
STATUTORY INSTRUMENTS

1993 No. 3050

The Notification of New Substances Regulations 1993

PART I

INTERPRETATION AND GENERAL

Application

3.—(1) Subject to paragraphs (2) and (3), these Regulations shall apply in relation to all new substances that are placed on the market either alone or in preparations.

(2) These Regulations shall not apply in relation to—

- (a) a new substance which is placed on the market exclusively as, or exclusively for use as an active ingredient in, either—
 - (i) a medicinal product as defined in section 130 of the Medicines Act 1968⁽¹⁾, or
 - (ii) a product specified in an order made under section 104 or 105 of that Act which is for the time being in force and which directs that specified provisions of that Act shall apply in relation to that substance or preparation as such provisions have effect in relation to medicinal products within the meaning of the Act;
- (b) a new substance which is placed on the market exclusively as, or exclusively for use in, food within the meaning of section 1 of the Food Safety Act 1990⁽²⁾ including any additives and flavourings;
- (c) a new substance which is placed on the market exclusively as, or exclusively for use in, an animal feeding stuff within the meaning of the Agriculture Feeding Stuffs Regulations 1991⁽³⁾ including any additives;
- (d) a new substance which is placed on the market exclusively as or in, or exclusively for use as an active ingredient in, a plant protection product covered by Council Directive No. 91/414/EEC⁽⁴⁾ concerning the placing of Plant Protection Products on the market;
- (e) a radioactive substance within the meaning of regulation 2(1) of the Ionising Radiations Regulations 1985⁽⁵⁾;
- (f) a substance in the form of waste which is covered by Council Directive No. 91/156/EEC⁽⁶⁾ or Council Directive No. 91/689/EEC⁽⁷⁾;
- (g) a new substance which is placed on the market exclusively as or in a cosmetic product within the meaning of the Cosmetic Products (Safety) Regulations 1989⁽⁸⁾;

(1) 1968 c. 67.

(2) 1990 c. 16.

(3) S.I.1991/2840.

(4) OJ No. L230, 19.8.91, p. 1.

(5) S.I. 1985/1333.

(6) OJ No. L75, 26.3.91, p. 32.

(7) OJ No. L377, 31.12.91, p. 20.

(8) S.I. 1989/2233.

- (h) a new substance which is in transit through the United Kingdom under customs control and which does not undergo any treatment or processing within the United Kingdom;
 - (i) subject to Council Regulation EC 2455/92⁽⁹⁾ on the export notification and information exchange of dangerous substances, a new substance intended exclusively for export to a country which is not a member State of the Communities;
or
 - (j) a new substance which is a substance no longer polymer.
- (3) Regulations 4 and 6 shall not apply to a new substance which has been duly notified by its manufacturer or other person responsible for placing it on the market in accordance with Article 7 or 8 of the Directive in Northern Ireland or another member State.
- (4) These Regulations shall not extend to Northern Ireland except insofar as they relate to the importation of new substances into the United Kingdom.

⁽⁹⁾ OJ No. L251, 29.8.92, p. 13.