Impact of Brexit on Zonal Approval Procedures and Mutual Recognition Procedures in Plant Protection Legislation

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On 29 March 2017, the UK made use of Article 50 of the Treaty on European Union (TEU) and thus initiated its withdrawal from the European Union. As a result, the UK left the European Union on 31 January 2020 (23:00 UTC). This paper provides a legal assessment of the impact of the UK's withdrawal from the European Union (Brexit) on zonal authorisation and mutual recognition procedures regarding the authorisation of plant protection products. Many legal issues are unclear in this respect due to the lack of European and national case law. The German Administrative Court of Braunschweig had to decide in an urgent procedure on the effects of Brexit with regards to the authorisation of a plant protection product in the mutual recognition procedure.

I. Introduction

Plant protection products (PPPs)[1] include products for weed control (herbicides) such as glyphosate-containing products,[2] products against fungal diseases (fungicides)[3] and products against insect pests (insecticides).[4] There are also pesticides against mites, nematodes, snails and rodents. Germicides and other growth regulators are also legally considered as PPPs.[5] PPPs are products in the form in which they are supplied to the user (commercial product), consisting of or containing active substances,

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[1] Also referred to as "pesticides". The term "plant protection product" is a legal term defined in Article 2(1) Regulation (EC) No 1107/2009.

[2] Glyphosate is a plant protection active substance used to control weeds. The active substance has been approved at the EU level and is approved for use in PPPs in several European countries. The active substance glyphosate has been approved in Germany since 1974 in herbicides for weed control. Glyphosate is the most widely used herbicide worldwide. It is absorbed by all green plant parts. Glyphosate is diffused throughout the plant and leads to complete wilting and death of plants.

[3] A fungicide is an active substance that kills fungi or their spores or prevents their growth.

[4] Insecticides are used to kill, repel or inhibit insects.

[5] Plant protection law makes no fundamental distinction between synthetic PPPs, natural substances and microorganisms, because natural substances and microorganisms can also pose risks. However, the special characteristics of these groups are taken into account in the approval procedure. Pesticides that are used outside of agriculture (eg pesticides against hygiene pests or wood preservatives) are not considered to be PPPs, but fall within a separate legal area in the EU as so-called biocide products.

European Journal of Risk Regulation, 14 (2023), pp. 165–177
Cambridge University Press
doi:10.1017/err.2020.46

safeners or synergists. A PPP usually contains more than one component and at least one approved active substance. The active component against pests/plant diseases is called the "active substance". The European Commission evaluates every active substance for safety before it reaches the market in a product.[6] After the approval of an active substance at the European Union (EU) level, each PPP still needs an authorisation, which is granted by the Member States.[7] Before a PPP can be placed on the market or used in a Member State, it must have been authorised by the specific Member State.

Regulation (EU) No 1107/2009[8] lays down the requirements, procedures and timeframes for the authorisation of PPPs in the EU.[9] Although authorisations for PPPs are granted nationally, the authorities of the Member States cooperate in the PPP authorisation procedures. For this purpose, the EU is divided into three zones: north, centre and south.[10] In order to remove existing trade barriers in the Member States and for reasons of acceleration and efficiency, Regulation (EC) No 1107/2009 established the zonal approval procedure according to Article 33 et sqq. Regulation (EC) No 1107/2009 and the mutual recognition procedure according to Article 40 et sqq. Regulation (EC) No 1107/2009. Applicants can apply for authorisations for several Member States in one zone at the same time. The purpose of the zonal approval procedure is to ensure that the *Member States concerned* of one zone (so-called concerned Member States, or cMS for short)[11] do not examine all authorisation requirements on their own, but use the examination made by the *examining Member*

[6] The European Commission maintains a database containing the most relevant information on all active substances: the current status in the EU, toxicological data, links to assessment reports and decisions and maximum residue levels: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database> (last accessed 30 November 2019). Various toxicological limit values are derived from the study results, such as the acceptable daily intake (ADI), the acute reference dose (ARfD) and the acceptable operator exposure level (AOEL).

[7] This is mainly due to the following circumstances: on the one hand, PPPs contain, in addition to one or more active substances, other ingredients such as solvents, emulsifiers and carriers. These co-formulants should also be taken into account in the authorisation procedure. On the other hand, the risk assessment of a PPP not only takes into account the substance properties, but also the intended use. For example, health risks for users depend on how the product is formulated (eg as a liquid concentrate or sprinkling granulate) and on the application technique.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21.10.2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ No L 309, p 1, Celex No 32009R1107; refer to the variants of plant protection authorisation procedures, P Koof, "Die Bedeutung des Unionsrechts für das Verhältnis des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit zu den Beteiligungsbehörden" (2018) 2 StoffR 65.

[9] In 1991, Directive 91/414/EEC started the harmonisation of the authorisation of PPPs in the EU. In 2009, this Directive was replaced by Regulation (EC) No 1107/2009 concerning the placing of PPPs on the market, which now forms the basis of Union law. In addition, there are implementing regulations and technical guidance documents that regulate details of the procedures. The main principles are as follows: (1) The active substances of PPPs are evaluated in an EU procedure. (2) Every PPP (ie commercial product) requires an authorisation in each Member State in which it is to be placed on the market. Such authorisations shall be granted by the European Member States. (3) EU legislation sets out the data requirements that an applicant must submit for an active substance approval and for a product authorisation. (4) Maximum residue levels for active substances of PPPs in food and feed are set at the EU level in a Community procedure. (5) European Member States are required to monitor the sale and use of PPPs and to check food and feed for residues. The EU lays down standards for this and checks compliance with them.

[10] See Annex I of Regulation (EC) No 1107/2009: the following Member States belong to zone A (north): Denmark, Estonia, Latvia, Lithuania, Finland and Sweden. The Member States Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia and the UK belongs to zone B (centre). Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta and Portugal belong to zone C (south).

[11] The EU is divided into three zones in accordance with Art 3(17) Regulation (EC) No 1107/2009 in conjunction with Annex I: north (Denmark, Estonia, Finland, Latvia, Lithuania and Sweden), central (Belgium, Germany, Ireland, Luxembourg, Netherlands, Austria, Poland, Romania, Slovakia, Slovenia, Czech Republic, Hungary and the UK) and south (Bulgaria, France, Greece, Italy, Malta, Portugal, Spain and Cyprus).

State (so-called zonal Rapporteur Member State, or short zRMS)[12] as the basis for their own decision.[13] The zRMS examines the dossier, carries out the assessment, gives the other Member States the opportunity to comment on the results of the assessment and then grants the authorisation. On the basis of this evaluation, the other cMSs shall then decide on the authorisation in a rapid procedure. An applicant who subsequently wishes to extend the authorisation to other Member States in the zone may do so in accordance with the mutual recognition procedure. The mutual recognition procedure according to Article 40 et sqq. Regulation (EC) No 1107/2009 aims at recognising an authorisation already granted by another Member State (so-called *reference Member State*). In the mutual recognition procedure, the *Member State of recognition* grants an authorisation under the same conditions as the reference Member State examining the application.[14]

On 29 March 2017, the UK[15] made use of Article 50 of the Treaty on European Union (TEU)[16] and thus initiated the withdrawal from the EU.[17] In the authorisation procedures in which the UK examines the authorisation requirements as a zRMS or reference Member State for the zone, the question arises as to the extent to which the withdrawal of the UK from the EU has an impact on pending authorisation procedures. Since the zonal approval procedure as well as the procedure for mutual recognition relate in most instances to the respective zone, the questions regarding the impact of Brexit mainly came up in the Member States of zone B (centre), such as Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia and Slovakia. As the UK initially intended to leave the EU on 29 March 2019 at 23:00 Central European Time, the effects of the UK's withdrawal from the EU on PPP authorisation and licensing procedures were discussed in Germany from summer 2018 onwards. The competent German authority, the Federal Office of Consumer Protection and Food Safety (BVL), was asked to make a legally binding declaration that the withdrawal of the UK from the EU would not have a negative impact on pending authorisation procedures in Germany.

After extensive discussions with the Federal Ministry of Food and Agriculture (BMEL), the BVL announced in a public notification of 18 September 2018[18] that existing evaluations or authorisations of PPPs already granted by the UK before Brexit can serve as a basis for ZV3[19] or ZVU[20] applications in Germany beyond the date of Brexit. Germany will complete zonal

[12] VG Braunschweig, Court decision from 12 April 2018 – 9 A 44/16, para 81.

[13] See Art 35 Regulation (EC) No 1107/2009.

[14] Refer to the variants of PPP authorisation procedures, Koof, supra, note 8. On the binding effect in the zonal approval procedure and the mutual recognition procedure, see VG Braunschweig, Court decision from 30 November 2016 – 9 A 27/16; VG Braunschweig, Court decision from 30 November 2016 – 9 A 28/16; VG Braunschweig, Court decision from 12 April 2018 – 9 A 26/16; VG Braunschweig, supra, note 12.

[15] United Kingdom of Great Britain and Northern Ireland; hereinafter referred to as the UK.

[16] Treaty on European Union (consolidated version), Official Journal EU No C 326, 26 October 2012, pp 1–39, OJ C 326, pp 13–39.

[17] In accordance with the request of the British government, the EU decided on 28 October 2019 to extend the withdrawal period pursuant to Art 50 (3) TEU until 31 January 2020.

[18] BVL, Notification of 18 September 2018, p 1.

[19] The abbreviation ZV3 is used by the BVL for zonal approval procedures in accordance with Art 33 et sqq. of the Regulation (EC) No 1107/2009, in which Germany acts as the cMS.

[20] The abbreviation ZVU is used by the BVL for mutual recognition procedures in accordance with Art 40 et sqq. Regulation (EC) No 1107/2009.

approval procedures as a cMS if the UK has completed its procedure, at a minimum having provided the conclusions of the evaluation according to Article 36 (2) Regulation (EC) No 1107/2009 until 29 March 2019.[21] All authorisations granted by the UK as a Member State of the EU would be generally – even beyond 29 March 2019 – suitable as a basis for mutual recognition in Germany.[22] Representatives of EU Member States from the central zone have also issued information on the handling of Brexit in the zonal procedure via the Central Zone Steering Committee (CZSC).[23]

In October 2018, the European Commission published a catalogue of questions and answers on the impact of the UK's withdrawal from the EU on PPPs.[24] Contrary to the public notification by BVL, the European Commission officially announced that from the date of withdrawal of the UK from the EU, an authorisation granted by the UK cannot be recognised by the remaining 27 Member States of the EU.[25] Therefore, mutual recognition should not be possible any longer.[26]

Despite the contradiction with regards to the public notification of 18 September 2018 and the violation of the legitimate expectation of the applicants, the BVL, in coordination with the BMEL, adopted the legal opinion of the European Commission.[27] The BVL published an updated notification on 26 February 2019. It finds regarding mutual recognition procedures that, after Brexit, the UK has to be treated as a third country for whom the provisions of Regulation (EC) No 1107/2009 no longer apply.[28] Therefore, authorisations from the UK can – after the date of Brexit – no longer be recognised under the mutual recognition procedure.[29] All procedures of mutual recognition that were not completed by the BVL until the leaving date must result in a rejection of the application regardless of the date of application in Germany.[30]

Due to the short-term change of the legal opinion by the BVL – only a few days before the UK's alleged withdrawal from the EU on 29 March 2019 – the Administrative Court

[21] BVL, supra, note 18, p 1.

[22] BVL, supra, note 18, pp 1–2.

[23] CZSC, "Brexit: what happens when the UK is zRMS" (2019) <https://circabc.europa.eu/sd/a/f7ac216c-37fc-43bd-93d6-760ada52261e/Communication%20Central%20Zone%20on%20ZRMS%20and%20Brexit.pdf> (last accessed 30 November 2019). According to the Guidance Document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010, rev. 9, 11 July 2014, p 5), communication within and between zones is crucial for the effective functioning of the zonal licensing system and should therefore be facilitated by the establishment of the following institutions: an inter-zonal steering committee and three zonal steering committees. A zonal steering committee is set up in each zone, in which all Member States of a zone participate. The zonal steering committee shall meet every two months to discuss specific applications and issues raised in the inter-zonal steering committee. For the Central Zone, the CZSC was established in 2010 with the aim of promoting harmonisation and avoiding duplication of work through cooperation. Since 2017, the CZSC has been supported by the CZSC Secretariat (zonal secretariat).

[24] European Commission, "Questions and answers related to the United Kingdom's withdrawal from the European Union with regard to plant protection products and pesticide residues" (18 February 2019) <https://ec.europa.eu/info/sites/info/files/file_import/qa-plant-protection-products_en_0.pdf> (last accessed 30 November 2019).

[25] ibid.

[26] ibid.

[27] BVL, "Zulassung von Pflanzenschutzmitteln – Deutschland schließt sich der Position der EU-Kommission zum Umgang mit dem Brexit an" (26 February 2019) <https://www.bvl.bund.de/SharedDocs/Fachmeldungen/04_pflanzenschutzmittel/2019/2019_02_26_Fa_Brexit_Zulassungsverfahren.html> (last accessed 30 November 2019).

[28] BVL, supra, note 27.

[29] ibid.

[30] ibid.

of Braunschweig had to decide on the effects of Brexit on pending mutual recognition procedures in an urgent procedure.[31] A referral to the European Court of Justice (ECJ) regarding the interpretation of Regulation (EC) No 1107/2009 would have been appropriate, but has not been made by the Administrative Court of Braunschweig. According to Article 267 Treaty on the Functioning of the European (TFEU),[32] the ECJ shall, on request or referral to the court of a Member State, give preliminary rulings on the interpretation of the Treaties and on the validity and interpretation of acts of the institutions, bodies, offices or agencies of the Union (secondary legislation).[33]

This article provides a legal assessment of the impact of the UK's withdrawal from the EU on authorisations already granted (see Section II), pending (see Section III.1) and not yet pending (see Section III.2) in the mutual recognition and zonal procedures (see Section IV).[34]

The following comments refer to the current legal situation under Regulation (EC) No 1107/2009. The EU and the UK concluded on 24 January 2020 a withdrawal agreement.[35]

II. Effects on authorisations already granted

The withdrawal of the UK from the EU has no effect on authorisations granted in the mutual recognition or the zonal procedures in another Member State such as Germany before the date of Brexit.[36] With the granting of the national authorisation, the procedure is completed. Only in the event that the authorisation of the PPP is due for a renewal according to Article 43 Regulation (EC) No 1107/2009 a new zRMS must be found. According to Union law, a third country cannot take over the role as a zRMS or cMS.[37]

III. Effects on mutual recognition procedures according to Article 40 et sqq. Regulation (EC) No 1107/2009

According to Article 40(1) lit. a) Regulation (EC) No 1107/2009, the holder of an authorisation granted in accordance with Article 29 may apply for an authorisation that was granted by another Member State (reference Member State) of the same

[31] VG Braunschweig, Court order from 03 April 2019 – 9 B 23/19.

[32] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, OJ C 326, 26.10.2012, pp 47–390.

[33] The national courts are responsible for applying EU law. However, when an issue relating to the interpretation of the law is raised before a national court or tribunal, the court or tribunal may seek a preliminary ruling from the ECJ. If it is a court of last instance, it is compulsory to refer the matter to the Court.

[34] See I Carreno and T Dolle, "The Regulatory Framework on Plant Protection Products in the United Kingdom after Brexit" (2017) 8 European Journal of Risk Regulation 766, 766–71.

[35] 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 of 31 January 2020, pp 7–187 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:22020A0131(01)> (last accessed 9 March 2020).

[36] See European Commission, supra, note 24, No 3.

[37] European Commission, "Notice to stakeholders – Withdrawal of the United Kingdom and EU rules on plant protection products" (23 January 2018) <https://ec.europa.eu/info/sites/info/files/file_import/plant_protection_products_en.pdf> (last accessed 30 November 2019).

zone for the same PPP, the same use and under comparable agricultural practices in another Member State (Member State of recognition) under the mutual recognition procedure. According to Article 41(1) Regulation (EC) No 1107/2009, the Member State of recognition is obliged to grant an authorisation under the same conditions as the reference Member State examining the application except where Article 36(3) Regulation (EC) No 1107/2009 applies.[38] The Member State of recognition is bound to the examination made by the reference Member State and may not conduct its own examination regarding the requirements for granting the authorisation according to Article 29 Regulation (EC) No 1107/2009.[39]

Authorisations granted by the UK after the withdrawal from the EU can no longer be subject to a mutual recognition procedure according to Article 40 Regulation (EC) No 1107/2009. After Brexit, the UK is to be considered as a third country,[40] for whom the provisions of Regulation (EC) No 1107/2009 no longer apply.[41] After the withdrawal, the UK can no longer act as a zRMS, and according to Article 128(6) of the withdrawal agreement,[42] not even during the transitional period. The withdrawal agreement provides for a transitional period until 31 December 2020, during which EU law will in principle continue to apply to the UK and the UK will remain part of the EU internal market and the EU customs union.

With regards to authorisations granted by the UK during its membership in the EU according to Article 29 et sqq. Regulation (EC) No 1107/2009, the question arises as to whether these authorisations may be subject to a mutual recognition procedure after the withdrawal. A distinction is made between, at the time of Brexit, pending mutual recognition procedures (see Section III.1) and mutual recognition applications filed after the withdrawal (see Section III.2).

1. Mutual recognition procedures pending prior to Brexit

Contrary to the legal opinion of the European Commission[43] and the BVL according to the public notification dated 26 February 2019,[44] an authorisation for a PPP granted by the UK prior to a withdrawal from the EU may still be subject to an authorisation by way of mutual recognition even after withdrawal.[45] This was confirmed by the German Administrative Court of Braunschweig in an urgent procedure regarding a mutual recognition procedure that is pending prior to the withdrawal of the UK from the

[38] See VG Braunschweig, Court decision from 30 November 2016 – 9 A 27/16; VG Braunschweig, Court decision from 30 November 2016 – 9 A 28/16.

[39] See VG Braunschweig, Court decision from 30 November 2016 – 9 A 27/16; VG Braunschweig, Court decision from 30 November 2016 – 9 A 28/16; VG Braunschweig, Court decision from 12 April 2018 – 9 A 26/16; VG Braunschweig, supra, note 12.

[40] A third country is a country that is not a member of the EU.

[41] See European Commission, supra, note 24; European Commission, supra, note 37.

[42] Supra, note 35.

[43] European Commission, supra, note 24, No 13.

[44] BVL, supra, note 27.

[45] VG Braunschweig, supra, note 31, p 4.

EU.[46] Even if a reference for a preliminary ruling to the ECJ would have been desirable, the legal arguments of the Administrative Court of Braunschweig are convincing.

The Court confirmed that the recognisability is already apparent from the wording of Regulation (EC) No 1107/2009.[47] According to Article 40(1) lit. a) Regulation (EC) No 1107/2009, the subject of mutual recognition may be an authorisation "*granted*" under Article 29 that "*was granted*" by a Member State of the same zone.[48] These conditions are met by an authorisation for a PPP granted by the UK under the provisions of Regulation (EC) No 1107/2009 prior to a withdrawal from the EU, even if a withdrawal occurs at a later stage.[49] The decisive factor is that the UK was a Member State of the EU at the time of the granting of the UK authorisation and that the UK authorisation was granted according to Regulation (EC) No 1107/2009.[50] The authorisation was granted by the UK under European rules that continue to apply for the remaining Member States of the EU after a withdrawal.[51]

For a mutual recognition, it is not required that the UK remains a member of the EU at the time of the decision by the Member State of recognition.[52] The German Court clearly expresses that there are no fundamental reasons that would require this.[53] Even if the UK should, after leaving the EU, be treated as a third country to whom the provisions of Regulation (EC) No 1107/2009 no longer apply, this does not preclude a mutual recognition by the Member State of recognition. The authorisation was still granted by the UK as a Member State of the EU and as a "European authorisation" in accordance with the requirements of Regulation (EU) No 1107/2009 as defined by Article 40(1) lit. a) Regulation (EC) No 1107/2009.[54] The withdrawal from the EU does not reduce the quality of authorisations granted under Regulation (EC) No 1107/2009 by the UK as a Member State of the EU in the application of European Law.[55]

Furthermore, the Court confirmed that there is no need for further participation by the UK as a reference Member State in the mutual recognition procedure.[56] The examination required under Article 40(1) Regulation (EC) No 1107/2009 is the sole responsibility of the Member State of recognition.[57] There are no apparent reasons as to why, in the zonal approval procedure, an assessment made by the UK as a zRMS prior to the withdrawal from the EU could be adopted according to Article 36(2) Regulation (EC) No 1107/2009

[46] ibid. It is wrong that the Administrative Court of Braunschweig refers in the resolution to the withdrawal of "Great Britain" from the EU. The court fails to recognize that the term "Great Britain" is the geographical name for the largest of the British Isles with the countries England, Wales and Scotland. The UK describes the political unity of Great Britain (England, Wales and Scotland) and Northern Ireland. The United Kingdom of Great Britain and Northern Ireland is a sovereign state that is an official member of the EU, NATO and the United Nations. On 29 March 2017, the UK triggered Art 50 TEU and thus initiated the withdrawal from the EU.

[47] VG Braunschweig, supra, note 31, p 4.

[48] ibid, p 4.

[49] ibid, p 5.

[50] ibid, p 5.

[51] ibid, p 5.

[52] ibid.

[53] ibid.

[54] ibid.

[55] ibid.

[56] ibid.

[57] ibid.

by a Member State as a cMS even after withdrawal,[58] whereas the mutual recognition of authorisations granted by the UK prior to withdrawal should not be.[59] According to Article 44 Regulation (EC) No 1107/2009, it is ensured that a reaction can be made to any possible future findings and developments independently of a withdrawal of the UK from the EU.[60] Any Member State that has granted an authorisation may amend or withdraw the authorisation according to Article 44 Regulation (EC) No 1107/2009, not only the reference Member State.[61] This ensures that any subsequent removal of the conditions for authorisation after a national authorisation has been granted can be addressed even if the UK is no longer a Member State of the EU.[62]

The Court further clarifies that Article 56(3) Regulation (EC) No 1107/2009 does not preclude a mutual recognition after the withdrawal of the UK.[63] The Member State that first granted an authorisation shall evaluate the information received and provided by the authorisation holder concerning the PPP, the active substance, its metabolites and any safener, synergist or co-formulant contained in the PPP, indicating that the PPP no longer satisfies the requirements for authorisation. If the zRMS decides to withdraw or amend the authorisation under Article 44 Regulation (EC) No 1107/2009, it has to inform the other Member States of the same zone. Notwithstanding the UK's withdrawal from the EU, the assessment required for UK reference authorisations would no longer be made according to the standards of Regulation (EC) No 1107/2009 by the reference Member State. However, this does not prevent mutual recognition.[64] The Court confirms that another Member State of the zone may adopt the role of the UK as a reference Member State. In addition, in any event, a Member State that granted a mutual recognition authorisation is entitled to examine and assess according to Article 44 Regulation (EC) No 1107/2009 independently of the granted authorisation.[65] According to the Court, the principle of proportionality must be taken into account in relation to the total denial of the possibility of continuing mutual recognitions after the withdrawal of the UK.[66] The European Commission and the BVL also assume in zonal approval procedures that the role of the UK as a zRMS can be adopted by another Member State of the zone.[67]

Another argument in favour of the possibility of proceeding with the mutual recognition is the history of Regulation (EC) No 1107/2009. According to the preliminary consultations on the draft of the Regulation (EC) No 1107/2009, the words "in accordance with Article 29" and "comparable" in the later Article 40(1) Regulation (EC) No 1107/2009 were introduced only because of the insistence of

58 See European Commission, supra, note 24, No 12; BVL, supra, note 27.
59 VG Braunschweig, supra, note 31, pp 5-6.
60 ibid, p 6.
61 ibid.
62 ibid.
63 ibid.
64 ibid.
65 ibid.
66 ibid, p 7.
67 See European Commission, supra, note 24, No 11; BVL, supra, note 27.

various Member States.[68] With the formulation "authorisations granted in accordance with Article 29", it should be ensured that only such authorisations could be recognised that were granted on the basis of a harmonised authorisation procedure within the EU. This clearly concerned the authorisation procedure itself and not which state was still a Member State of the EU at the time of the later recognition decision by the Member State of recognition. The same applies to the criterion of the comparability of agricultural conditions. This, too, is an exclusively product-related characteristic in the way that the conditions of use of the product in the reference and recognition Member States should be comparable – and independent of the question of whether or not the reference Member State is a Member of the EU at the point of decision-making by the Member State of recognition.

Thus, an authorisation for a PPP granted by the UK before a withdrawal from the EU may still be subject to mutual recognition after a withdrawal. Due to the decision of the Administrative Court of Braunschweig, the BVL has corrected its legal position again and published a corresponding notification on 26 June 2019.[69] The BVL informs that all applications of mutual recognition for authorised PPPs from the UK submitted before Brexit will be processed to the end and, if necessary, decided on, after Brexit.[70]

2. Filing of mutual recognition applications after Brexit

In the urgent procedure, the Administrative Court of Braunschweig did not decide on whether a recognition of an authorisation granted by the US as a reference Member State before Brexit will be possible if the mutual recognition is applied by the Member State of Germany as a recognising Member State after the UK has left the EU.[71] This is to be affirmed.[72] Regarding the mutual recognition of an authorisation granted by the UK according to Article 29 Regulation (EC) No 1107/2009 during its membership of the EU, it makes no legal difference whether the application for mutual recognition was submitted in the Member State of recognition before or after the UK's withdrawal from the EU.

It is not apparent from the wording of Article 40(1) lit. a) Regulation (EC) No 1107/2009 that the reference Member State must still be a Member State of the EU at the time when the application for mutual recognition is submitted. The only decisive factor is that at the time the authorisation was granted by the reference Member State, the reference Member State was still a member of the EU and the authorisation was granted in application of the Regulation (EC) No 1107/2009. In the case that the UK as a reference Member State granted the authorisation according to Article 29 Regulation (EC) No 1107/2009 as a

[68] Council of the European Union, Note of 11 April 2008 – 8034/08.

[69] BVL, "Zulassung von Pflanzenschutzmitteln - Zulassungen aus UK können anerkannt werden, sofern die Antragstellung vor dem Brexit erfolgt" (26 June 2019) <https://www.bvl.bund.de/SharedDocs/Fachmeldungen/04_pflanzenschutzmittel/2019/2019_06_26_Fa_Korrektur_Brexit_Zulassungsverfahren.html> (last accessed 30 November 2019).

[70] ibid.

[71] VG Braunschweig, supra, note 31, p 7.

[72] The BVL has not announced its legal opinion in this respect. However, according to the corrected BVL report of 26 February 2019, the BVL does not seem to share this legal opinion because the BVL emphasises the application for mutual recognition before Brexit. See BVL, supra, note 27.

valid Member State of the EU, the UK is no longer involved in the mutual recognition procedure according to Article 40 Regulation (EC) No 1107/2009. It does not matter whether the application for mutual recognition was made by the UK before or after leaving the EU. Thus, the mere function of membership of the reference Member State in the EU is not relevant, neither at the time of the application nor at the time of the decision by the Member State of recognition. An authorisation granted under Union law remains valid for the Member States remaining in the EU after a withdrawal by the UK. The applicant obtains with the granting of the authorisation the subjective public right to apply for mutual recognition in another Member State of the same zone. This expectant right can be taken away neither by a hard Brexit nor by a withdrawal agreement.

The purpose of Regulation (EC) No 1107/2009 does not preclude this either. According to recitals 8 and 9, the aim of the Regulation is to ensure a high level of protection of human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. In addition, in order to remove as far as possible the obstacles to trade in PPPs existing due to the different levels of protection in the Member States, Regulation (EC) No 1107/2009 implements harmonised rules for the approval of active substances and the placing on the market of PPPs, including the rules on the mutual recognition of authorisations. The purpose of the Regulation is to increase the free movement of such products and their availability in Member States. According to recital 29 Regulation (EC) No 1107/2009, the principle of mutual recognition is one of the means of ensuring the free movement of goods within the Community. To avoid any duplication of work, in order to reduce the administrative burden for industry and for Member States and to provide for more harmonised availability of PPPs, authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. This aim would not be achieved if a Member State had to re-examine the authorisation requirements according to Article 29 Regulation (EC) No 1107/2009 again. Irrespective of the UK's withdrawal from the EU, the PPP has already been examined according to the provisions of Regulation (EC) No 1107/2009 and was found to be approvable by a Member State of the EU. A re-examination of the requirements for granting the authorisation according to Article 29 Regulation (EC) No 1107/2009 would not achieve the aim of efficiency of Regulation (EC) No 1107/2009.

IV. Effects on zonal approval procedures according to Article 33 et sqq. Regulation (EC) No 1107/2009

PPPs can also be authorised in the zonal approval procedure according to Articles 29, 33 et sqq. Regulation (EU) No 1107/2009. The applicant shall propose to the Member States of the zone which Member State is to become the zRMS.[73] As far as the proposal is accepted, the applicant applies for the zonal authorisation to the zRMS according to

[73] VG Braunschweig, supra, note 12, paras 57, 72.

Article 35 Regulation (EC) No 1107/2009.[74] At the same time, the applicant shall submit the application for authorisation to all other Member States of the same zone in which he or she seeks an authorisation.[75] These Member States then become cMSs. The cMSs shall refrain from proceeding with the file until the evaluation by the zRMS is completed.[76] According to Article 36(1) Regulation (EC) No 1107/2009, the zRMS conducts an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. The zRMS gives all Member States of the same zone the opportunity to submit their comments.[77] The cMSs shall subsequently grant or refuse the authorisation on the basis of the conclusions of the examination by the zRMS. According to Article 37(4) Regulation (EC) No 1107/2009, the cMSs shall decide according to Article 36(2) and (3) of Regulation (EC) No 1107/2009 on granting the application within a maximum of 120 days after receipt of the Registration Report and the copy of the authorisation certificate.[78] Where the UK acts as the zRMS in zonal approval procedures, the question arises as to the extent to which the withdrawal of the UK from the EU has an impact on pending zonal approval procedures.

1. Completion of evaluation and granting of authorisation by the UK as the zRMS

A withdrawal of the UK from the EU has no negative impact on the subsequent authorisation decision of the cMS if the UK has completed the evaluation as the zRMS of the PPP and has granted a national authorisation before the withdrawal. This is confirmed by the European Commission, CZSC and BVL. The European Commission considers the assessment as being complete as soon as the assessment according to Article 36(1) Regulation (EC) No 1107/2009 is available to the other Member States of the same zone. If the UK as the zRMS completes the approval procedure (ie finalises the registration report and issues the national authorisation before the withdrawal date), the cMSs have to decide within 120 days on granting the authorisation on the basis of the evaluation by the UK as the zRMS according to Article 37(4) and Article 36(2) Regulation (EC) No 1107/2009.[79] The cMSs may grant an authorisation even if the UK as the zRMS is no longer a Member State of the EU at the time of the national authorisation decision by the cMSs.[80] In the zonal approval procedure, the adoption by a Member State of an assessment of a PPP conducted by the UK as the zRMS before leaving the EU is lawful even after the withdrawal. If the UK has assessed the application as the zRMS for all cMSs in accordance with the provisions of Article 29 et sqq. Regulation (EC) No 1107/2009 and has granted the national authorisation, a valid authorisation of a Member State of

[74] ibid.

[75] ibid.

[76] See Art 35(3) Regulation (EC) No 1107/2009.

[77] See Art 36(1) (3) Regulation (EC) No 1107/2009.

[78] VG Braunschweig, supra, note 12, para 57.

[79] European Commission, supra, note 24, No 12; CZSC, supra, note 23.

[80] European Commission, supra, note 24, No 12.

the EU of the same zone exists. The registration report issued by the UK as the zRMS and the authorisation certificate remain unchanged, even if the UK as the zRMS is at a later stage no longer a Member State of the EU. There will be no change in the acceptable legal quality of the assessment and authorisation. To the cMSs, it is irrelevant in terms of their evaluation within the scope of Article 36(2) and (3) Regulation (EC) No 1107/2009 that, in future, the UK as the zRMS may no longer be a Member State of the EU because, according to Article 36(2) Regulation (EC) No 1107/2009, cMSs shall grant or refuse authorisations on the basis of the conclusions of the assessment of the zRMS and the zRMS no longer participates in the evaluation of the cMSs.[81] If the UK makes its authorisation decision as the zRMS before the leaving date, the adoption in the zonal procedure by Germany can therefore still take place after the leaving date.[82]

2. Incomplete assessment by the UK as the zRMS at the time of withdrawal

If the UK as the zRMS does not complete the authorisation procedure in time, the applicant must seek a new zRMS.[83] This is confirmed by the European Commission, CZSC and BVL.[84] Pending proceedings of the UK as the zRMS that have not been concluded at the time of withdrawal on 31 January 2020 cannot be further assessed by the UK.[85] After the withdrawal, the UK can no longer act as the zRMS, and according to Article 128(6) of the withdrawal agreement,[86] not even during the transitional period. In this case, the role of the zRMS must be adopted by another Member State.[87] The CZSC will determine a fall-back zRMS immediately after the withdrawal date.[88] The European Commission and the CZSC shall work out a way for a coordinated and timely adoption of the initial evaluation and the documentation.[89] According to Article 44 of the withdrawal agreement,[90] the UK as the zRMS shall transfer without delay to the competent authority of a Member State all relevant files or documents in relation to assessments, approvals and authorisations ongoing on the day before the withdrawal date.

3. Pending approval by the UK as the zRMS at the time of withdrawal

There is also a need for action if the UK as the zRMS has completed the evaluation of the PPP, but has not granted a national authorisation before the date of withdrawal on 31 January 2020. The European Commission, CZSC and BVL confirm that, in this

[81] VG Braunschweig, supra, note 31, p 6; VG Braunschweig, Court decision from 30 November 2016 – 9 A 27/16; VG Braunschweig, Court decision from 30 November 2016 – 9 A 28/16; A Koof, "Zulassung von Pflanzenschutzmitteln im zonalen Zulassungsverfahren – Anmerkung zu VG Braunschweig, Urt. v. 12.04.2018, Az. 9 A 44/16" (2018) 5 StoffR 205, 206.

[82] BVL, supra, note 27.

[83] ibid.

[84] European Commission, supra, note 24, No 11; CZSC, supra, note 23.

[85] European Commission, supra, note 24, No 11.

[86] Supra, note 35.

[87] The so-called fall-back zRMS. European Commission, supra, note 24, No 12.

[88] CZSC, supra, note 23.

[89] European Commission, supra, note 24, No 11.

[90] Supra, note 35.

case, it is necessary that another Member State adopts the role of the zRMS and takes an authorisation decision on the basis of the evaluation by the UK as the zRMS.[91] The authorisation, which would actually be granted by the UK as the zRMS, must be substituted by an authorisation of a cMS.[92] This is necessary because, according to Article 37(4) Regulation (EC) No 1107/2009, the 120-day deadline does not begin before the registration report and a copy of the authorisation certificate by the zRMS is available to the cMSs. The cMSs will issue the authorisation on the basis of the assessment by the UK as the zRMS.[93] Affected applicants should propose a cMS that adopts the function of the UK as the zRMS.[94] The cMS will then make the necessary agreements within the CZSC.[95]

V. Summary

The withdrawal of the UK from the EU will have some impact on the authorisation of PPPs in the zonal approval and mutual recognition procedure. National authorisations already granted in Member States based on an assessment by the UK as the zRMS or reference Member State remain valid notwithstanding the withdrawal. Authorisations granted by the UK as the reference Member State during its membership of the EU and in accordance with the provisions of Regulation (EC) No 1107/2009 may also, after the withdrawal, be basis to a mutual recognition according to Article 40 et sqq. Regulation (EC) No 1107/2009. This applies to mutual recognition procedures pending both before and after the date of withdrawal by the Member State of recognition. Furthermore, the withdrawal of the UK from the EU has no negative impact on the authorisation decisions of the cMSs in the zonal approval procedure if the UK has completed the evaluation of the PPP as the zRMS and has granted a national authorisation before withdrawal. The cMSs then have to decide within 120 days on granting the authorisation on the basis of the assessment by the UK as the zRMS, and may also grant an authorisation even if the UK is no longer a Member State of the EU at the time of the national authorisation decision by the cMSs. Pending proceedings by the UK as the zRMS that have not been completed at the time of withdrawal on 31 January 2020 cannot be further assessed by the UK after the withdrawal. From the time of withdrawal, the UK can no longer act as the zRMS. In this case, the role of the zRMS has to be adopted by another Member State in the zone.

[91] No 11; CZSC, supra, note 23; European Commission, supra, note 24; BVL, supra, note 27.
[92] European Commission, supra, note 24, No 12.
[93] ibid.
[94] ibid.
[95] ibid.