SCHEDULE 9 Regulation 12

Amendment of the General Product Safety Regulations 2005

Introduction

1. The General Product Safety Regulations 2005 are amended in accordance with paragraphs 2 to 10.

Amendment of regulation 2

2. In regulation 2—

(a) omit the definition of "EU law";

(b) omit the definition of "the GPS Directive";

(c) after the definition of "magistrates' court" insert—

""the market" means the United Kingdom market;";

(d) omit the definition of "Member State";

(e) in the definition of "producer"—

(i) for "a Member State", in the first, second and third place it occurs, substitute "the United Kingdom"; and

(ii) in paragraph (b)(ii), for the words "importer of the product from a state that is not a Member State into a Member State" substitute "person established in the United Kingdom that places a product from a country outside the United Kingdom on the market";

(f) after the definition of "record" insert—

""relevant enactment" means any retained EU law derived from an EU instrument harmonising the conditions for the marketing of products in the EU but does not include Regulation (EC) No 765/2008 of the European Parliament and the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;".

Amendment of regulation 3

3. In regulation 3—

(a) for "rules of EU law" substitute "any relevant enactment", in both places it occurs;

(b) omit "other than the GPS Directive", in both places it occurs; and

(c) in paragraph (2)(a) for "rules" substitute "provisions of the enactment".

Amendment of regulation 6

4.—(1) Regulation 6 is amended as follows.

(2) In paragraph (1)—

(a) for "rules of EU law" substitute "any relevant enactment"; and

(b) for "the law" substitute "any other law".

(3) In paragraph (2)—

(a) for the words from "giving" to "Directive", substitute "("S") which meets the conditions in paragraph (2A)";

(b) for "that national standard" substitute "S"; and

(c) omit the final sentence.

(4) After paragraph (2) insert—

"(2A) The conditions referred to in paragraph (2) are that—

(a) the Secretary of State considers S appropriate for the purposes of giving rise to the presumption of conformity; and

(b) the Secretary of State has published the reference to S in a manner the Secretary of State considers appropriate."

(5) In paragraph (3)—

(a) omit sub-paragraph (a);

(b) in sub-paragraph (b) omit "other"; and

(c) in sub-paragraph (c), for "European Commission" substitute "Secretary of State".

Amendment of regulation 9

5. In regulation 9—

(a) in paragraph (1)(a), omit "and"; and

(b) omit paragraph (1)(b).

Amendment of regulation 33

6.—(1) Regulation 33 is amended as follows.

(2) In the heading, omit "and Commission".

(3) At the beginning insert—

"(A1) The Secretary of State must establish and operate a database containing information relating to market surveillance and product safety.".

(4) Before paragraph (1) insert—

"(B1) The database referred to in paragraph (A1) must be designed so as to enable notifications required under paragraphs (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.".

(5) For paragraph (1), substitute—

"(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).".

(6) In paragraph (2), after "Secretary of State", in the first place it occurs, insert "of the action taken through the database referred to in paragraph (A1)";

(7) Omit paragraph (3).

(8) In paragraph (4)—

(a) for "pharmaceutical" substitute "medicinal";

(b) after "Secretary of State", in the first place it occurs, insert "of the measure or action taken through the database referred to in paragraph (A1)"; and

(c) after "withdrawal of any such measure or action" insert "through the database referred to in paragraph (A1).

(9) Omit paragraphs (5) to (9).

(10) For paragraph (10)(b), substitute—

"(b) "medicinal product" has the meaning given to it in regulation 2 of the Human Medicines Regulations 2012(**1**).".

Amendment of regulation 34

7. In regulation 34—

(a) in paragraph (1)—

(i) for "to (6), (8) or (9)", substitute "or (4)";

(ii) omit "or the Commission"; and

(iii) omit "be in writing and shall"; and

(b) omit paragraphs (2) and (3).

Omission of regulation 35

8. Omit regulation 35.

Amendment of regulation 36

9. In regulation 36, omit "and competent authorities of other Member States".

Amendment of regulation 38

10. In regulation 38, omit paragraph (2).

(**1**) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.