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23 January 2018 and the Q&A document
(REV2) dated 18 February 2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES ON PLANT PROTECTION PRODUCTS

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a “third country”.¹ The Withdrawal Agreement² provides for a transition period ending on 31 December 2020.³ Until that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

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.

below), as well as the rules applicable to Northern Ireland after the end of the transition period (Part C below).

Advice to stakeholders:

To address the consequences set out in this notice, stakeholders are in particular advised to adapt distribution channels, in particular in case of parallel trade with plant protection products sourced in the United Kingdom.

Please note:

This notice does not address

- EU rules on intellectual property rights (patents, trademarks), and exhaustion;
- EU food and feed law, incl. rules on official controls;
- EU chemicals law.

For these aspects, other notices are in preparation or have been published.⁶

A. LEGAL SITUATION AFTER THE END OF THE TRANSITION PERIOD

After the end of the transition period, 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 market⁷ and Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin⁸ no longer apply to the United Kingdom.⁹ This has in particular the following consequences:¹⁰

1. APPROVALS OF ACTIVE SUBSTANCES

The Withdrawal Agreement provides that the United Kingdom, already during the transition period, cannot act as leading authority for risk-assessments, examinations

⁶ https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period_en

⁷ OJ L 309, 24.11.2009, p. 1.

⁸ OJ L 70, 16.3.2005, p.1.

⁹ Regarding the applicability of these Regulations in Northern Ireland, see Part C of this notice.

¹⁰ Regarding **establishment requirements**, neither Regulation (EC) No 1107/2009 nor Regulation (EC) No 396/2005 require applicants for authorisations for plant protection products and authorisation holders to be established in the EU. Nor does Regulation (EC) No 1107/2009 or Regulation (EC) No 396/2005 set any specific requirements regarding the **location of the manufacturing site(s)** of active substances or plant protection products.

approvals or authorisations as referred to in Annex VII of the Withdrawal Agreement.¹¹ This annex includes Regulation (EC) No 1107/2009.

Hence, since the withdrawal of the United Kingdom, and already during the transition period, the United Kingdom can no longer act as rapporteur Member State (RMS) for the evaluation of applications for approval of new active substances or for renewal of approval of active substances.

The new RMS (and where applicable co-RMS) which has taken over the role as Rapporteur Member State (or co-Rapporteur Member State) from the United Kingdom is entitled, in accordance with and under the conditions set by Article 74 of Regulation (EC) No 1107/2009, to recover costs of work carried out under these Regulations by fees established in a transparent manner and corresponding to the actual cost of the work involved. This applies also to evaluations already commenced by the United Kingdom.

Where the approval had been granted under the condition of submission of confirmatory information, to be assessed by the original RMS (Article 13(3) of Regulation (EC) No 1107/2009), and where the United Kingdom had acted as RMS, this task has been reallocated to another Member State.¹²

2. SETTING OF MRLS

The Withdrawal Agreement provides that the United Kingdom, already during the transition period, cannot act as leading authority for risk-assessments, examinations approvals or authorisations as referred to in Annex VII of the Withdrawal Agreement.¹³ This annex includes Regulation (EC) No 396/2005.

Hence, since the withdrawal of the United Kingdom, and already during the transition period, the United Kingdom can no longer act as Evaluating Member State (EMS).

Member States have agreed on the reallocation of the role as EMS in the framework of Regulation (EC) No 396/2005.¹⁴

3. AUTHORISATIONS OF PLANT PROTECTION PRODUCTS

The Withdrawal Agreement provides that the United Kingdom, already during the transition period, cannot act as leading authority for risk-assessments, examinations approvals or authorisations as referred to in Annex VII of the Withdrawal Agreement.¹⁵ This annex includes Regulation (EC) No 1107/2009.

¹¹ Article 128(6) of the Withdrawal Agreement.

¹² https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_brexit_mrl-files-reallocation.pdf

¹³ Article 128(6) of the Withdrawal Agreement.

¹⁴ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_brexit_mrl-files-reallocation.pdf.

¹⁵ Article 128(6) of the Withdrawal Agreement.

Hence, since the withdrawal of the United Kingdom, and already during the transition period, the United Kingdom can no longer act as zonal rapporteur Member State (zRMS), and authorisations by the United Kingdom can no longer be mutually recognised. Authorisations granted by EU Member States prior to the withdrawal for which the UK was the zRMS remain valid.

- New applications: since the withdrawal of the United Kingdom, a new application for an authorisation of a plant protection product cannot be submitted to the United Kingdom as zRMS (Article 35 of Regulation (EC) No 1107/2009).
- Assessments with the United Kingdom acting as zRMS and pending on the withdrawal date: assessments have to be completed by an EU Member State acting as zRMS.
- Assessments with the United Kingdom acting as zRMS which have been completed, i.e. made available to the EU Member States¹⁶, but the United Kingdom has not issued its national authorisation before the withdrawal date: The role of zRMS has to be taken over by an EU Member State which will decide on its national authorisation on the basis of the completed evaluation report. Other authorisations have to be issued on that basis (Article 37(4) of Regulation (EC) No 1107/2009).
- Assessments with the United Kingdom acting as zRMS which have been completed, i.e. made available to the EU Member States¹⁷, and the United Kingdom has issued its national authorisation before the withdrawal date: The other Member States have to decide on their national authorisations in accordance with Article 37(4) of Regulation (EC) No 1107/2009 on the basis of the assessment carried out and completed by the United Kingdom.
- Authorisation in the mutual recognition procedure of an authorisation by the United Kingdom issued before the withdrawal date: an EU Member State of the same zone or another zone (in accordance with Article 40(1) (a), (b) and (c) of Regulation (EC) No 1107/2009) can no longer accept an application for mutual recognition nor issue an authorisation by recognising an authorisation issued by the United Kingdom, even if this authorisation was granted by the United Kingdom prior to the withdrawal date. Authorisations based on mutual recognition of a United Kingdom authorisation granted prior to the withdrawal date remain valid.

During the transition period, the United Kingdom has to still accept and review new applications for authorisations in its territory, i.e. assume its role as the Member State concerned (cMS) in the meaning of Article 36(2) and 37(4) of Regulation (EC) No 1107/2009. The United Kingdom will have to accept and review applications for mutual recognition under the rules laid down in Article 40 to 42 of authorisations issued by an EU 27 Member State.

¹⁶ Article 36(1) of Regulation (EC) No 1107/2009.

¹⁷ Article 36(1) of Regulation (EC) No 1107/2009.

Thus, an EU Member State can no longer accept an application for mutual recognition and grant the related authorisation recognising an authorisation issued by the United Kingdom, even if this authorisation was granted by the United Kingdom prior to the withdrawal date.

4. PARALLEL TRADE PERMITS¹⁸

Article 52 of Regulation (EC) No 1107/2009 provides for issuance of parallel trade permits for parallel trade between Member States.

During the transition period, parallel trade permits remain valid and can be issued.

A parallel trade permit issued by an EU Member State for a plant protection product of which the United Kingdom was the Member State of origin is no longer valid after the end of the transition period.¹⁹

After the end of the transition period, Member States cannot issue parallel trade permits based on Article 52 of Regulation (EC) No. 1107/2009 where the country of origin is the United Kingdom.

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

Article 41(1) of the Withdrawal Agreement provides that an existing and individually identifiable good lawfully placed on the market in the EU or 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 the United Kingdom before the end of the transition period.²⁰

For the purposes of that provision, “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.²¹ “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

¹⁸ It is recalled that this notice does not address issues of intellectual property, and exhaustion of intellectual property rights.

¹⁹ A condition for granting a parallel trade permit under Article 52 is that it is granted to a product that is identical to a plant protection product authorised in an EU Member State (Member State of Origin).

²⁰ Article 42 of the Withdrawal Agreement.

²¹ Article 40(a) and (b) of the Withdrawal Agreement.

the subject matter of an offer to a legal or natural person or persons to conclude such an agreement.”²²

Example: An individual plant protection product sold by the UK-based producer to a UK-based or Member State-based wholesaler before the end of the transition period on the basis of a parallel trade permit can still be distributed further until it reaches the end-user, and used.^{23 24}

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.²⁵ 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.²⁶

The IE/NI Protocol makes certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland. In the IE/NI Protocol, the EU and the United Kingdom have furthermore agreed that insofar as EU rules apply to and in the United Kingdom in respect of Northern Ireland, Northern Ireland is treated as if it were a Member State.²⁷

The IE/NI Protocol provides that Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 apply to and in the United Kingdom in respect of Northern Ireland.²⁸

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:

- Plant protection products placed on the market in Northern Ireland have to comply with Regulation (EC) No 1107/2009;
- Food and feed placed on the market in Northern Ireland have to comply with the maximum residue limits set in accordance with Regulation (EC) No 396/2005;

²² Article 40(c) of the Withdrawal Agreement.

²³ This means that only goods that were placed on the market in the United Kingdom or an EU Member State on the basis of a parallel trade permit prior to the end of the transition period, can continue to be sold to the end user and used by the end user.

²⁴ This is without prejudice to the possibility of national authorities to restrict sale and use conditions to the products concerned where and to the extent permitted by Union law, cf. Article 41(5) Withdrawal Agreement.

²⁵ Article 185 of the Withdrawal Agreement.

²⁶ Article 18 of the IE/NI Protocol.

²⁷ Article 7(1) of the Withdrawal Agreement in conjunction with Article 13(1) of the IE/NI Protocol.

²⁸ Article 5(4) of the IE/NI Protocol and section 24 of annex 2 to that IE/NI Protocol.

- A plant protection product manufactured in Northern Ireland and shipped to the EU is not an imported plant protection product;
- A plant protection product shipped from Great Britain to Northern Ireland is an imported plant protection product;
- A plant protection product authorised in the United Kingdom in respect of Northern Ireland can be subject of a parallel trade permit by an EU Member State; a plant protection product authorised by an EU Member State can be subject of a parallel trade permit by the United Kingdom in respect of Northern Ireland.²⁹

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;³⁰
- 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;³¹
- act as leading authority for assessments, examinations and authorisations;³²
- invoke the country of origin principle or mutual recognition for products placed legally on the market in Northern Ireland.³³

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

- The United Kingdom in respect of Northern Ireland cannot act as rapporteur Member State (active substance), zonal rapporteur Member State (plant protection products), or evaluating Member State (maximum residue levels);
- An authorisation by the United Kingdom in respect of Northern Ireland cannot be mutually recognised in accordance with Article 40 of Regulation (EC) No 1107/2009.

Moreover, it should be stressed that the United Kingdom in respect of Northern Ireland cannot request scientific opinions in accordance with Article 43 of Regulation (EC) No 396/2005.³⁴

²⁹ This is without prejudice of aspects of intellectual property and exhaustion.

³⁰ 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.

³¹ Fifth subparagraph of Article 7(3) of the IE/NI Protocol.

³² Article 13(6) of the IE/NI Protocol.

³³ First subparagraph of Article 7(3) of the IE/NI Protocol.

³⁴ Cf. section 24 of annex 2 to the IE/NI Protocol.

The website of the Commission on pesticides (https://ec.europa.eu/food/plant/pesticides_en) provides general information in relation to Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. These pages will be updated where necessary.

European Commission
Directorate-General Health and Food Safety