



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Biotechnology

**NOTICE TO BUSINESS OPERATORS IN THE FIELD OF
REGULATION (EC) No 1829/2003 ON GENETICALLY MODIFIED FOOD AND FEED AND
DIRECTIVE 2001/18/EC ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED
ORGANISMS INTO THE ENVIRONMENT**

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. This means that unless the withdrawal agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'.

In this regard, business operators involved in the activities falling under the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed and Directive 2001/18/EC on the deliberate release of genetically modified organisms into the environment are reminded that preparing for the withdrawal is therefore not just a matter for European and national authorities, but also for private parties.

In particular, authorisation holders and applicants are reminded of certain legal repercussions, which need to be considered and anticipated:

- under Regulation (EC) No 1829/2003, authorisation holders or their representatives must be established in the European Union;
- applications for the placing on the market of genetically-modified organisms under Directive 2001/18/EC must designate a person responsible for the placing on the market which must be established in the European Union (or in one of the contracting states of the European Economic Area).

Business operators should consider that applications and notifications pursuant to Regulation (EC) No 1829/2003 and Directive 2001/18/EC can only be submitted to the competent authorities of EU Member States (or, in the case of Directive 2001/18/EC, of contracting states of the European Economic Area). In particular, business operators should carefully take into account the expected timelines before the submission of any new application in which the United Kingdom would be acting as rapporteur Member State under Directive 2001/18/EC.

The Commission Services stand ready to provide further clarification to business operators. If necessary, Questions & Answers (Q&A) in relation to Regulation (EC) No 1829/2003 and Directive 2001/18/EC will be made publicly available on a dedicated page of the Directorate-General for Health and Food Safety's website.