5 March 2020

GENERIC EXEMPTIONS FROM THE AUTHORISATION REQUIREMENT[1]

1. Exemptions for all intrinsic properties

On-site isolated intermediates and transported isolated intermediates (Art. 2(8)(b) REACH).
Use in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products* and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Art. 2(5)(a) REACH). * Directive 2001/82/EC will be repealed and replaced by Regulation (EU) 2019/6 on veterinary medicinal products from 28 January 2022
Use in food or feedingstuffs according to Regulation (EC) No 178/2002 including use: - as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC* of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption; - as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC* 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 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; - as an additive in feeding stuffs 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; - in animal nutrition within the scope of Council Directive 82/471/EEC*** of 30 June 1982 concerning certain products used in animal nutrition (Art. 2(5)(b) REACH). * Council Directive 89/107/EEC and Council Directive 88/388/EEC have been replaced by Regulation (EC) No 1333/2008 on food additive from 20 January 2010 ** Commission Decision 1999/217/EC has been replaced by Regulation (EU) No 872/2012 from 22 April 2013 *** Council Directive 82/471/EEC has been replaced by Regulation (EC) 767/2009 from 1 September 2010
Scientific research and development, i.e., use in scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year (Art. 3(23) and 56(3) REACH).

[1] It is noted that, in addition to the generic exemptions, entries in Annex XIV to REACH (List of Substances Subject to Authorisation) may include the following exemptions:

- product and process oriented research and development below the specified maximum quantity (Art. 56(3) REACH);
- uses or categories of uses exempted from the authorisation requirement on the basis of existing EU legislation (Article 58(1)(e) and Article 58(2) of REACH)

Use in plant protection products within the scope of Council Directive 91/414/EEC* (Art.56(4)(a) REACH). * Directive 91/414/EEC has been replaced by Council Regulation (EC) No 1107/2009 from 14 June 2011
Use in biocidal products within the scope of Directive 98/8/EC* (Art. 56(4)(b) REACH). * Directive 98/8/EC has been replaced by the Biocidal Product Regulation (EU) No 528/2012 from 1 September 2013
Use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels (Art. 56(4)(c) REACH).
Use as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems (Art. 56(4)(d) REACH).
Use of substances when present in mixtures below a concentration limit of 0.1% weight by weight (w/w) for substances referred to in Article 57(d), (e) and (f) REACH. For all other substances, use of substances when present in mixtures below the values specified in Article 11(3) of Regulation (EC) No 1272/2008 which result in the classification of the mixture as hazardous. (Art. 56(6)(a) and (b) REACH).

2. Exemptions specific to certain intrinsic properties

Use in cosmetic products within the scope of Council Directive 76/768/EEC* in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health (Art. 56(5)(a) REACH). * Council Directive 76/768/EEC has been replaced by the Cosmetic Regulation (EC) No 1223/2009 from 11 July 2013
Use in food contact materials within the scope of Regulation (EC) No 1935/2004 in the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a),(b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health (Art. 56(5)(b) REACH).
Use in medical devices, within the scope of Directives 90/385/EEC*, 93/42/EEC* or 98/79/EC** in the case of substances that are subject to authorisation only because of hazards to human health (Art. 60(2) and 62(6) REACH) * Council Directives 90/385/EEC and 93/42/EEC will be mainly repealed and replaced by the Medical Devices Regulation 2017/745 from 26 May 2020 ** Council Directive 98/79/EC will be mainly repealed and replaced by the In Vitro Diagnostic Medical Devices Regulation 2017/746 from 26 May 2022

Further details on the application of these exemptions can be found in ECHA's Q&As on authorisation published on ECHA's website at the following link:
http://echa.europa.eu/support/qas-support/qas