinal product" has the meaning given to it in regulation 2 of the Human Medicines Regulations 2012.**]**

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F1 Words in reg. 33 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(2)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F2 Reg. 33(A1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(3)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Reg. 33(B1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(4)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F4 Reg. 33(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(5)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F5 Words in reg. 33(2) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(6)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Reg. 33(3) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(7)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in reg. 33(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(8)(a)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in reg. 33(4) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(8)(b)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 33(4) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(8)(c)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F10 Reg. 33(5)-(9) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(9)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Reg. 33(10)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 9 para. 6(10)** (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to notify Secretary of State and Commission **N.I.**

33.—[[F12](A1) The Secretary of State must establish and operate a database containing information relating to market surveillance and product safety.

(B1) The database referred to in paragraph (A1) must be designed to enable notifications by enforcement authorities under paragraphs (1), (2) or (4), to be made to the Secretary of State, through the database.**]**

(1) An enforcement authority which has received a notification under regulation 9(1) shall immediately pass **[**F13the information contained in that notification**]** on to the Secretary of State **[**F14through the database referred to in paragraph (A1)**]**, who shall immediately pass it on to the competent authorities appointed for the purpose in the **[**F15relevant states**]** where the product in question is or has been marketed or otherwise supplied to consumers.

(2) Where an enforcement authority takes a measure which restricts the placing on the market of a product, or requires its withdrawal or recall, it shall immediately notify the Secretary of State **[**F16of the action taken through the database referred to in paragraph (A1)**]**, specifying its reasons for taking the action. It shall also immediately notify the Secretary of State of any modification or lifting of such a measure.

(3) On receiving a notification under paragraph (2), or if he takes a measure which restricts the placing on the market **[**F17of Northern Ireland**]** of a product, or requires its withdrawal or recall, the Secretary of State shall (to the extent that such notification is not required under article 12 of the GPS Directive or any other **[**F18NI Protocol obligation**]**) immediately notify the European Commission of the measure taken, specifying the reasons for taking it. The Secretary of State shall also immediately notify the European Commission of any modification or lifting of such a measure. If the Secretary of State considers that the effects of the risk do not or cannot go beyond the territory of **[**F19Northern Ireland**]**, he shall notify the European Commission of the measure concerned insofar as it involves information likely to be of interest to **[**F20relevant states**]** from the product safety standpoint, and in particular if it is in response to a new risk which has not yet been reported in other notifications.

(4) Where an enforcement authority adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, a measure or action to prevent, restrict or impose specific conditions on the possible marketing or use of a product (other than a pharmaceutical product) by reason of a serious risk, it shall immediately notify the Secretary of State **[**F21of the measure or action taken through the database referred to in paragraph (A1)**]**. It shall also immediately notify the Secretary of State of any modification or withdrawal of any such measure or action **[**F22through the database referred to in paragraph (A1)**]**.

(5) On receiving a notification under paragraph (4), or if he adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, a measure or action to prevent, restrict or impose specific conditions on the possible marketing or use of a product (other than a pharmaceutical product) **[**F23on the market of Northern Ireland**]** by reason of a serious risk, the Secretary of State shall immediately notify the European Commission of it through the Community Rapid Information System, known as RAPEX. The Secretary of State shall also inform the European Commission without delay of any modification or withdrawal of any such measure or action.

(6) If the Secretary of State considers that the effects of the risk do not or cannot go beyond the territory of **[**F24Northern Ireland**]**, he shall notify the European Commission of the measures or action concerned insofar as they involve information likely to be of interest to **[**F25relevant states**]** from the product safety standpoint, and in particular if they are in response to a new risk which has not been reported in other notifications.

(7) Before deciding to adopt such a measure or take such an action as is referred to in paragraph (5), the Secretary of State may pass on to the European Commission any information in his possession regarding the existence of a serious risk. Where he does so, he must inform the European Commission, within 45 days of the day of passing the information to it, whether he confirms or modifies that information.

(8) Upon receipt of a notification from the European Commission under article 12(2) of the GPS Directive, the Secretary of State shall notify the Commission of the following—

(a) whether the product the subject of the notification has been marketed in **[**[F26]Northern Ireland**]**;

(b) what measure concerning the product the enforcement authorities in **[**[F26]Northern Ireland**]** may be adopting, stating the reasons, including any differing assessment of risk or any other special circumstance justifying the decision as to the measure, in particular lack of action or follow-up; and

(c) any relevant supplementary information he has obtained on the risk involved, including the results of any test or analysis carried out.

(9) The Secretary of State shall notify the European Commission without delay of any modification or withdrawal of any measures notified to it under paragraph (8)(b).

(10) In this regulation—

(a) references to a product excludes a second hand product supplied as an antique or as a product to be repaired or reconditioned prior to being used, provided the supplier clearly informs the person to whom he supplies the product to that effect;

(b) "pharmaceutical product" means a product falling within Council Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [F27]**[**[F28]as amended by Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components, Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use**]**.

Extent Information

E2 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F12 Reg. 33(A1)(B1) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(a)**

F13 Words in reg. 33(1) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(b)(i)**

F14 Words in reg. 33(1) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(b)(ii)**

F15 Words in reg. 33(1) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(b)(iii)**

F16 Words in reg. 33(2) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(c)**

F17 Words in reg. 33(3) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(d)(i)**

F18 Words in reg. 33(3) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(d)(ii)**

F19 Words in reg. 33(3) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(d)(iii)**

F20 Words in reg. 33(3) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(d)(iv)**

F21 Words in reg. 33(4) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(e)(i)**

F22 Words in reg. 33(4) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(e)(ii)**

F23 Words in reg. 33(5) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(f)**

F24 Words in reg. 33(6) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(g)(i)**

F25 Words in reg. 33(6) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(g)(ii)**

F26 Words in reg. 33(8) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), **Sch. 3 para. 1(6)(h)**

F27 OJ No L311, 28/11/2001, p.67.

F28 Words in reg. 33(10)(b) inserted (30.10.2005) by The Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), reg. 1(a), **Sch. para. 18**

Status:
There are multiple versions of this provision on screen. These apply to different geographical extents.
Skip to:
- E+W+S - England, Wales and Scotland extent
- N.I. - Northern Ireland extent

Changes to legislation:
There are currently no known outstanding effects for the The General Product Safety Regulations 2005, Section 33.