EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Brussels, 19 June 2020
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28 June 2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF GOOD LABORATORY PRACTICE (GLP)

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a "third country".[1] The Withdrawal Agreement[2] provides for a transition period ending on 31 December 2020.[3] Until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 applicable after the end of the transition period (Part A below). This notice also explains the rules applicable in Northern Ireland after the end of the transition period (Part B below).

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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.

Please note:

This notice does not address:

- EU general chemicals law;
- Sectorial EU legislation referring to good laboratory practice, such as EU law on plant protection products, medicinal products, or cosmetic products.

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, EU rules in the field of Good Laboratory Practice, and in particular Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)[7] and Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances[8] no longer apply to the United Kingdom.[9] This has in particular the following consequences:

1. RECOGNITION OF TESTS OF CHEMICAL PRODUCTS

According to Article 5(1) of Directive 2004/10/EC, Member States may not, on grounds relating to good laboratory practice (GLP), prohibit, restrict or impede the placing on the market of chemical products if the tests on the chemical product were performed in another Member State.

After the end of the transition period, this principle of mutual recognition set out in EU law no longer applies to the tests that were conducted in the United Kingdom.

Instead, the "**Mutual Acceptance of Data" (MAD) system** established under the auspices of the Organisation for Economic Co-operation and Development (OECD) will apply as of the withdrawal date.[10] All Member States participating in the MAD system must accept data from OECD members, which are full adherents to the MAD system having passed a successful evaluation by OECD under the OECD GLP Compliance Monitoring Programme.

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

7 OJ L 50, 20.02.2004, p. 28.

8 OJ L 50, 20.02.2004, p. 44.

9 Regarding the applicability of these Directives to Northern Ireland, see Part B of this notice.

10 Decision of the OECD Council concerning the mutual acceptance of data in the assessment of chemicals, C(81)30(final).

The United Kingdom is an OECD member and a full adherent to the MAD system, as are Belgium, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Italy, Hungary, the Netherlands, Austria, Poland, Portugal, Slovenia, Slovakia, Finland and Sweden. Thus, the mutual acceptance under the MAD system will apply, as of the withdrawal date, between the United Kingdom and these EU Member States.

The mutual acceptance under the MAD system in relation to the United Kingdom does not apply to EU Member States which are:

- participating in the OECD GLP Compliance Monitoring Programme, but have not yet been successfully evaluated (Latvia, Lithuania and Luxembourg). While these EU Member States have to accept data from the United Kingdom under the MAD system, the United Kingdom does not have to accept data from them; or

- not participating in the OECD GLP Compliance Monitoring Programme (Bulgaria, Croatia, Cyprus, Malta and Romania). These Member States do not have to accept data from the United Kingdom and *vice versa*.

2. OTHER ASPECTS

Directive 2004/9/EC provides for a system of cooperation and information exchange between EU Member States. At the end of the transition period, all cooperation procedures based on EU law between the EU Member States and the United Kingdom stop.

B. 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.[11] 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.[12]

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.[13]

The IE/NI Protocol provides that EU GLP legislation applies to and in the United Kingdom in respect of Northern Ireland.[14]

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[11] Article 185 of the Withdrawal Agreement.

[12] Article 18 of the IE/NI Protocol.

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

[14] Article 5(4) of the IE/NI Protocol and section 23 of annex 2 to that Protocol.

This means that references to the EU in Part A 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:

- Tests carried out in Northern Ireland have to comply with Directive 2004/10/EC;
- The United Kingdom in respect of Northern Ireland has to comply with the requirements set out in Directive 2004/9/EC;
- The United Kingdom in respect of Northern Ireland may not, on grounds relating to the principles of GLP, impede the placing on the market of chemical products 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;[15]
- 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;[16]
- act as leading authority for risk assessments, examinations, approvals and authorisations;[17]
- invoke the country of origin principle or mutual recognition in respect of Northern Ireland.[18]

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

- The United Kingdom in respect of Northern Ireland cannot invoke Article 6 of Directive 2004/9/EC nor Article 5(2) of Directive 2004/10/EC.

The website of the Commission on Good Laboratory Practice (http://ec.europa.eu/growth/sectors/chemicals/good-laboratory-practice_en) provides general information concerning GLP. These pages will be updated with further information, where necessary.

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[15] 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.

[16] Fifth subparagraph of Article 7(3) of the IE/NI Protocol.

[17] Article 13(6) of the IE/NI Protocol.

[18] First subparagraph of Article 7(3) of the IE/NI Protocol.