PART THREE

SEPARATION PROVISIONS

TITLE I

GOODS PLACED ON THE MARKET

ARTICLE 40

Definitions

For the purposes of this Title, the following definitions shall apply:

(a) "making available on the market" means any supply of a good for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge;

(b) "placing on the market" means the first making available of a good on the market in the Union or the United Kingdom;

(c) "supply of a good for distribution, consumption or use" means that an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or is the subject matter of an offer to a legal or natural person or persons to conclude such an agreement;

(d) "putting into service" means the first use of a good within the Union or the United Kingdom by the end user for the purposes for which it was intended or, in the case of marine equipment, placing on board;

(e) "market surveillance" means the activities carried out and measures taken by market surveillance authorities to ensure that goods comply with the applicable requirements and do not endanger health, safety or any other aspect of public interest protection;

(f) "market surveillance authority" means an authority of a Member State or of the United Kingdom responsible for carrying out market surveillance on its territory;

(g) "conditions for the marketing of goods" means requirements concerning the characteristics of goods such as levels of quality, performance, safety or dimensions, including on the composition of such goods or on the terminology, symbols, testing and testing methods, packaging, marking, labelling, and conformity assessment procedures used in relation to such goods; the term also covers requirements concerning production methods and processes, where these have an effect on product characteristics;

(h) "conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(i) "notified body" means a conformity assessment body authorised to carry out third-party conformity assessment tasks under Union law harmonising the conditions for the marketing of goods;

(j) "animal products" means products of animal origin, animal by-products and derived products, as referred to in points (29), (30) and (31) of Article 4 of Regulation (EU) 2016/429 of the European Parliament and of the Council[1], respectively, feed of animal origin, and food and feed containing products of animal origin.

[1] Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ("Animal Health Law") (OJ L 84, 31.3.2016, p. 1).

ARTICLE 41

Continued circulation of goods placed on the market

1. Any good that was lawfully placed on the market in the Union or the United Kingdom before the end of the transition period may:

(a) be further made available on the market of the Union or of the United Kingdom and circulate between these two markets until it reaches its end-user;

(b) where provided in the applicable provisions of Union law, be put into service in the Union or in the United Kingdom.

2. The requirements set out in Articles 34 and 35 TFEU and the relevant Union law governing the marketing of goods, including the conditions for the marketing of goods, applicable to the goods concerned shall apply in respect of the goods referred to in paragraph 1.

3. Paragraph 1 shall apply to all existing and individually identifiable goods within the meaning of Title II of Part Three of the TFEU, with the exception of the circulation between the Union market and the United Kingdom's market or vice-versa of:

(a) live animals and germinal products;

(b) animal products.

4. In respect of a movement of live animals or of germinal products between a Member State and the United Kingdom, or vice-versa, the provisions of Union law listed in Annex II shall apply, provided that the date of departure was before the end of the transition period.

5. This Article shall be without prejudice to the possibility for the United Kingdom, a Member State or the Union to take measures to prohibit or restrict the making available on its market of a good referred to in paragraph 1, or a category of such goods, where and to the extent permitted by Union law.

6. The provisions of this Title shall be without prejudice to any applicable rules on modalities of sale, intellectual property, customs procedures, tariffs and taxes.

ARTICLE 42

Proof of placing on the market

Where an economic operator relies on Article 41(1) with respect to a specific good, that operator shall bear the burden of proof of demonstrating, on the basis of any relevant document, that the good was placed on the market in the Union or the United Kingdom before the end of the transition period.

ARTICLE 43

Market surveillance

1. The market surveillance authorities of the Member States and the market surveillance authorities of the United Kingdom shall exchange without delay any relevant information collected with regard to the goods referred to in Article 41(1) in the context of their respective market surveillance activities. They shall, in particular, communicate to each other and to the European Commission any information relating to those goods presenting a serious risk, as well as any measures taken in relation to non-compliant goods, including relevant information drawn from networks, information systems and databases established under Union or United Kingdom law in relation to those goods.

2. The Member States and the United Kingdom shall transmit without delay any request from the market surveillance authorities of the United Kingdom or of a Member State, respectively, to a conformity assessment body established in their territory, where that request concerns a conformity assessment carried out by that body in its capacity as notified body before the end of the transition period. Member States and the United Kingdom shall ensure that any such request is promptly addressed by the conformity assessment body.

ARTICLE 44

Transfer of files and documents relating to ongoing procedures

The United Kingdom shall transfer without delay to the competent authority of a Member State designated in accordance with the procedures provided for in the applicable Union law all relevant files or documents in relation to assessments, approvals and authorisations ongoing on the day before the date of entry into force of this Agreement and led by a United Kingdom competent authority in accordance with Regulation (EU) No 528/2012[1], Regulation (EC) No 1107/2009[2], Directive 2001/83/EC[3] and Directive 2001/82/EC[4] of the European Parliament and of the Council.

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1 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1).

3 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 (OJ L 311, 28.11.2001, p. 67).

4 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 (OJ L 311, 28.11.2001, p. 1).

ARTICLE 45

Making available of information in relation to past authorisation procedures for medicinal products

1. The United Kingdom shall, upon a reasoned request from a Member State or the European Medicines Agency, make available without delay the marketing authorisation dossier of a medicinal product authorised by a competent authority of the United Kingdom before the end of the transition period, where that dossier is necessary for the assessment of a marketing authorisation application in accordance with Articles 10 and 10a of Directive 2001/83/EC or Articles 13 and 13a of Directive 2001/82/EC.

2. A Member State shall, upon a reasoned request from the United Kingdom, make available without delay the marketing authorisation dossier of a medicinal product authorised by a competent authority of that Member State before the end of the transition period, where that dossier is necessary for the assessment of a marketing authorisation application in the United Kingdom in accordance with the United Kingdom's legislative requirements, to the extent that those legislative requirements replicate the circumstances of Articles 10 and 10a of Directive 2001/83/EC or Articles 13 and 13a of Directive 2001/82/EC.

ARTICLE 46

Making available of information held by notified bodies established in the United Kingdom or in a Member State

1. The United Kingdom shall ensure that information held by a conformity assessment body established in the United Kingdom in relation to its activities as a notified body under Union law before the end of the transition period is made available at the request of the certificate holder, without delay, to a notified body established in a Member State as indicated by the certificate holder.

2. Member States shall ensure that information held by a notified body established in the Member State concerned in relation to its activities before the end of the transition period is made available at the request of the certificate holder, without delay, to a conformity assessment body established in the United Kingdom as indicated by the certificate holder.