

- (ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ⁽¹⁾ and Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council ⁽²⁾;
- (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽³⁾;
- (iv) in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽⁴⁾.
6. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user:
- (a) medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;
- (b) cosmetic products as defined in Directive 76/768/EEC;
- (c) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;
- (d) food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:
- (i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;
- (ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;
- (iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;
- (iv) in animal nutrition within the scope of Directive 82/471/EEC.
7. The following shall be exempted from Titles II, V and VI:
- (a) substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;
- (b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;
- (c) substances on their own or in preparations, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:
- (i) the substance being re-imported is the same as the exported substance;
- (ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;
- (d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:
- (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
- (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.
8. On-site isolated intermediates and transported isolated intermediates shall be exempted from:
- (a) Chapter 1 of Title II, with the exception of Articles 8 and 9; and
- (b) Title VII.
9. The provisions of Titles II and VI shall not apply to polymers.

CHAPTER 2

Definitions and general provision

Article 3

Definitions

For the purposes of this Regulation:

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

⁽¹⁾ OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003.

⁽²⁾ OJ L 84, 27.3.1999, p. 1. Decision as last amended by Decision 2006/253/EC (OJ L 91, 29.3.2006, p. 48).

⁽³⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽⁴⁾ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).