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STATUTORY INSTRUMENTS

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**2022 No. 486**

**AGRICULTURE, ENGLAND**  
**FOOD, ENGLAND**

**The Genetically Modified Food and Feed  
(Authorisations) (England) Regulations 2022**

<i>Made</i>	- - - -	<i>27th April 2022</i>
<i>Laid before Parliament</i>		<i>28th April 2022</i>
<i>Coming into force</i>	- -	<i>20th May 2022</i>

The Secretary of State makes these Regulations in exercise of the powers conferred by Articles 7(3), 9(2), 11, 19(3), 21(2), 23 and 35 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed<sup>(1)</sup>.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(2)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Citation, commencement, extent and application**

**1. These Regulations—**

- (a) may be cited as the Genetically Modified Food and Feed (Authorisations) (England) Regulations 2022;
- (b) come into force on 20th May 2022;
- (c) extend to England and Wales; and
- (d) apply in relation to England only.

**Interpretation**

**2. In these Regulations—**

“Regulation 1829/2003” means Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed;

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(1) EUR 1829/2003; relevant amending instruments are S.I. 2019/705, 2020/1504 and 2022/377. The terms “appropriate authority” and “prescribe” are defined in Article 2 of Regulation 1829/2003.

(2) EUR 178/2002; relevant amending instruments are S.I. 2019/641 and 2020/1504.

“Regulation 1830/2003” means Regulation (EC) No. 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC(3);

“Decision 2009/770” means Commission Decision 2009/770/EC establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of the placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council(4).

### **Authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified organisms**

3. Schedules 1 to 9 have effect.

### **Revocations**

4. The following Decisions are revoked—

- (a) Commission Decision 2009/813/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 (MON-89Ø34-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(5);
- (b) Commission Decision 2009/814/EC authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 88017 (MON-88Ø17-3) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(6);
- (c) Commission Decision 2009/866/EC authorising the placing on the market of products, containing, consisting of, or produced from genetically modified maize MIR604 (SYN-IR6Ø4-5) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council(7);
- (d) Commission Decision 2010/419/EU renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No. 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC(8);
- (e) Commission Implementing Decision (EU) 2018/1111 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 (MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU(9).

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(3) EUR 1830/2003; relevant amending instruments are S.I. 2019/90, 2019/778 and 2020/1421.

(4) EUD 2009/770, amended by S.I. 2019/90.

(5) EUD 2009/813, amended by S.I. 2019/705.

(6) EUD 2009/814, amended by S.I. 2019/705.

(7) EUD 2009/866, amended by S.I. 2019/705.

(8) EUD 2010/419, amended by S.I. 2019/705.

(9) EUD 2018/1111, amended by S.I. 2019/705.

27th April 2022

*Maggie Throup*  
Parliamentary Under Secretary of State  
Department of Health and Social Care

## SCHEDULES

### SCHEDULE 1

Regulation 3

Renewal of the authorisation of the placing on the market of products containing, consisting of, or produced from genetically modified maize MIR604

#### **Genetically modified organism and unique identifier**

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier SYN-IR604-5 is specified for genetically modified maize MIR604.

#### **Authorisation**

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this Schedule—

- (a) food and food ingredients containing, consisting of, or produced from genetically modified maize SYN-IR604-5;
- (b) feed containing, consisting of, or produced from genetically modified maize SYN-IR604-5; and
- (c) products containing or consisting of genetically modified maize SYN-IR604-5 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

#### **Labelling**

3.—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the ‘name of the organism’ is ‘maize’.

(2) The words ‘not for cultivation’ must appear on the label of and in documents accompanying the products containing or consisting of the genetically modified maize SYN-IR604-5, with the exception of food and food ingredients.

#### **Method for detection**

4.—(1) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the method specified in sub-paragraph (2) is to be used for the detection of genetically modified maize SYN-IR604-5.

(2) Event-specific real-time quantitative PCR based method of detection of the genetically modified maize as set out in the document entitled “Event-specific Method for the Quantification of Maize Line MIR604 using Real time PCR”, reference “CRLVL04/05VP corrected version 1” and dated 30 March 2010.

(3) The method of DNA extraction for use in the detection method specified in sub-paragraph (2) is as set out in the document entitled “Maize Seeds Sampling and DNA Extraction Report on the Validation of a DNA Extraction Method from Maize Seeds”, reference “CRLVL04/05XP” and dated 3 April 2007.

(4) For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the reference material “ERM-BF423” is accessible via the Joint Research Centre of the European Commission<sup>(10)</sup>.

### **Monitoring plan for environmental effects**

5.—(1) The authorisation holder must ensure that the monitoring plan for environmental effects<sup>(11)</sup>, which accompanied the application for the renewal of the authorisation of genetically modified maize SYN-IR604-5, reference number “RP476” submitted to the Food Safety Authority<sup>(12)</sup> on 3 March 2021, is implemented.

(2) The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

### **Authorisation holder**

6.—(1) The name and address of the authorisation holder is Syngenta Crop Protection AG of Rosentalstrasse 67, CH-4058 Basel, Switzerland.

(2) The authorisation holder is represented in Great Britain by Syngenta Limited of Jealott’s Hill International Research Centre, Bracknell, Berkshire, England, RG42 6EY.

## **SCHEDULE 2**

Regulation 3

Authorisation of the placing on the market of products containing,  
consisting of, or produced from genetically modified maize MZIR098

### **Genetically modified organism and unique identifier**

1. For the purposes of Articles 7(3) and 19(3) of Regulation 1829/2003, the unique identifier SYN-00098-3 is specified for genetically modified maize MZIR098.

### **Authorisation**

2. The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation 1829/2003, in accordance with the conditions set out in this Schedule—

- (a) food and food ingredients containing, consisting of, or produced from genetically modified maize SYN-00098-3;
- (b) feed containing, consisting of, or produced from genetically modified maize SYN-00098-3; and
- (c) products containing or consisting of genetically modified maize SYN-00098-3 for uses other than those provided for in sub-paragraphs (a) and (b), with the exception of cultivation.

### **Labelling**

3.—(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation 1829/2003, and in Article 4(6) of Regulation 1830/2003, the ‘name of the organism’ is ‘maize’.

<sup>(10)</sup> <https://crm.jrc.ec.europa.eu>.

<sup>(11)</sup> A copy of this document can be obtained from the Food Standards Agency (see Explanatory Note for further details).

<sup>(12)</sup> “Food Safety Authority” is defined in Article 2(17) of 1829/2003, as regards England, as the Food Standards Agency.