



Brussels, 17 June 2020  
REV1 – replaces the notice dated  
23 January 2018 and the Q&A  
document (REV1) dated 23 October  
2018

## **NOTICE TO STAKEHOLDERS**

### **WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF BIOCIDAL PRODUCTS**

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## INTRODUCTION

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a “third country”.<sup>1</sup> The Withdrawal Agreement<sup>2</sup> provides for a transition period ending on 31 December 2020.<sup>3</sup> Until that date, EU law in its entirety applies to and in the United Kingdom.<sup>4</sup>

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,<sup>5</sup> 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 applicable 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:**

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

- UK-based suppliers included in the list established under Article 95 of Regulation (EU) No 528/2012 should appoint a representative established within the Union and communicate this to the European Chemicals Agency (ECHA) (by submitting a “request for correction”<sup>6</sup>) in due time, so that the information on the Article 95 list is updated before the end of the transition period.
- Suppliers included in the Article 95 list and located in third countries with a representative in the United Kingdom should appoint a new representative established within the Union and communicate this to ECHA (by means of a “request

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<sup>1</sup> A third country is a country not member of the EU.

<sup>2</sup> 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”).

<sup>3</sup> 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.

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

<sup>5</sup> 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.

<sup>6</sup> <https://echa.europa.eu/information-on-chemicals/active-substance-suppliers>.

for correction”<sup>7)</sup> in due time, so that the information on the Article 95 list is updated before the end of the transition period.

- UK-based holders of authorisations should transfer the authorisation to a new holder established within an EU Member State. UK-based authorisation holders can trigger the amendment of their existing authorisation by means of an administrative change requiring prior notification before implementation.<sup>8</sup> Such a change has to be submitted sufficiently in time before the end of the transition period.

**Please note:**

This notice does not address

- general EU chemicals law;
- EU rules on intellectual property (trademarks, designs, etc.), including aspects of exhaustion of intellectual property rights.

For these aspects, other notices are in preparation or have been published.<sup>9</sup>

**A. LEGAL SITUATION AFTER THE END OF THE TRANSITION PERIOD**

After the end of the transition period, the EU rules in the field of biocidal products, as set out by 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<sup>10</sup> and relevant implementing and delegated acts adopted by the Commission no longer apply to and in the United Kingdom.<sup>11</sup> This has in particular the following consequences:

**1. ESTABLISHMENT REQUIREMENTS**

According to Article 3(1)(p) of Regulation (EC) No 528/2012, authorisation holders for biocidal products must be established within the EU.

According to Article 95(1) of Regulation (EU) No 528/2012, active substance or product suppliers listed in the Article 95 list must be established within the EU. At the end of the transition period, UK suppliers and representatives of non-EU

<sup>7</sup> <https://echa.europa.eu/information-on-chemicals/active-substance-suppliers>.

<sup>8</sup> Cf. point 3 in section 1 of Title I of the Annex to Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012, OJ L 109, 19.4.2013, p. 4.

<sup>9</sup> [https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period\\_en](https://ec.europa.eu/info/european-union-and-united-kingdom-forging-new-partnership/future-partnership/preparing-end-transition-period_en)

<sup>10</sup> OJ L 167, 27.6.2012, p. 1.

<sup>11</sup> Regarding the applicability of the EU biocidal product law to Northern Ireland, see Part C of this notice.

suppliers based in the UK will be removed from the Article 95 list, and active substances or biocidal products from this source will no longer be allowed to be made available on the EU market.

## **2. LABELLING**

Article 69(2)(d) of Regulation (EU) No 528/2012 requires that the name and address of the authorisation holder are shown on the label. If an authorisation holder is changed (see point A.1 of this notice), this has to be reflected in the labelling for products placed on the EU market.

## **3. APPROVALS OF ACTIVE SUBSTANCES AND THE INCLUSION OF ACTIVE SUBSTANCES IN ANNEX I**

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 at the level of the Union or at the level of Member States acting jointly as referred to in the acts and provisions listed in Annex VII of the Withdrawal Agreement.<sup>12</sup> This annex includes Regulation (EU) No 528/2012.

Hence, since the withdrawal of the United Kingdom, and already during the transition period, the United Kingdom can no longer act as evaluating Competent Authority (eCA). Therefore, as regards the active substances/product-type combinations for which the competent authority of the United Kingdom had been designated as the eCA, it has been necessary to designate a new eCA.<sup>13</sup> The Withdrawal Agreement obliges the United Kingdom to transfer all relevant files and documents to the new eCA.<sup>14</sup> Notwithstanding the stage of evaluation of the application, the Member States whose competent authorities are to replace that of the United Kingdom are entitled to recover the costs of the work carried out by fees established in accordance with Article 80 of Regulation (EU) No 528/2012.<sup>15</sup>

Renewal of approval of active substances after the withdrawal of the United Kingdom: Article 13(3) of Regulation (EU) No 528/2012 does not require that the eCA for the renewal or approval must be the eCA for the first approval, although it is usually recommended as a means to streamline the process. When submitting an application for renewal, the applicant is to submit the name of the competent

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<sup>12</sup> Article 128(6) of the Withdrawal Agreement.

<sup>13</sup> Commission Delegated Regulation (EU) 2019/227 amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority, OJ L 37, 8.2.2019, p. 1.

<sup>14</sup> Article 44 of the Withdrawal Agreement. See also section B of this notice.

<sup>15</sup> Cf. Article 6a(2) of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1); Recital 5 of Commission Delegated Regulation (EU) 2019/227 of 28 November 2018 amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority, OJ L 37, 8.2.2019, p. 1.

authority of the Member State that is proposed for evaluating the application for renewal and provide written confirmation that that competent authority agrees to do so.

Substances already approved or already included in Annex I to Regulation (EU) No 528/2012 before the UK withdrawal: The withdrawal of the United Kingdom has no effect in the EU on the validity of existing approvals of active substances by the Commission, nor on the active substances already included in Annex I to Regulation (EU) No 528/2012.

#### **4. DATA SHARING AND DATA PROTECTION**

The data sharing mechanism provided for in Articles 62 and 63 of Regulation (EU) No 528/2012 applies to all companies, i.e. it continues to apply to UK-based companies.

The data protection provided for in Articles 59 and 60 of Regulation (EU) No 528/2012 continue to apply to UK-based companies.

#### **5. AUTHORISATIONS OF BIOCIDAL 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 at the level of the Union or at the level of Member States acting jointly as referred to in the acts and provisions listed in Annex VII of the Withdrawal Agreement.<sup>16</sup> This annex includes Regulation (EU) No 528/2012.

Hence, since the withdrawal of the United Kingdom, and already during the transition period, the United Kingdom can no longer act as reference Member State in the mutual recognition in sequence or in parallel.

New applications: since the withdrawal of the United Kingdom, a new application for an authorisation for a biocidal product cannot be submitted to the United Kingdom as reference Member State.

Mutual recognition procedures for which the United Kingdom was acting as reference Member State and which were pending on the withdrawal date: assessments have to be completed by an EU Member State acting as reference Member State or the authorisation process has to be terminated without granting an authorisation. The Withdrawal Agreement obliges the United Kingdom to transfer all relevant files and documents to the new reference Member State.<sup>17</sup> According to Article 80(2) of Regulation (EU) No 528/2012, Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation.

Assessments with the United Kingdom acting as reference Member State for mutual recognition procedures, or as evaluating Member State for Union authorisation

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<sup>16</sup> Article 128(6) of the Withdrawal Agreement.

<sup>17</sup> Article 44 of the Withdrawal Agreement. See also section B of this notice.

applicants, which have been completed, i.e. the assessment is made available to the concerned Member States in accordance with Article 34(4) of Regulation (EU) No 528/2012, or the conclusions of the evaluation are submitted to ECHA in accordance with Article 44 of Regulation (EU) No 528/2012, but the United Kingdom has not issued its national authorisation before the withdrawal date, ECHA has not submitted its opinion to the Commission in accordance with Article 44(3) of Regulation (EU) No 528/2012, or a referral or objection to the coordination group took place in accordance with Article 35 of Regulation (EU) No 528/2012: the role of reference Member State or evaluating competent authority has to be taken over by the competent authority of an EU Member State. The Withdrawal Agreement obliges the United Kingdom to transfer all relevant files and documents to the new reference Member State.<sup>18</sup> According to Article 80(2) of Regulation (EU) No 528/2012, Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation.

Authorisation in the mutual recognition procedure of an authorisation by the United Kingdom issued before the withdrawal date: an EU Member State 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 by Member States before 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 in the meaning of Articles 33 and 34 of Regulation (EU) No 528/2012.

During the transition period, a Union authorisation issued by the Commission in accordance with Article 44(5) of Regulation (EU) No 528/2012 is valid in the United Kingdom.

Renewal of the authorisation of a biocidal product after the UK withdrawal: Both, Commission Implementing Regulation (EU) No 354/2013<sup>19</sup> and Commission Delegated Regulation (EU) No 492/2014<sup>20</sup> allow the authorisation holder to choose another reference Member State. The holder will, however, need to submit within the application a written confirmation that the new competent authority agrees to act as reference Member State. According to Article 80(2) of Regulation (EU) No 528/2012, Member States shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation.

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<sup>18</sup> Article 44 of the Withdrawal Agreement.

<sup>19</sup> Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 109, 19.4.2013, p. 4.

<sup>20</sup> Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition, OJ L 139, 14.5.2014, p. 1.

## **6. AUTHORISATIONS GRANTED UNDER ARTICLE 26 AND NOTIFICATIONS UNDER ARTICLE 27(1) OF REGULATION (EU) No 528/2012 (SIMPLIFIED PROCEDURE)**

Authorisations granted by the United Kingdom under Article 26 and notifications under Article 27(1) of Regulation (EU) No 528/2012 of a low risk biocidal product authorised in the United Kingdom via the simplified procedure are no longer valid in the EU **after** the end of the transition period.

Thus, low-risk biocidal products authorised in the United Kingdom via the simplified procedure and notified to EU Member States in accordance with Article 27(1) of Regulation (EU) No 528/2012 can no longer be placed on the EU market **after** the end of the transition period.

## **7. TREATED ARTICLES**

Any treated article placed on the EU market is subject to the provisions of Regulation (EU) No 528/2012, in particular Articles 58 and 94. After the end of the transition period, shipments from the United Kingdom to the EU of a treated article will be considered as import and, consequently, placing on the market of such treated article. If the treated article was placed on the UK market before UK withdrawal, it can be expected to be compliant with Regulation (EU) No 528/2012, and there should be no specific consequences as regards to compliance with Regulation (EU) No 528/2012, unless the active substance contained in the treated article is no longer approved or the approval regulation of the active substance specifies other conditions or restrictions after the treated article had been placed on the UK market. It remains the responsibility of the person placing on the market a treated article to ensure compliance with Articles 58 and 94 of Regulation (EU) No 528/2012.

## **8. IT ISSUES – REGISTER FOR BIOCIDAL PRODUCTS (R4BP)**

Companies based in third countries, including the United Kingdom, have access to R4BP for certain processes, e.g., approval, notifications and submissions of active substances.

UK-based companies will be able to perform the same actions allowed for non-EU companies (e.g. active substance approval submissions).

A UK-based company can continue to act as a “case owner” in R4BP. This means that it will be able, among other things, to submit applications/notifications for active substances and monitor the progress of a given case. For instance, UK-based companies can continue to request active substance approvals (or renewals of approval) after the withdrawal of the United Kingdom. However, it is worthwhile recalling here that a biocidal product authorisation can only be granted to a person established within the EU.

## 9. PARALLEL TRADE<sup>21</sup>

Article 53 of Regulation (EU) No 528/2012 provides for issuance of a parallel trade permit for a biocidal product that is authorised in another Member State (“Member State of origin”).<sup>22</sup>

During the transition period, parallel trade permits issued by the United Kingdom or issued by an EU Member State with the United Kingdom being the Member State of origin remain valid.

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

After the end of the transition period, Member States cannot issue parallel trade permits based on Article 53 of Regulation (EU) No 528/2012 where the country of origin is the United Kingdom.

## B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

Article 41(1)(a) 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.<sup>23</sup>

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.<sup>24</sup> “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.”<sup>25</sup>

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<sup>21</sup> It is recalled that this notice does not address issues of intellectual property, and exhaustion of intellectual property rights

<sup>22</sup> A condition for granting a parallel trade permit under Article 53 is that it is granted to a product that is identical to a biocidal product already authorised in the Member State of introduction.

<sup>23</sup> Article 42 of the Withdrawal Agreement.

<sup>24</sup> Article 40(a) and (b) of the Withdrawal Agreement.

<sup>25</sup> Article 40(c) of the Withdrawal Agreement.



**Example:** An individual pack of a biocidal product having a Union authorisation granted by the Commission and sold by an EU-based manufacturer to 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.<sup>26</sup> 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.<sup>27</sup>

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.<sup>28</sup>

The IE/Ni Protocol provides that Regulation (EU) No 528/2012 applies to and in the United Kingdom in respect of Northern Ireland.<sup>29</sup>

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:

- a biocidal product placed on the market in Northern Ireland has to comply with Regulation (EU) No 528/2012;
- a biocidal product produced in Northern Ireland and shipped to the EU is not an imported biocidal product (see above, section A);
- a biocidal product shipped from Great Britain to Northern Ireland is an imported biocidal product (see above, section A);
- establishment requirements (see above, section A) are fulfilled by being established in Northern Ireland.

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;<sup>30</sup>

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<sup>26</sup> Article 185 of the Withdrawal Agreement.

<sup>27</sup> Article 18 of the IE/Ni Protocol.

<sup>28</sup> Article 7(1) of the Withdrawal Agreement in conjunction with Article 13(1) of the IE/Ni Protocol.

<sup>29</sup> Article 5(4) of the IE/Ni Protocol and section 24 of annex 2 to that Protocol.

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

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

- The United Kingdom, in respect of Northern Ireland cannot act as eCA for active substance procedures nor as reference Member State for product authorisation procedures;
- The United Kingdom, in respect of Northern Ireland cannot trigger referrals or propose refusing to grant an authorisations or adjust the terms and conditions in accordance with Articles 35 and 37 of Regulation (EU) No 528/2012.
- Moreover, with regard to Regulation (EU) No 528/2012 it should be stressed that: the United Kingdom, in respect of Northern Ireland cannot request the Commission to decide in accordance with Article 3(3) of Regulation (EU) No 528/2012);
- The United Kingdom, in respect of Northern Ireland cannot request the Commission to review the approval on an active substance in accordance with Article 15(1) of Regulation (EU) No 528/2012);
- The United Kingdom, in respect of Northern Ireland cannot request the Commission to amend Annex I in accordance with Article 28(4) of Regulation (EU) No 528/2012).
- The United Kingdom, in respect of Northern Ireland cannot request the Biocidal Products Committee of ECHA to establish an opinion in accordance with point g of Article 75(1) of Regulation (EU) No 528/2012).
- The United Kingdom, in respect of Northern Ireland cannot take provisional measures in accordance with the safeguard clause in Article 88 of Regulation (EU) No 528/2012);

However, the IE/Ni Protocol does not exclude the following:

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<sup>30</sup> 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.

<sup>31</sup> Fifth subparagraph of Article 7(3) of the IE/Ni Protocol.

<sup>32</sup> Article 13(6) of the IE/Ni Protocol.

<sup>33</sup> First subparagraph of Article 7(3) of the IE/Ni Protocol.

- The United Kingdom, in respect of Northern Ireland may permit a derogation provided for in Article 55 of Regulation (EU) No 528/2012.

The website of the Commission on EU rules on biocidal products ([https://ec.europa.eu/health/biocides/biocidal\\_products\\_en](https://ec.europa.eu/health/biocides/biocidal_products_en)) provides general information. These pages will be updated with further information, where necessary.

European Commission  
Directorate-General Health and Food safety