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QUESTIONS AND ANSWERS RELATED TO THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION WITH REGARD EU RULES ON ANIMAL FEED

On 23 January 2018, the European Commission services published a "*Notice to stakeholders - Withdrawal of the United Kingdom and EU rules on animal feed*".¹ This notice recalled the following:

"The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that, unless a ratified withdrawal agreement² establishes another date, all Union primary and secondary law will cease to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ('the withdrawal date').³ The United Kingdom will then become a 'third country'.⁴

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, business operators involved in the activities falling under the scope of animal nutrition, such as applicants and authorisation holders of feed additives, applicants requesting an update of the list of feed intended for particular nutritional purposes ("PARNUTS") and feed business operators (FBOs) intending to export to the EU, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of animal nutrition no longer apply to the United Kingdom."

This list of Questions and Answers (Q&A pairs) which has been drafted by the European Commission services, aims at giving further guidance on the basis of the above-

¹ https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notice_en#sante.

² Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

³ Furthermore, in accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

⁴ A third country is a country not member of the EU.

mentioned notice to stakeholders. The list of Q&A pairs will be further updated and complemented when necessary.

1. WHAT ARE THE EU RULES FOR FEED?

Four different pieces of feed legislation lay down requirements for non-EU countries that will entail certain obligations for UK feed business operators (FBOs) as regards:

- Operators intending to export to the EU: Regulation (EC) No 183/2005 laying down requirements for feed hygiene⁵ and Commission Directive 98/51/EC;⁶
- Applicants for an authorisation of feed additives: Regulation (EC) No 1831/2003 on additives for use in animal nutrition;⁷
- Applicants for the authorisation of particular nutritional purposes (PARNUTs): Regulation (EC) No 767/2009 on the placing on the market and use of feed.⁸

2. OPERATORS INTENDING TO EXPORT TO THE EU

2.1. What are the requirements for importing feed into the EU?

The list of third countries from which feed may be imported into the EU⁹ is not yet drawn up. In accordance with Article 24 of Regulation (EC) No 183/2005, the conditions set out in Article 6 of Commission Directive 98/51/EC¹⁰ apply, which provide for the following:

- Third country establishments must have a representative established in the European Union;

⁵ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1.

⁶ Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, OJ L 208, 24.7.1998, p. 43. This Directive was repealed by Regulation (EC) No 183/2005; however interim measures apply pursuant to Article 24 thereof.

⁷ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, 18.10.2003, p. 29.

⁸ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, OJ L 229, 1.9.2009, p. 1.

⁹ Article 23 of Regulation (EC) No 183/2005.

¹⁰ Commission Directive 98/51/EC of 9 July 1998 laying down certain measures for implementing Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, OJ L 208, 24.7.1998, p. 43

- The representative must ensure that the establishments comply with feed hygiene requirements at least equivalent to those established in the EU;
- The representative must keep a register of products placed on the EU market from the establishments that he represents.

3. AUTHORISATION OF FEED ADDITIVES LINKED TO AN AUTHORISATION HOLDER

3.1. I am a UK operator that applied for an authorisation for a feed additive linked to an authorisation holder but my product is not yet authorised. Do I have any obligation?

According to Article 3(3) of Regulation (EC) No 1831/2003, with regard to certain additives¹¹ no person other than the holder of the authorisation shall first place the product on the market. The name of the authorisation holder is included in the Regulation granting the authorisation of those additives.¹²

According to Article 4 of Regulation (EC) No 1831/2003, the applicant for an authorisation or his representative shall be established in the EU.

Therefore, where the applicant for an authorisation or his representative is currently established in the United Kingdom, the applicant should establish in the EU or designate a representative established in the EU. The relevant new contact details should be communicated to the European Commission.

3.2. What are the obligations for a UK holder of an authorisation of a feed additive already authorised?

According to Article 4 of Regulation (EC) No 1831/2003, the applicant for an authorisation or his representative shall be established in the EU.

Therefore, a holder established in the UK should establish in the EU or designate a representative established in the EU.

The authorisation has to be amended accordingly.

The authorisation holder should communicate the relevant contact details to the European Commission, so that the Commission can take steps to amend the Regulation authorising the additive following the procedure laid down in Article 13(3) of Regulation (EC) No 1831/2003. This procedure requires some months to be completed (around 4 months), therefore, UK holders of authorisation must start the procedure well in advance so it is completed before the withdrawal date.

¹¹ Additives linked to an authorisation holder are those containing, consisting of or produced from GMOs and additives belonging to the following categories: zootechnical additives, coccidiostats and histomonostats.

¹² Article 9(6) of Regulation (EC) No 1831/2003.

4. AUTHORISATION OF GENERIC FEED ADDITIVES

For feed additives that are not linked to a specific authorisation holder (i.e. feed additives other than those referred to in section 3) ("generic feed additives")¹³ the following applies:

- According to Article 4(3) of Regulation (EC) No 1831/2003, an applicant for an authorisation or his representative shall be established in the EU. If the authorisation has not yet been granted, the applicant established in the United Kingdom should establish in the EU or designate, in accordance with Article 7(1), a representative established in the EU and communicate their relevant contact details to the European Commission;
- The same applies, according to Article 13(5) of Regulation (EC) No 1831/2003, where applicants request a new use, a modification or a renewal of an authorisation;
- If the additive is already authorised, the (former) applicant does not need to be established in the EU or designate a representative in the EU.

5. LIST OF INTENDED USES OF FEED INTENDED FOR PARTICULAR NUTRITIONAL PURPOSES (PARNUTs)

The applications for PARNUTs are regulated in Articles 9 and 10 of Regulation (EC) No 767/2009. According to Article 10(2) of Regulation (EC) No 767/2009, an applicant for updating the list of intended uses has to be established in the EU.

If the authorisation is not yet granted, the applicant has to be established in the EU.

If the PARNUT is already authorised, the (former) applicant does not need to be established in the EU.

¹³ Technological additives, sensory additives, and nutritional additives. See Annex I to Regulation (EC) No 1831/2003.