



Brussels, 28 June 2019

NOTICE TO STAKEHOLDERS

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

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union (TEU). Following a request by the United Kingdom, the European Council (Article 50) agreed on 11 April 2019¹ to extend further² the period provided for in Article 50(3) TEU until 31 October 2019.³ This means that the United Kingdom will be, as of 1 November 2019 ('the withdrawal date'), a 'third country'.^{4 5}

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the uncertainties surrounding the ratification of the Withdrawal Agreement, all interested parties, and especially economic operators, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.

Subject to the transition period provided for in the Withdrawal Agreement,⁶ as of the withdrawal date the 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

¹ European Council Decision (EU) 2019/584, OJ L 101, 11.4.2019, p. 1.

² Following a request by the United Kingdom, the European Council had decided a first extension on 22 March 2019 (European Council Decision (EU) 2019/476, OJ L 80 I, 22.3.2019, p. 1).

³ On 11 April 2019, following a second request for an extension by the United Kingdom, the European Council also decided that the decision to extend until 31 October 2019 would cease to apply on 31 May 2019 if the United Kingdom had not held elections to the European Parliament and had not ratified the Withdrawal Agreement by 22 May 2019. As the United Kingdom had not ratified the Withdrawal Agreement by 22 May 2019, it held European elections on 23 May 2019.

⁴ A third country is a country not member of the EU.

⁵ In addition, if the Withdrawal Agreement is ratified by both parties before that date, the withdrawal takes place on the first day of the month following the completion of the ratification procedures.

⁶ Cf. Part four of the 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 C 144 I, 25.4.2019, p. 1).

⁷ OJ L 50, 20.02.2004, p. 28.

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 substances⁸ no longer apply to the United Kingdom. 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.

As of the withdrawal date, 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.⁹ 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.

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 would have to accept data from the United Kingdom under the MAD system, the United Kingdom would not have to accept data from them; or
- not participating in the OECD GLP Compliance Monitoring Programme (Bulgaria, Croatia, Cyprus, Malta and Romania).

2. OTHER ASPECTS

Directive 2004/9/EC provides for a system of cooperation and information exchange between EU Member States. As of the withdrawal date, all cooperation procedures based on EU law between the EU-27 Member States and the United Kingdom stop.

⁸ OJ L 50, 20.02.2004, p. 44.

⁹ Decision of the OECD Council concerning the mutual acceptance of data in the assessment of chemicals, C(81)30(final).

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.

European Commission

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