



Brussels, 1 April 2020
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23 January 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES ON GENETICALLY MODIFIED ORGANISMS

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a “third country”.¹ The Withdrawal Agreement² provides for a transition period ending on 31 December 2020.³ Until that date, EU law in its entirety applies to and in the United Kingdom.⁴

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will be concluded and will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom’s participation in the internal market,⁵ in the EU Customs Union, and in the VAT and excise duty area.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation after the end of the transition period (Part A below). This notice also explains certain relevant separation provisions of the Withdrawal Agreement (Part B below), as well as the rules applicable in Northern Ireland after the end of the transition period (Part C below).

Advice to stakeholders:

¹ A third country is a country not member of the EU.

² Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 (“Withdrawal Agreement”).

³ The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

⁴ Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

⁵ In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the “country of origin principle”, and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

To address the consequences set out in this notice, stakeholders are in particular advised to:

- ensure establishment of an authorisation holder (or a representative) in the EU where this is required by EU law; and
- adapt distribution channels, to take account importation requirements.

Please note:

This notice does not address

- EU rules on exportation of genetically modified organisms;⁶
- EU food and feed law.

For these aspects, other notices are in preparation or have been published.⁷

A. LEGAL SITUATION AFTER THE END OF THE TRANSITION PERIOD

After the end of the transition period, the EU rules in the field of genetically modified organisms (GMO) no longer apply to the United Kingdom.⁸ This has in particular the following consequences:

1. ESTABLISHMENT REQUIREMENTS FOR AUTHORISATION HOLDERS AND APPLICANTS

According to Article 4(6) of Regulation (EC) No 1829/2003, authorisation holders or their representatives must be established in the European Union. According to Point A.2 of Annex IV to Directive 2001/18/EC, applications for the placing on the market of GMOs under Directive 2001/18/EC must designate a person responsible for the placing on the market which must be established in the European Union.

2. SUBMISSIONS OF APPLICATIONS AND NOTIFICATIONS

Applications and notifications pursuant to Regulation (EC) No 1829/2003 and Directive 2001/18/EC can only be submitted to the competent authorities of EU Member States. In particular, business operators should carefully take into account the expected timelines before the submission of any new application in which the United Kingdom would be acting as rapporteur Member State under Directive 2001/18/EC.

⁶ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms, OJ L 287, 5.11.2003, p. 1.

⁷ https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period_en

⁸ Regarding the applicability of certain provisions of EU GMO law to Northern Ireland, see Part C of this notice.

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT⁹

Article 41(1) of the Withdrawal Agreement provides that an existing and individually identifiable good (here: genetically modified food or feed) lawfully placed on the market in the EU or in the United Kingdom before the end of the transition period may be further made available on the market of the EU or of the United Kingdom and circulate between these two markets until it reaches its end-user.

The economic operator relying on that provision bears the burden of proof of demonstrating on the basis of any relevant document that the good was placed on the market in the EU or in the United Kingdom before the end of the transition period.¹⁰

For the purposes of these provisions, “placing on the market” means the first 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.¹¹ “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.”¹²

Example: An individual genetically modified food or feed authorised by the Commission produced in the EU or imported into the EU from a third country by an EU-based wholesale distributor before the end of the transition period can still be imported into the United Kingdom on the basis of the EU authorisation.

C. APPLICABLE RULES IN NORTHERN IRELAND AFTER THE END OF THE TRANSITION PERIOD

After the end of the transition period, the Protocol on Ireland/Northern Ireland (“IE/Ni Protocol”) applies.¹³ The IE/Ni Protocol is subject to periodic consent of the Northern Ireland Legislative Assembly, the initial period of application extending to 4 years after the end of the transition period.¹⁴

⁹ If an individual food or feed has been held in the EU, before the end of the transition period, for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, this “stock” of food can be sold, distributed or transferred in the EU after the end of the transition period (see the definition in Article 3(8) of Regulation (EC) No 178/2002: “‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves”).

¹⁰ Article 42 of the Withdrawal Agreement.

¹¹ Article 40(a) and (b) of the Withdrawal Agreement.

¹² Article 40(c) of the Withdrawal Agreement.

¹³ Article 185 of the Withdrawal Agreement.

¹⁴ Article 18 of the IE/Ni Protocol.

The IE/Ni Protocol makes certain provisions of EU law applicable also “*to and in the United Kingdom in respect of Northern Ireland*”. It also provides that insofar as EU rules apply “*to and in the United Kingdom in respect of Northern Ireland*”, it is assimilated to a Member State.¹⁵

The IE/Ni Protocol provides that certain EU rules in the field of GMOs apply “*to and in the United Kingdom in respect of Northern Ireland*”.¹⁶

This means that references to the EU in Parts A and B of this Notice have to be understood as including Northern Ireland, whereas references to the United Kingdom have to be understood as referring only to Great Britain.

More specifically, this means *inter alia* the following:

- GMOs and genetically food and feed placed on the market in Northern Ireland or released into the environment in Northern Ireland have to comply with Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003 and Part C of Directive 2001/18/EC;
- GMOs and genetically modified food and feed shipped from Northern Ireland to the EU are not imports;
- GMOs and genetically modified food and feed shipped from Great Britain to Northern Ireland are imports;
- An authorisation holder/applicant established in Northern Ireland complies with the establishment requirements in EU law (see above, section A);
- The United Kingdom in respect of Northern Ireland can invoke the limitations of scope provided for in Articles 26b and 26c of Directive 2001/18/EC.

However, the IE/Ni Protocol excludes the possibility for the United Kingdom in respect of Northern Ireland to

- participate in the decision-making and decision-shaping of the Union;¹⁷
- initiate objections, safeguard or arbitration procedures to the extent that they concern regulations, standards, assessments, registrations, certificates, approvals and authorisations issued or carried out by EU Member States;¹⁸
- act as leading authority for assessments, examinations and authorisations;¹⁹

¹⁵ Article 7(1) of the Withdrawal Agreement in conjunction with Article 13(1) of the IE/Ni Protocol.

¹⁶ Article 5(4) of the IE/Ni Protocol and section 35 of annex 2 to that Protocol.

¹⁷ Where an information exchange or mutual consultation is necessary, this will take place in the joint consultative working group established by Article 15 of the IE/Ni Protocol.

¹⁸ Fifth subparagraph of Article 7(3) of the IE/Ni Protocol.

¹⁹ Article 13(6) of the IE/Ni Protocol.

- invoke the country of origin principle or mutual recognition for products placed legally on the market in Northern Ireland.²⁰

More specifically, this means *inter alia* the following:

- The United Kingdom in respect of Northern Ireland cannot invoke safeguard clauses²¹ or reasoned objections;²²
- The United Kingdom in respect of Northern Ireland cannot request opinions under Articles 10 and 22 of Regulation (EC) No 1829/2003;²³
- The United Kingdom in respect of Northern Ireland cannot act as notified authority²⁴ nor conduct risk assessments in accordance with point (c) of Article 6(3) of Regulation (EC) No 1829/2003;²⁵
- The United Kingdom in respect of Northern Ireland cannot establish a reference laboratory as provided for in EU law.²⁶

The website of the Commission on EU rules on genetically modified food and feed and the deliberate release of genetically modified organisms into the environment (https://ec.europa.eu/food/plant/gmo/legislation_en) provides general information concerning Union legislation applicable to genetically modified food and feed.

These pages will be updated with further information, where necessary.

European Commission
Directorate-General Health and Food Safety

²⁰ First subparagraph of Article 7(3) of the IE/Ni Protocol.

²¹ Cf. Article 23 of Directive 2001/18.

²² Cf. Article 15 of Directive 2001/18/EC.

²³ Cf. section 35 of annex 2 to the IE/Ni Protocol.

²⁴ Cf. Article 13 of Directive 2001/18/EC.

²⁵ Article 13(6) of the IE/Ni Protocol.

²⁶ Cf. section 35 of annex 2 to the IE/Ni Protocol