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## Contents

### II *Non-legislative acts*

#### INTERNATIONAL AGREEMENTS

- ★ **Council Decision (EU) 2018/1107 of 20 July 2018 on the conclusion of a Partnership and Cooperation Agreement between the European Union and its Member States, of the one part, and the Republic of Iraq, of the other part** ..... 1

#### REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2018/1108 of 7 May 2018 supplementing Directive (EU) 2015/849 of the European Parliament and of the Council with regulatory technical standards on the criteria for the appointment of central contact points for electronic money issuers and payment service providers and with rules on their functions <sup>(1)</sup>** ..... 2

#### DECISIONS

- ★ **Commission Implementing Decision (EU) 2018/1109 of 1 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2018) 4978) <sup>(1)</sup>** ..... 7
- ★ **Commission Implementing Decision (EU) 2018/1110 of 3 August 2018 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU (notified under document C(2018) 4937) <sup>(1)</sup>** ..... 13

<sup>(1)</sup> Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

|                                                                                                                                                                                                                                                                                                                                                                                                                                                               |    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----|
| ★ Commission Implementing Decision (EU) 2018/1111 of 3 August 2018 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-89034-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (notified under document C(2018) 5014) <sup>(1)</sup> ..... | 20 |
| ★ Commission Implementing Decision (EU) 2018/1112 of 3 August 2018 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2018) 5020) <sup>(1)</sup> .....                                                                          | 26 |
| ★ Commission Implementing Decision (EU) 2018/1113 of 3 August 2018 renewing the authorisation for the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2018) 5029) <sup>(1)</sup> .....                                                                                              | 32 |
| ★ Commission Implementing Decision (EU) 2018/1114 of 9 August 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (notified under document C(2018) 5510) <sup>(1)</sup> .....                                                                                                                                                                     | 37 |

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<sup>(1)</sup> Text with EEA relevance.

## II

*(Non-legislative acts)*

## INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2018/1107

of 20 July 2018

**on the conclusion of a Partnership and Cooperation Agreement between the European Union and its Member States, of the one part, and the Republic of Iraq, of the other part**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 91, 100, 207 and 209 in conjunction with Article 218(6)(a) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament <sup>(1)</sup>,

Whereas:

- (1) The Partnership and Cooperation Agreement between the European Union and its Member States, of the one part, and the Republic of Iraq, of the other part, ('the Agreement'), was signed on 11 May 2012, subject to its possible conclusion at a later date.
- (2) The Agreement should be approved,

HAS ADOPTED THIS DECISION:

*Article 1*

The Partnership and Cooperation Agreement between the European Union and its Member States, of the one part, and the Republic of Iraq, of the other part, together with the Annexes and the declaration made unilaterally by the Union, attached to the Final Act, is hereby approved on behalf of the Union <sup>(2)</sup>.

*Article 2*

The President of the Council shall, on behalf of the Union, give the notification, provided for in Article 116 of the Agreement, in order to express the consent of the Union to be bound by the Agreement <sup>(3)</sup>.

*Article 3*

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 20 July 2018.

*For the Council*  
*The President*  
G. BLÜMEL

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<sup>(1)</sup> Consent of 4 July 2018 (not yet published in the Official Journal).

<sup>(2)</sup> The Agreement has been published in OJ L 204 of 31 July 2012, p. 20 together with the decision on signature.

<sup>(3)</sup> The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2018/1108

of 7 May 2018

**supplementing Directive (EU) 2015/849 of the European Parliament and of the Council with regulatory technical standards on the criteria for the appointment of central contact points for electronic money issuers and payment service providers and with rules on their functions**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC <sup>(1)</sup>, and in particular Article 45(11) thereof,

Whereas:

- (1) Electronic money issuers and payment service providers may appoint central contact points to ensure, on behalf of the appointing institutions, compliance with anti-money laundering and counter-terrorist financing rules and to facilitate supervision by competent authorities. Member States may require the appointment of a central contact point where payment service providers and electronic money issuers provide services in their territory through establishments in forms other than a branch, but not where they provide services without an establishment.
- (2) The appointment of a central contact point to ensure compliance with anti-money laundering and counter-terrorist financing rules appears to be justified where the size and scale of the activities carried out by payment service providers and electronic money issuers through establishments in forms other than a branch meets or exceeds certain thresholds. Those thresholds should be set at a level that is proportionate to the aim of Directive (EU) 2015/849 to facilitate supervision by competent authorities of such establishments' compliance, on behalf of their appointing institution, with local anti-money laundering and countering the financing of terrorism (AML/CFT) obligations, while at the same time not creating undue regulatory burden on payment service providers and electronic money issuers.
- (3) The requirement to appoint a central contact point appears also to be justified where a Member State considers that the risk of money laundering and terrorist financing associated with the operation of such establishments is increased, as demonstrated, for instance, on the basis of an assessment of the money laundering and terrorist financing risk associated with certain categories of payment service providers or electronic money issuers. Member States should not be required to perform a risk assessment of individual institutions for that purpose.
- (4) However, in exceptional cases, where Member States have reasonable grounds to believe that the money laundering and terrorist financing risk associated with a particular payment service provider or electronic money issuer that operates establishments in their territory is high, they should be able to require that issuer or provide to appoint a central contact point, even if it does not meet the thresholds laid down in this Regulation or does not belong to a category of institutions that is required to appoint a central contact point based on the Member State's assessment of money laundering and terrorist financing risk.

<sup>(1)</sup> OJ L 141, 5.6.2015, p. 73.

- (5) Where a central contact point is appointed, it should ensure, on behalf of the appointing electronic money issuer or payment services provider, the compliance by its establishments with the applicable AML/CFT rules. To that end, the central contact point should have a sound understanding of applicable AML/CFT requirements and facilitate the development and implementation of AML/CFT policies and procedures.
- (6) The central contact point should, among others, have a central coordinating role between the appointing electronic money issuer or payment services provider and its establishments, and between the electronic money issuer or payment services provider and the competent authorities of the Member State where the establishments operate, to facilitate their supervision.
- (7) Member States should be entitled to determine, based on their overall assessment of money laundering and terrorist financing risks associated with the activity of payment service providers and electronic money issuers that are established in their territory in forms other than a branch, that central contact points are required to perform certain additional functions as part of their duty to ensure compliance with local AML/CFT obligations. In particular, it could be appropriate for Member States to require central contact points to submit, on behalf of the appointing electronic money issuer or payment services provider, suspicious transaction reports to the Financial Intelligence Unit (FIU) of the host Member State in whose territory the obliged entity is established.
- (8) It is for each Member State to determine whether or not central contact points should take a particular form. Where the form is prescribed, Member States should ensure that the requirements are proportionate and do not go beyond what is necessary to achieve the aim of compliance with AML/CFT rules and facilitate supervision.
- (9) This Regulation is based on the draft regulatory technical standards by the European Supervisory Authorities (the European Banking Authority, the European Insurance and Occupational Pensions Authority and the European Securities and Markets Authority) to the Commission.
- (10) The European Supervisory Authorities have conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council <sup>(1)</sup>, Regulation (EU) No 1094/2010 of the European Parliament and of the Council <sup>(2)</sup> and Regulation (EU) No 1095/2010 of the European Parliament and of the Council <sup>(3)</sup> respectively,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

### **Subject matter and scope**

This Regulation lays down:

- (a) criteria for determining the circumstances in which the appointment of a central contact point pursuant to Article 45(9) of Directive (EU) 2015/849 is appropriate;
- (b) rules concerning the functions of central contact points.

#### *Article 2*

### **Definitions**

For the purposes of this Regulation, the following definitions apply:

- (1) 'competent authority' means the authority of a Member State competent for ensuring compliance of electronic money issuers and payment service providers that are established in their territory in forms other than a branch and whose head office is situated in another Member State with the requirements of Directive (EU) 2015/849 as transposed by national legislation;

<sup>(1)</sup> Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

<sup>(2)</sup> Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/79/EC (OJ L 331, 15.12.2010, p. 48).

<sup>(3)</sup> Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

- (2) 'host Member State' means the Member State in whose territory electronic money issuers and payment service providers whose head office is situated in another Member State are established in forms other than a branch;
- (3) 'electronic money issuers and payment services providers' means electronic money issuers as defined in point (3) of Article 2 of Directive 2009/110/EC of the European Parliament and of the Council <sup>(1)</sup> and payment services providers as defined in point (9) of Article 4 of Directive 2007/64/EC of the European Parliament and of the Council <sup>(2)</sup>.

### Article 3

#### Criteria for the appointment of a central contact point

1. Host Member States may require electronic money issuers and payment services providers that have establishments in their territory in forms other than a branch, and whose head office is situated in another Member State, to appoint a central contact point where any of the following criteria is met:

- (a) the number of such establishments is 10 or more;
- (b) the cumulative amount of the electronic money distributed and redeemed, or the cumulative value of the payment transactions executed by the establishments is expected to exceed EUR 3 million per financial year or has exceeded EUR 3 million in the previous financial year;
- (c) the information necessary to assess whether or not the criterion in point (a) or (b) is met is not made available to the host Member State's competent authority upon request and in a timely manner.

2. Without prejudice to the criteria set out in paragraph 1, host Member States may require categories of electronic money issuers and payment services providers that have establishments in their territory in forms other than a branch, and whose head office is situated in another Member State, to appoint a central contact point where this requirement is commensurate to the level of money laundering or terrorist financing risk associated with the operation of those establishments.

3. Host Member States shall base their assessment of the level of money laundering or terrorist financing risk associated with the operation of those establishments on the findings of risk assessments carried out in accordance with Article 6(1) and Article 7(1) of Directive (EU) 2015/849 and other credible and reliable sources available to them. As part of this assessment, host Member States shall take into account at least the following criteria:

- (a) the money laundering and terrorist financing risk associated with the types of products and services offered and the distribution channels used;
- (b) the money laundering and terrorist financing risk associated with the types of customers;
- (c) the money laundering and terrorist financing risk associated with the prevalence of occasional transactions over business relationships;
- (d) the money laundering and terrorist financing risk associated with the countries and geographic areas serviced.

4. Without prejudice to the criteria set out in paragraphs 1 and 2, a host Member State may, in exceptional cases, empower the host Member State's competent authority require an electronic money issuer or payment services provider that has establishments in its territory in forms other than a branch, and whose head office is situated in another Member State, to appoint a central contract point providing that the host Member State has reasonable grounds to believe that the operation of establishments of that electronic money issuer or payment services provider presents a high risk of money laundering and terrorist financing.

<sup>(1)</sup> Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC (OJ L 267, 10.10.2009, p. 7).

<sup>(2)</sup> Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 5.12.2007, p. 1).

*Article 4***Ensuring compliance with AML/CFT rules**

The central contact point shall ensure that establishments specified in Article 45(9) of Directive (EU) 2015/849 comply with AML/CFT rules of the host Member State. To this end, the central contact point shall:

- (a) facilitate the development and implementation of AML/CFT policies and procedures pursuant to Article 8(3) and (4) of Directive (EU) 2015/849 by informing the appointing electronic money issuer or payment services provider of AML/CFT requirements applicable in the host Member State;
- (b) oversee, on behalf of the appointing electronic money issuer or payment services provider, the effective compliance by those establishments with AML/CFT requirements applicable in the host Member State and the appointing electronic money issuer's or payment services provider's policies, controls and procedures adopted pursuant to Article 8(3) and (4) of Directive (EU) 2015/849;
- (c) inform the head office of the appointing electronic money issuer or payment services provider of any breaches or compliance issues encountered in those establishments, including any information that may affect the establishment's ability to comply effectively with the appointing electronic money issuer's or payment services provider's AML/CFT policies and procedures or that may otherwise affect the appointing electronic money issuer or payment services provider's risk assessment;
- (d) ensure, on behalf of the appointing electronic money issuer or payment services provider, that corrective action is taken in cases where those establishments do not comply, or are at risk of not complying, with applicable AML/CFT rules;
- (e) ensure, on behalf of the appointing electronic money issuer or payment services provider, that those establishments and their staff participate in training programs referred to in Article 46(1) of Directive (EU) 2015/849;
- (f) represent the appointing electronic money issuer or payment services provider in its communications with the competent authorities and the FIU of the host Member State.

*Article 5***Facilitation of supervision by competent authorities of the host Member State**

The central contact point shall facilitate the supervision by competent authorities of the host Member State of establishments specified in Article 45(9) of Directive (EU) 2015/849. To this end, the central contact point shall, on behalf of the appointing electronic money issuer or payment services provider:

- (a) represent the appointing electronic money issuer or payment services provider in its communications with competent authorities;
- (b) access information held by those establishments;
- (c) respond to any request made by competent authorities related to the activity of those establishments, provide relevant information held by the appointing electronic money issuer or payment services provider and those establishments to competent authorities and report on a regular basis where appropriate;
- (d) facilitate on-site inspections of those establishments where required by the competent authorities.

*Article 6***Additional functions of a central contact point**

1. In addition to the functions specified in Articles 4 and 5, host Member States may require central contact points to perform, on behalf of the appointing electronic money issuer or payment services provider, one or more of the following functions:

- (a) file reports pursuant to Article 33(1) of Directive (EU) 2015/849 as transposed in national law of the host Member State;
- (b) respond to any request of the FIU related to the activity of establishments specified in Article 45(9) of Directive (EU) 2015/849, and providing relevant information related to such establishments to the FIU;

(c) scrutinise transactions to identify suspicious transactions where appropriate, in light of the size and complexity of the electronic money issuer's or payment services provider's operations in the host Member State.

2. Host Member States may require central contact points to perform one or more of the additional functions specified in paragraph 1 where those additional functions are commensurate to the overall level of money laundering and terrorist financing risk associated with the operation of those payment service providers and electronic money issuers that have establishments in their territory in forms other than a branch.

3. Host Member States shall base their assessment of the level of money laundering or terrorist financing risk associated with the operation of such establishments on the findings of risk assessments carried out in accordance with Article 6(1) and Article 7(1) of Directive (EU) 2015/849, Article 3(2) of this Regulation where applicable, and other credible and reliable sources available to them.

#### *Article 7*

#### **Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 May 2018.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2018/1109

of 1 August 2018

**renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council**

*(notified under document C(2018) 4978)*

**(Only the Dutch, English and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2007/702/EC <sup>(2)</sup> authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize 59122 (hereinafter 'maize 59122'). The scope of that authorisation also covered products other than food and feed containing or consisting of maize 59122, for the same uses as any other maize with the exception of cultivation.
- (2) On 19 July 2016, Pioneer Overseas Corporation and Dow AgroSciences Ltd jointly submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) Pioneer Overseas Corporation and Dow AgroSciences Ltd had submitted another application on 12 October 2005 covering the same products as those concerned by the present Decision as well as the cultivation of maize 59122. Pioneer Overseas Corporation and Dow AgroSciences Ltd withdrew on 27 July 2017 all the other uses than cultivation from the scope of that application.
- (4) On 29 June 2017, the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded <sup>(3)</sup> that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment <sup>(4)</sup> on maize 59122.
- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 42).

<sup>(3)</sup> Scientific opinion on an application for renewal of authorisation for continued marketing of maize 59122 and derived food and feed submitted under articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. The EFSA Journal (2017); 15(6):4861.

<sup>(4)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003, from Pioneer Hi-Bred International, Inc. and Mycogen Seeds, c/o Dow Agrosciences LLC. The EFSA Journal 2007;470, 1-25.

- (6) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicants, is in line with the intended uses of the products.
- (7) Taking into account those considerations, the authorisation for the placing on the market of food and feed containing, consisting of, or produced from maize 59122 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.
- (8) A unique identifier has been assigned to maize 59122, in accordance with Commission Regulation (EC) No 65/2004 <sup>(1)</sup>, by Decision 2007/702/EC. That unique identifier should continue to be used.
- (9) On the basis of the abovementioned EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(2)</sup>, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of products containing or consisting of maize 59122 remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize 59122, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holders should submit joint annual reports on the implementation and on the results of the activities set out in the monitoring plan for environmental effects. These results should be presented in accordance with Commission Decision 2009/770/EC <sup>(3)</sup>.
- (11) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(4)</sup>.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The measures provided for in this Decision are in accordance with the opinion of the appeal committee,

HAS ADOPTED THIS DECISION:

#### Article 1

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

Genetically modified maize (*Zea mays* L.) line 59122, as specified in point (b) of the Annex, is assigned the unique identifier DAS-59122-7, in accordance with Regulation (EC) No 65/2004.

#### Article 2

##### **Renewal of authorisation**

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) food and food ingredients containing, consisting of or produced from maize 59122;

<sup>(1)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(2)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 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 (OJ L 268, 18.10.2003, p. 24).

<sup>(3)</sup> Commission Decision 2009/770/EC of 13 October 2009 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 placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

<sup>(4)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (b) feed containing, consisting of or produced from maize 59122;
- (c) maize 59122 in products containing it or consisting of it for any other use than those provided for in points (a) and (b), with the exception of cultivation.

#### *Article 3*

#### **Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of maize 59122, with the exception of food and food ingredients.

#### *Article 4*

#### **Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of maize 59122.

#### *Article 5*

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

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex is put in place and implemented.
2. The authorisation holders shall submit to the Commission joint annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

#### *Article 6*

#### **Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

#### *Article 7*

#### **Authorisation holders**

1. The authorisation holders shall be:
  - (a) Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, Inc., United States; and
  - (b) Dow AgroSciences Ltd, United Kingdom, representing Dow AgroSciences LLC, United States.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

#### *Article 8*

#### **Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to:

- (a) Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium; and
- (b) Dow AgroSciences Europe Ltd, European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 1 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicants and Authorisation holders:**

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels, Belgium

On behalf of Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States

and

Name: Dow AgroSciences Europe Ltd

Address: European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

On behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

**(b) Designation and specification of the products:**

(1) food containing, consisting of, or produced from maize 59122;

(2) feed containing, consisting of, or produced from maize 59122;

(3) maize 59122 in products containing it or consisting of it for any other use than those provided for in points (1) and (2), with the exception of cultivation.

Maize 59122, as described in the application, expresses the Cry34Ab1 and Cry35Ab1 proteins, derived from *Bacillus thuringiensis*, which confer resistance to certain coleopteran pests, including Western corn rootworm, and the PAT protein, derived from *Streptomyces viridochromogenes*, which confers tolerance to glufosinate-ammonium based herbicides and was used as a selection marker.

**(c) Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of maize 59122, with the exception of food and food ingredients.

**(d) Method for detection:**

(1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize DAS-59122-7.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: ERM®-BF424 (for DAS-59122-7) is accessible via the Joint Research Centre (JRC) of the European Commission, at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

**(e) Unique identifier:**

DAS-59122-7

**(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

**(g) Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>.

[Link: *plan published in the register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

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<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

**COMMISSION IMPLEMENTING DECISION (EU) 2018/1110****of 3 August 2018****authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU***(notified under document C(2018) 4937)***(Only the Dutch, English and French texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 3 February 2011, Pioneer Overseas Corporation submitted, on behalf of Pioneer Hi-Bred International Inc., United States, an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603 ('the application') to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products consisting of or containing genetically modified maize 1507 × 59122 × MON 810 × NK603 for uses other than food and feed, with the exception of cultivation.
- (2) In addition, the application covered 10 sub-combinations of the single transformation events constituting maize 1507 × 59122 × MON 810 × NK603, of which five were already authorised. Eight of those sub-combinations are governed by this Decision. The two sub-combinations that are not covered are 1507 × NK603, which is authorised by Commission Decision 2007/703/EC <sup>(2)</sup>, and NK603 × MON 810, which is authorised by Commission Decision 2007/701/EC <sup>(3)</sup>.
- (3) Sub-combinations 59122 × 1507 × NK603 and 59122 × NK603 were already authorised under, respectively, Commission Decisions 2010/428/EU <sup>(4)</sup> and 2009/815/EC <sup>(5)</sup>. The authorisation holder, Pioneer Overseas Corporation, requested the Commission to repeal those earlier Decisions when adopting this Decision and to incorporate them in the scope of this Decision.
- (4) Sub-combination 1507 × 59122 was already authorised by Commission Decision 2010/432/EU <sup>(6)</sup>. By letter dated 28 January 2018, Dow Agro Sciences Ltd, as co-authorisation holder for maize 1507 × 59122, asked

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2007/703/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × NK603 (DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 47).

<sup>(3)</sup> Commission Decision 2007/701/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603×MON810 (MON-ØØ6Ø3-6 × MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 37).

<sup>(4)</sup> Commission Decision 2010/428/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 × 1507 × NK603 (DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 201, 3.8.2010, p. 41).

<sup>(5)</sup> Commission Decision 2009/815/EC of 30 October 2009 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 × NK603 (DAS-59122-7 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 289, 5.11.2009, p. 29).

<sup>(6)</sup> Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 (DAS-Ø15Ø7-1 × DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

to transfer its rights and obligations to Pioneer Overseas Corporation. By letter dated 26 January 2018, Pioneer Overseas Corporation agreed to this transfer and asked the Commission to repeal Decision 2010/432/EU when adopting this present Decision and to incorporate the authorisation for maize 1507 × 59122 in the scope of the present Decision.

- (5) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup> and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.
- (6) On 28 November 2017, the European Food Safety Authority ('the Authority') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 <sup>(2)</sup>. The Authority concluded that genetically modified maize 1507 × 59122 × MON 810 × NK603 is as safe and as nutritious as the non-genetically modified comparator in the context of the scope of the application. No new safety concerns were identified for the five previously assessed sub-combinations (59122 × 1507 × NK603, 1507 × 59122, 59122 × NK603, 1507 × NK603 and NK603 × MON 810) and previous conclusions on those sub-combinations remain valid.
- (7) As regards the five remaining sub-combinations (1507 × 59122 × MON 810, 1507 × MON 810 × NK603, 59122 × MON 810 × NK603, 1507 × MON 810 and 59122 × MON 810), the Authority concluded that they are expected to be as safe as the single maize events 1507, 59122, MON 810 and NK603, the previously assessed five sub-combinations and the four-event stack maize 1507 × 59122 × MON 810 × NK603.
- (8) In its opinion, the Authority considered the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (9) The Authority also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, was in line with the intended uses of the products.
- (10) Taking those considerations into account, the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and the following eight sub-combinations thereof, consisting of: four sub-combinations of three events (1507 × 59122 × MON 810, 59122 × 1507 × NK603, 1507 × MON 810 × NK603 and 59122 × MON 810 × NK603) and four sub-combinations of two events (1507 × 59122, 1507 × MON 810, 59122 × MON 810 and 59122 × NK603) listed in the application should be authorised.
- (11) In the interest of simplification, Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU should be repealed.
- (12) A unique identifier should be assigned to each genetically modified organism ('GMO') covered by this Decision in accordance with Commission Regulation (EC) No 65/2004 <sup>(3)</sup>. The unique identifiers assigned by Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU should continue to be used.
- (13) On the basis of the Authority's opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(4)</sup>, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products covered by this Decision, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(2)</sup> EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2017. Scientific opinion on the assessment of genetically modified maize 1507 × 59122 × MON810 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-92). *EFSA Journal* 2017;15(11):5000, 29 pp. <https://doi.org/10.2903/j.efsa.2017.5000>

<sup>(3)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(4)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 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 (OJ L 268, 18.10.2003, p. 24).

- (14) The authorisation holder should submit annual reports on the implementation of the activities set out in the monitoring plan for environmental effects and on the results. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC <sup>(1)</sup>.
- (15) The Authority's opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(2)</sup>.
- (18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### Article 1

#### Genetically modified organisms and unique identifiers

The following unique identifiers are assigned to genetically modified maize as specified in point (b) of the Annex to this Decision, in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 1507 × 59122 × MON 810 × NK603;
- (b) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 1507 × 59122 × MON 810;
- (c) the unique identifier DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × 1507 × NK603;
- (d) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 1507 × MON 810 × NK603;
- (e) the unique identifier DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × MON 810 × NK603;
- (f) the unique identifier DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) 1507 × 59122;
- (g) the unique identifier DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 1507 × MON 810;
- (h) the unique identifier DAS-59122-7 × MON-ØØ81Ø-6 for genetically modified maize (*Zea mays* L.) 59122 × MON 810;
- (i) the unique identifier DAS-59122-7 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) 59122 × NK603.

<sup>(1)</sup> Commission Decision 2009/770/EC of 13 October 2009 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 placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

<sup>(2)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (c) genetically modified maize referred to in Article 1 in products containing them or consisting of them, for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified maize referred to in Article 1, with the exception of foods and food ingredients.

*Article 4***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of the genetically modified maize referred to in Article 1.

*Article 5***Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Pioneer Hi-Bred International, Inc., United States, represented by Pioneer Overseas Corporation, Belgium.

*Article 8***Repeal**

Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU are hereby repealed.

*Article 9***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 10***Addressee**

This Decision is addressed to:

- Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels, Belgium,
- Dow Agro Sciences Ltd, European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 3 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

(a) **Applicant and authorisation holder:**

Name: Pioneer Hi-Bred International, Inc.

Address: 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, U.S.A.

Represented by Pioneer Overseas Corporation, Avenue des Arts, 44, 1040 Brussels, Belgium.

(b) **Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) referred to in point (e);
- (2) feed containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) referred to in point (e);
- (3) genetically modified maize (*Zea mays* L.) referred to in point (e) in products containing them or consisting of them for uses other than those provided for in points (1) and (2), with the exception of cultivation.

DAS-Ø15Ø7-1 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

DAS-59122-7 maize expresses Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and the PAT protein, which confers tolerance to glufosinate-ammonium-based herbicides.

MON-ØØ81Ø-6 maize expresses the Cry1Ab protein, which confers protection against certain lepidopteran pests.

MON-ØØ6Ø3-6 maize expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-containing herbicides.

(c) **Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the maize specified in (e) with the exception of foods and food ingredients.

(d) **Method for detection:**

- (1) The quantitative event-specific PCR detection methods for maize 1507 × 59122 × MON 810 × NK603 are those validated for genetically modified maize events DAS-Ø15Ø7-1, DAS-59122-7, MON-ØØ81Ø-6 and MON-ØØ6Ø3-6.
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1), ERM®-BF424 (for DAS-59122-7), ERM®-BF413 (for MON-ØØ81Ø-6) and ERM®-BF415 (for MON-ØØ6Ø3-6) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

(e) **Unique identifiers:**

DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6;

DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6;

DAS-Ø15Ø7-1 × DAS-59122-7;

DAS-Ø15Ø7-1 × MON-ØØ81Ø-6;

DAS-59122-7 × MON-ØØ81Ø-6;

DAS-59122-7 × MON-ØØ6Ø3-6.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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**COMMISSION IMPLEMENTING DECISION (EU) 2018/1111****of 3 August 2018**

**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-89034-3 × MON-ØØ6Ø3-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU**

*(notified under document C(2018) 5014)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 13 September 2013, Monsanto Europe SA/NV submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from MON 87427 × MON 89034 × NK603 maize ('the application') to the national competent authority of Belgium in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of products consisting of or containing genetically modified maize MON 87427 × MON 89034 × NK603 for uses other than food and feed, with the exception of cultivation.
- (2) The application covered, for those uses, all three sub-combinations of the single genetic modification events constituting maize MON 87427 × MON 89034 × NK603. One of those sub-combinations, MON 89034 × NK603, was already authorised under Commission Decision 2010/420/EU <sup>(2)</sup>. Monsanto Europe SA/NV asked the Commission to repeal that Decision when authorising maize MON 87427 × MON 89034 × NK603 and all its sub-combinations.
- (3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council <sup>(3)</sup> and the information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to Directive 2001/18/EC.
- (4) On 1 August 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 <sup>(4)</sup>. EFSA concluded that genetically modified maize MON 87427 × MON 89034 × NK603, as described in the application, is as safe and as nutritious as the non-genetically modified comparator and the tested non-genetically modified reference varieties in the context of the scope of the application. No new safety concerns were identified for the previously assessed sub-combination MON 89034 × NK603 and previous conclusions on this sub-combination remain valid.
- (5) For the remaining two sub-combinations, the EFSA concluded that they are expected to be as safe and as nutritious as the single events MON 87427, MON 89034 and NK603, as the previously assessed sub-combination MON 89034 × NK603 and as the three-event stack maize MON 87427 × MON 89034 × NK603.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2010/420/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 89034 × NK603 (MON-89034-3 × MON-ØØ6Ø3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 197, 29.7.2010, p. 15).

<sup>(3)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

<sup>(4)</sup> EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific Opinion on application EFSA-GMO-BE-2013-117 for authorisation of genetically modified maize MON 87427 × MON 89034 × NK603 and subcombinations independently of their origin, for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Company. EFSA Journal 2017;15(8):4922, 26 pp. <https://doi.org/10.2903/j.efsa.2017.4922>

- (6) In its opinion, the EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (7) The EFSA also concluded that the monitoring plan for environmental effects submitted by the applicant, consisting of a general surveillance plan, is in line with the intended uses of the products. However, the proposed monitoring plan was revised, as recommended by the EFSA, to cover explicitly the sub-combinations.
- (8) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × NK603 and its three possible sub-combinations for the uses listed in the application should be authorised.
- (9) Decision 2010/420/EU authorising maize MON 89034 × NK603 should be repealed.
- (10) A unique identifier should be assigned to each genetically modified organism ('GMO') covered by this Decision in accordance with Commission Regulation (EC) No 65/2004 <sup>(1)</sup>. The unique identifier assigned to maize MON 89034 × NK603 by Decision 2010/420/EU should continue to be used.
- (11) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(2)</sup>, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize MON 87427 × MON 89034 × NK603, MON 87427 × NK603, MON 89034 × NK603 and MON 87427 × MON 89034, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (12) The authorisation holder should submit annual reports on the implementation of the activities set out in the monitoring plan for environmental effects and on the results. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC <sup>(3)</sup>.
- (13) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (14) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (15) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(4)</sup>.
- (16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The measures provided for in this Decision are in accordance with the opinion of the appeal committee,

<sup>(1)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(2)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 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 (OJ L 268, 18.10.2003, p. 24).

<sup>(3)</sup> Commission Decision 2009/770/EC of 13 October 2009 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 placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

<sup>(4)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

#### Article 1

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

The following unique identifiers are assigned to genetically modified maize as specified in point (b) of the Annex to this Decision, in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034 × NK603;
- (b) the unique identifier MON-87427-7 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) MON 87427 × NK603;
- (c) the unique identifier MON-89Ø34-3 × MON-ØØ6Ø3-6 for genetically modified maize (*Zea mays* L.) MON 89034 × NK603;
- (d) the unique identifier MON-87427-7 × MON-89Ø34-3 for genetically modified maize (*Zea mays* L.) MON 87427 × MON 89034.

#### Article 2

##### **Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (b) feed containing, consisting of, or produced from genetically modified maize referred to in Article 1;
- (c) genetically modified maize, referred to in Article 1, in products containing them or consisting of them, for uses other than those provided for in points (a) and (b) of this Article, with the exception of cultivation.

#### Article 3

##### **Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of genetically modified maize referred to in Article 1, with the exception of foods and food ingredients.

#### Article 4

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

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of maize MON 87427 × MON 89034 × NK603, MON 87427 × NK603, MON 89034 × NK603 and MON 87427 × MON 89034.

*Article 6***Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Monsanto Europe SA/NV, Belgium, representing Monsanto Company, United States.

*Article 8***Repeal**

Decision 2010/420/EU is hereby repealed.

*Article 9***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 10***Addressee**

This Decision is addressed to Monsanto Europe SA/NV, Scheldelaan 460, 2040 Antwerp, Belgium.

Done at Brussels, 3 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicant and authorisation holder:**

Name: Monsanto Europe SA/NV

Address: Scheldelaan 460, 2040 Antwerp, Belgium

On behalf of:

Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, USA.

**(b) Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) referred to in point (e);
- (2) feed containing, consisting of, or produced from genetically modified maize (*Zea mays* L.) referred to in point (e);
- (3) genetically modified maize (*Zea mays* L.) referred to in point (e) in products containing them or consisting of them for uses other than those provided for in points (1) and (2), with the exception of cultivation.

MON-87427-7 maize expresses CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.

MON-89Ø34-3 maize expresses the Cry1A.105 and Cry2Ab2 proteins, which confer protection against certain lepidopteran pests.

MON-ØØ6Ø3-6 maize expresses CP4 EPSPS protein and the variant CP4 EPSPS L214P, which confer tolerance to glyphosate-based herbicides.

**(c) Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of the maize specified in (e), with the exception of foods and food ingredients.

**(d) Method for detection:**

- (1) The quantitative event-specific PCR detection methods for maize MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6 are those validated for genetically modified maize events MON-87427-7, MON-89Ø34-3 and MON-ØØ6Ø3-6.
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM®-BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/> as well as AOCS 0512-A (for MON-87427-7), AOCS 0906-E (for MON-89Ø34-3) are accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

**(e) Unique identifiers:**

MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6;

MON-87427-7 × MON-ØØ6Ø3-6;

MON-89Ø34-3 × MON-ØØ6Ø3-6;

MON-87427-7 × MON-89Ø34-3.

**(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: published in the Community register of genetically modified food and feed when notified].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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**COMMISSION IMPLEMENTING DECISION (EU) 2018/1112****of 3 August 2018****renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2018) 5020)***(Only the Dutch and French texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Article 11(3) and Article 23(3) thereof,

Whereas:

- (1) Commission Decision 2008/280/EC <sup>(2)</sup> authorised the placing on the market of food and feed containing, consisting of, or produced from genetically modified maize GA21 (hereinafter 'maize GA21'). The scope of that authorisation also covered products other than food and feed containing or consisting of maize GA21, for the same uses as any other maize with the exception of cultivation.
- (2) On 6 October 2016, Syngenta France SAS submitted to the Commission, on behalf of Syngenta Crop Protection AG, Switzerland, an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (3) On 24 October 2017, the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. Based on the data provided, it concluded <sup>(3)</sup> that there was no evidence in the renewal application for new hazards, modified exposure or scientific uncertainties that would change the conclusions of the original risk assessment <sup>(4)</sup> on maize GA21.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) EFSA also concluded that the environmental monitoring plan submitted by the applicant, consisting of a general surveillance plan, was in line with the intended uses of the products.
- (6) By a letter dated 27 February 2018, Syngenta France SAS asked the transfer of its rights and obligations as authorisation holder of Decision 2008/280/EC to Syngenta Crop Protection NV/SA, Belgium. By a letter dated 27 February 2018, Syngenta Crop Protection NV/SA, Belgium, confirmed its agreement to this transfer and indicated that it acts as representative in the Union of Syngenta Crop Protection AG, Switzerland.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2008/280/EC of 28 March 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize GA21 (MON-ØØØ21-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 87, 29.3.2008, p. 19).

<sup>(3)</sup> Scientific opinion on the assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-005). *EFSA Journal* 2017;15(10):5006.

<sup>(4)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on applications (references EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21) for the placing on the market of glyphosate-tolerant genetically modified maize GA21, for food and feed uses, import and processing and for renewal of the authorisation of maize GA21 as existing product, both under Regulation (EC) No 1829/2003 from Syngenta Seeds S.A.S. on behalf of Syngenta Crop Protection AG. *EFSA Journal* (2007) 541, 1-25.

- (7) Taking into account those considerations, the authorisation for the placing on the market of food and feed containing, consisting of, or produced from maize GA21 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.
- (8) A unique identifier has been assigned to maize GA21 by Decision 2008/280/EC, in accordance with Commission Regulation (EC) No 65/2004 <sup>(1)</sup>. That unique identifier should continue to be used.
- (9) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council <sup>(2)</sup>, appear to be necessary for the products covered by this Decision. However, in order to ensure that the use of products containing or consisting of maize GA21 remains within the limits of the authorisation granted by this Decision, the labelling of those products, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holder should submit annual reports on the implementation and on the results of the activities set out in the environmental monitoring plan. These results should be presented in accordance with Commission Decision 2009/770/EC <sup>(3)</sup>.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council <sup>(4)</sup>.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### Article 1

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

Genetically modified maize (*Zea mays* L.) GA21, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ21-9, in accordance with Regulation (EC) No 65/2004.

#### Article 2

##### **Renewal of the authorisation**

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) food and food ingredients containing, consisting of or produced from maize GA21;

<sup>(1)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(2)</sup> Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 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 (OJ L 268, 18.10.2003, p. 24).

<sup>(3)</sup> Commission Decision 2009/770/EC of 13 October 2009 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 placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

<sup>(4)</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (b) feed containing, consisting of or produced from maize GA21;
- (c) maize GA21 in products containing it or consisting of it for any other use than those provided for in points (a) and (b), with the exception of cultivation.

#### *Article 3*

#### **Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of maize GA21, with the exception of food and food ingredients.

#### *Article 4*

#### **Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of maize GA21.

#### *Article 5*

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

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex is put in place and implemented.
2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

#### *Article 6*

#### **Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

#### *Article 7*

#### **Authorisation holder**

The authorisation holder shall be Syngenta Crop Protection AG, Switzerland, represented by Syngenta Crop Protection NV/SA, Belgium.

#### *Article 8*

#### **Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium.

Done at Brussels, 3 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicant and authorisation holder:**

Name: Syngenta Crop Protection AG

Address: Schwarzwaldallee 215, CH-4058 Basel, Switzerland

Represented by Syngenta Crop Protection NV/SA, Avenue Louise 489, 1050 Brussels, Belgium.

**(b) Designation and specification of the products:**

(1) food containing, consisting of, or produced from maize GA21;

(2) feed containing, consisting of, or produced from maize GA21;

(3) maize GA21 in products containing it or consisting of it for any other use than those provided for in points (1) and (2), with the exception of cultivation.

Maize GA21, as described in the application, expresses the mEPSPS protein which confers tolerance to glyphosate herbicide.

**(c) Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

(2) The words 'not for cultivation' shall appear on the label of and in documents accompanying the products containing or consisting of maize GA21, with the exception of food and food ingredients.

**(d) Method for detection:**

(1) Event-specific real-time quantitative PCR-based method for detection of the genetically modified maize MON-ØØØ21-9.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at [http://gmo-crl.jrc.ec.europa.eu/summaries/GA21Syngenta\\_validated\\_Method\\_correctedVersion1.pdf](http://gmo-crl.jrc.ec.europa.eu/summaries/GA21Syngenta_validated_Method_correctedVersion1.pdf)

(3) Reference Material: AOCS 0407-A and AOCS 0407-B are accessible via the American Oil Chemists Society (AOCS) at <https://www.aocs.org/crm>

**(e) Unique identifier:**

MON-ØØØ21-9

**(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the register of genetically modified food and feed when notified*].

**(g) Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

**(h) Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>.

[Link: *plan published in the register of genetically modified food and feed*]

<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

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**COMMISSION IMPLEMENTING DECISION (EU) 2018/1113****of 3 August 2018****renewing the authorisation for the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2018) 5029)***(Only the Dutch, French and German texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed <sup>(1)</sup>, and in particular Articles 11(3) and 23(3) thereof,

Whereas:

- (1) Commission Decision 2007/692/EC <sup>(2)</sup> authorised the placing on the market of foods, food ingredients and feed produced from genetically modified sugar beet H7-1 (hereinafter 'sugar beet H7-1').
- (2) On 22 January 2018, KWS SAAT SE informed the Commission that it became, on 15 April 2015, the legal successor of the previous co-authorisation holder KWS SAAT AG. Therefore, the rights and obligations of KWS SAAT AG as co-authorisation holder were taken over by KWS SAAT SE.
- (3) On 20 October 2016, KWS SAAT SE and Monsanto Europe S.A./N.V. jointly submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation.
- (4) On 16 November 2017, the European Food Safety Authority ('EFSA') published a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded <sup>(3)</sup> that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment <sup>(4)</sup> on sugar beet H7-1.
- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) Taking into account those considerations, the authorisation for the placing on the market of foods, food ingredients and feed produced from genetically modified sugar beet H7-1 should be renewed.
- (7) A unique identifier has been assigned to sugar beet H7-1, in accordance with Commission Regulation (EC) No 65/2004 <sup>(5)</sup>, by Commission Decision 2007/702/EC <sup>(6)</sup>. That unique identifier should continue to be used.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 1.

<sup>(2)</sup> Commission Decision 2007/692/EC of 24 October 2007 authorising the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-ØØØH71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 283, 27.10.2007, p. 69).

<sup>(3)</sup> Assessment of genetically modified sugar beet H7-1 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-006). *EFSA Journal* 2017;15(11):5065

<sup>(4)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA GMO-UK-2004-08) for the placing on the market of products produced from glyphosate-tolerant genetically modified sugar beet H7-1, for food and feed uses, under Regulation (EC) No 1829/2003 from KWS SAAT and Monsanto. *EFSA Journal* 2006;4(12):431

<sup>(5)</sup> Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

<sup>(6)</sup> Commission Decision 2007/702/EC of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 285, 31.10.2007, p. 42).

- (8) On the basis of the abovementioned EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for the products covered by this Decision.
- (9) Similarly, the EFSA opinion does not justify the imposition of specific conditions or restrictions on the placing on the market or for use and handling, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (10) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (11) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

#### *Article 1*

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

Genetically modified sugar beet (*Beta vulgaris subsp. vulgaris*) H7-1, as specified in point (b) of the Annex, is assigned the unique identifier KM-ØØØH71-4, in accordance with Regulation (EC) No 65/2004.

#### *Article 2*

##### **Renewal of authorisation**

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients produced from KM-ØØØH71-4 sugar beet;
- (b) feed produced from KM-ØØØH71-4 sugar beet.

#### *Article 3*

##### **Labelling**

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'sugar beet'.

#### *Article 4*

##### **Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of sugar beet H7-1.

#### *Article 5*

##### **Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

*Article 6***Authorisation holders**

1. The authorisation holders shall be:
  - (a) KWS SAAT SE, Germany; and
  - (b) Monsanto Company, United States of America, represented by Monsanto Europe S.A./N.V., Belgium.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

*Article 7***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8***Addressee**

This Decision is addressed to:

- (a) KWS SAAT SE, Grimsehlstrasse 31, 37574 Einbeck, Germany; and
- (b) Monsanto Europe S.A./N.V., Scheldelaan 460, Haven 627, 2040 Antwerp, Belgium.

Done at Brussels, 3 August 2018.

*For the Commission*  
Vytenis ANDRIUKAITIS  
*Member of the Commission*

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## ANNEX

**(a) Applicants and Authorisation holders:**

Name: KWS SAAT SE

Address: Grimsehlstrasse 31, 37574 Einbeck, Germany

and

Name: Monsanto Company

Address: 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America

Represented by Monsanto Europe S.A./N.V., Scheldelaan 460, Haven 627, 2040 Antwerp, Belgium.

**(b) Designation and specification of the products:**

(1) Foods and food ingredients produced from KM-ØØØH71-4 sugar beet;

(2) Feed produced from KM-ØØØH71-4 sugar beet.

The genetically modified KM-ØØØH71-4 sugar beet, as described in the application, expresses the CP4 EPSPS protein after insertion of the *cp4 epsps* gene from *Agrobacterium* sp. strain CP4 into sugar beet (*Beta vulgaris* subsp. *vulgaris*).

The CP4 EPSPS protein confers tolerance to glyphosate containing herbicides.

**(c) Labelling:**

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'sugar beet'.

**(d) Method for detection:**

(1) Event specific realtime PCR-based method for the quantification of KM-ØØØH71-4 sugar beet.

(2) Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>

(3) Reference Material: ERM®-BF419 is accessible via the Joint Research Centre (JRC) of the European Commission, at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

**(e) Unique identifier:**

KM-ØØØH71-4

**(f) Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Not applicable.

**(g) Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

**(h) Monitoring plan for environmental effects:**

Not applicable.

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the register of genetically modified food and feed.

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**COMMISSION IMPLEMENTING DECISION (EU) 2018/1114****of 9 August 2018****amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States***(notified under document C(2018) 5510)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market <sup>(1)</sup>, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market <sup>(2)</sup>, and in particular Article 10(4) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption <sup>(3)</sup>, and in particular Article 4(3) thereof,

Whereas:

- (1) Commission Implementing Decision 2014/709/EU <sup>(4)</sup> lays down animal health control measures in relation to African swine fever in certain Member States, where there have been confirmed cases of that disease in domestic or feral pigs (the Member States concerned). The Annex to that Implementing Decision demarcates and lists certain areas of the Member States concerned in Parts I to IV thereof, differentiated by the level of risk based on the epidemiological situation as regards that disease. The Annex to Implementing Decision 2014/709/EU has been amended several times to take account of changes in the epidemiological situation in the Union as regards African swine fever that need to be reflected in that Annex. The Annex to Implementing Decision 2014/709/EU was last amended by Commission Implementing Decision (EU) 2018/1068 <sup>(5)</sup>, following recent instances of African swine fever in Latvia, Lithuania and Poland.
- (2) The risk of the spread of African swine fever in wildlife is linked to the natural slow spread of that disease among feral pig populations, and also the risks linked to human activity, as demonstrated by the recent epidemiological evolution of that disease in the Union, and as documented by the European Food Safety Authority (EFSA) in the Scientific Opinion of the Panel on Animal Health and Welfare, published on 14 July 2015; in the Scientific Report of EFSA on Epidemiological analyses on African swine fever in the Baltic countries and Poland, published on 23 March 2017; and in the Scientific Report of EFSA on Epidemiological analyses of African swine fever in the Baltic States and Poland, published on 7 November 2017 <sup>(6)</sup>.
- (3) Since the date of adoption of Implementing Decision (EU) 2018/1068, the epidemiological situation in the Union has evolved as regards African swine fever, and there have been further instances of that disease that need to be reflected in the Annex to Implementing Decision 2014/709/EU.
- (4) In July 2018, several outbreaks of African swine fever in domestic pigs were observed in the counties of Bartoszyce, Chełmski, Kętrzyn, Lubartów, Mińsk and Węgorzewski in Poland. These outbreaks of African swine fever in domestic pigs constitute an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, these areas of Poland affected by African swine fever should now be listed in Part III of that Annex instead of in Part I and Part II thereof.

<sup>(1)</sup> OJ L 395, 30.12.1989, p. 13.

<sup>(2)</sup> OJ L 224, 18.8.1990, p. 29.

<sup>(3)</sup> OJ L 18, 23.1.2003, p. 11.

<sup>(4)</sup> Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

<sup>(5)</sup> Commission Implementing Decision (EU) 2018/1068 of 27 July 2018 amending the Annex to Implementing Decision 2014/709/EU concerning animal health control measures relating to African swine fever in certain Member States (OJ L 192, 30.7.2018, p. 43).

<sup>(6)</sup> EFSA Journal 2015;13(7):4163; EFSA Journal 2017;15(3):4732; EFSA Journal 2017;15(11):5068.

- (5) In July and August 2018, two outbreaks of African swine fever in domestic pigs were observed in the county of Galați in Romania. These outbreaks of African swine fever in domestic pigs constitute an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Romania affected by African swine fever should now be listed in Part III of that Annex instead of in Part I thereof.
- (6) In July 2018, an outbreak of African swine fever in domestic pigs was observed in the county of Šiauliai in proximity to the border with the county of Telšiai in Lithuania. This outbreak of African swine fever in domestic pigs constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Lithuania affected by African swine fever should now be listed in Part III of that Annex instead of in Part II thereof.
- (7) In August 2018, an outbreak of African swine fever in domestic pigs was observed in the county of Saldus in Latvia. This outbreak of African swine fever in domestic pigs constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, this area of Latvia affected by African swine fever should now be listed in Part III of that Annex instead of in Part II thereof.
- (8) In August 2018, an outbreak of African swine fever in domestic pigs was observed in the county of Lubaczowski in Poland. This outbreak of African swine fever in domestic pigs constitutes an increased level of risk which should be reflected in the Annex to Implementing Decision 2014/709/EU. Accordingly, new areas of Poland affected by African swine fever should be listed in Part III of that Annex.
- (9) In order to take account of recent developments in the epidemiological evolution of African swine fever in the Union, and in order to combat the risks associated with the spread of that disease in a proactive manner, new high-risk areas of a sufficient size should be demarcated for Latvia, Lithuania, Poland and Romania and duly listed in the Annex to Implementing Decision 2014/709/EU. That Annex should therefore be amended accordingly.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*

The Annex to Implementing Decision 2014/709/EU is replaced by the text set out in the Annex to this Decision.

*Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 9 August 2018.

*For the Commission*

Vytenis ANDRIUKAITIS

*Member of the Commission*

## ANNEX

The Annex to Implementing Decision 2014/709/EU is replaced by the following:

## ‘ANNEX

## PART I

**1. The Czech Republic**

The following areas in the Czech Republic:

- okres Uherské Hradiště,
- okres Kroměříž,
- okres Vsetín,
- katastrální území obcí v okrese Zlín:
  - Bělov,
  - Biskupice u Luhačovic,
  - Bohuslavice nad Vláří,
  - Brumov,
  - Bylnice,
  - Divnice,
  - Dobrkovice,
  - Dolní Lhota u Luhačovic,
  - Drnovice u Valašských Klobouk,
  - Halenkovice,
  - Haluzice,
  - Hrádek na Vlárské dráze,
  - Hřivínův Újezd,
  - Jestřabí nad Vláří,
  - Kaňovice u Luhačovic,
  - Kelníky,
  - Kladná-Žilín,
  - Kochavec,
  - Komárov u Napajedel,
  - Křekov,
  - Lipina,
  - Lipová u Slavičína,
  - Ludkovice,
  - Luhačovice,
  - Machová,
  - Mirošov u Valašských Klobouk,
  - Mysločovice,
  - Napajedla,
  - Návojná,

- Nedašov,
- Nedašova Lhota,
- Nevšová,
- Otrokovice,
- Petrůvka u Slavičína,
- Pohořelice u Napajedel,
- Polichno,
- Popov nad Vlárí,
- Poteč,
- Pozlovice,
- Rokytnice u Slavičína,
- Rudimov,
- Řetechov,
- Sazovice,
- Sidonie,
- Slavičín,
- Smolina,
- Spytihněv,
- Svatý Štěpán,
- Šanov,
- Šarovy,
- Štítná nad Vlárí,
- Tichov,
- Tlumačov na Moravě,
- Valašské Klobouky,
- Velký Ořechov,
- Vlachova Lhota,
- Vlachovice,
- Vrbětice,
- Žlutava.

## 2. Estonia

The following areas in Estonia:

- Hiiu maakond.

## 3. Hungary

The following areas in Hungary:

- Borsod-Abaúj-Zemplén megye 650100, 650200, 650300, 650400, 650500, 650600, 650700, 650800, 651000, 651100, 651200, 652100, 652200, 652300, 652400, 652500, 652601, 652602, 652603, 652700, 652800, 652900 és 653403 kódszámúvalamint 656100, 656200, 656300, 656400, 656701, 657010, 657100, 657400, 657500, 657600, 657700, 657800, 657900, 658000, 658100, 658201, 658202, 658310, 658401, 658402, 658403, 658404, 658500, 658600, 658700, 658801, 658802, 658901, 658902, 659000, 659100, 659210, 659220, 659300, 659400, 659500, 659601, 659602, 659701, 659800, 659901, 660000, 660100, 660200, 660400, 660501, 660502, 660600 és 660800 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye 900850, 900860, 900930, 900950 és 903350 kódszámú vadgazdálkodási egységeinek teljes területe,

- Heves megye 700150, 700250, 700260, 700350, 700450, 700460, 700550, 700650, 700750, 700850, 702350, 702450, 702550, 702750, 702850, 703350, 703360, 703450, 703550, 703610, 703750, 703850, 703950, 704050, 704150, 704250, 704350, 704450, 704550, 704650, 704750, 704850, 704950, 705050, 705250, 705350, 705510 és 705610 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750150, 750160, 750250, 750260, 750350, 750450, 750460, 750550, 750650, 750750, 750850, 750950 és 750960 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye 550110, 550120, 550130, 550210, 550310, 550320, 550450, 550460, 550510, 550610, 550710, 550810, 550950, 551010, 551150, 551160, 551250, 551350, 551360, 551450, 551460, 551550, 551650, 551710, 551810, 551821, 552010, 552150, 552250, 552350, 552360, 552450, 552460, 552520, 552550, 552610, 552620, 552710, 552850, 552860, 552950, 552960, 552970, 553110, 553250, 553260 és 553350 kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 571250, 571350, 571550, 571610, 571750, 571760, 572350, 572550, 572850, 572950, 573360 és 573450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850150, 850250, 850260, 850350, 850450, 850550, 850650, 850850, 851851, 851852, 851950, 852050, 852150, 852250, 852350, 852450, 852550, 852750, 853560, 853650, 853751, 853850, 853950, 853960, 854050, 854150, 854250, 854350, 855250, 855350, 855450, 855460, 855550, 855650, 855660, 855750, 855850, 855950, 855960, 856012, 856050, 856150, 856250, 856260, 856850, 856950, 857050, 857150, 857350, 857450 és 857550.

#### 4. Latvia

The following areas in Latvia:

- Aizputes novads,
- Alsungas novads,
- Kuldīgas novada Gudenieku, Turlavas un Laidu pagasts,
- Pāvilostas novada Sakas pagasts un Pāvilostas pilsēta,
- Skrundas novada, Nīkrācesun Rudbāržu pagasts un Skrundas pagasta daļa, kas atrodas uz dienvidiem no autoceļa A9, Skrundas pilsēta,
- Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Vaiņodes novads,
- Ventspils novada Jūrkalnes pagasts.

#### 5. Lithuania

The following areas in Lithuania:

- Jurbarko rajono savivaldybė: Eržvilko, Smalininkų ir Viešvilės seniūnijos,
- Kelmės rajono savivaldybė: Kelmės, Kelmės apylinkių, Kražių, Kukečių, Liolių, Pakražančio, Šaukėnų seniūnijos, Tytuvėnų seniūnijos dalis į vakarus ir šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į šiaurę nuo kelio Nr. 157 ir į vakarus nuo kelio Nr. 2105, Užvenčio ir Vaiguvo seniūnijos,
- Mažeikių rajono savivaldybė: Sedos, Šerkšnėnų ir Židikų seniūnijos,
- Pagėgių savivaldybė,
- Plungės rajono savivaldybė,
- Raseinių rajono savivaldybė: Girkalnio ir Kalnųjų seniūnijos dalis į šiaurę nuo kelio Nr A1, Nemakščių, Paliepių, Raseinių, Raseinių miesto ir Viduklės seniūnijos,
- Rietavo savivaldybė,
- Šakių rajono savivaldybė: Barzdų, Griškabūdžio, Kriūkų, Kudirkos Naumiesčio, Lekėčių, Lukšių, Sintautų, Slavikų, Sudargo ir Žvirgždaičių seniūnijos,
- Šilalės rajono savivaldybė,
- Šilutės rajono savivaldybė: Juknaičių, Kintų, Šilutės ir Usėnų seniūnijos,
- Tauragės rajono savivaldybė,

## 6. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gmina Stare Juchy w powiecie ełckim,
- gminy Dubeninki, Gołdap i część gminy Banie Mazurskie położona na południe od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,
- gmina Pozezdrze i część gminy Węgorzewo położona na południe od linii wyznaczonej przez drogę nr 650 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą biegnącą do miejscowości Przysań i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Przysań, Pniewo, Kamionek Wielki, Radziejewo, Dłużec w powiecie węgorzewskim,
- gmina Ruciane – Nida i część gminy Pisz położona na południe od linii wyznaczonej przez drogę nr 58 oraz miasto Pisz w powiecie piskim,
- gminy Giżycko z miastem Giżycko, Kruklanki, Miłki, Wydminy i Ryn w powiecie giżyckim,
- gmina Mikołajki w powiecie mrągowskim,
- gmina Bisztynek w powiecie bartoszyckim,
- gminy Kętrzyn z miastem Kętrzyn i część gminy Korsze położona na południe od linii wyznaczonej przez drogę biegnącą od zachodniej granicy łączącą miejscowości Kreliekajmy i Sątoczno i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na wschód od drogi nr 590 do skrzyżowania z drogą nr 592 i na południe od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- część gminy Lidzbark Warmiński położona na południe od linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński, na południe i zachód od granic miasta Lidzbark Warmiński i na zachód od linii wyznaczonej przez drogę nr 511, miasto Lidzbark Warmiński, Lubomino, Orneta i część gminy Kiwity położona na południe od linii wyznaczonej przez drogę nr 513 w powiecie lidzbarskim,
- część gminy Wilczęta położona na południe od linii wyznaczonej przez drogę nr 509 w powiecie braniewskim,
- gminy Elbląg, Godkowo, Pasłęk i Tolkmicko i część gminy Milejewo położona na północ od linii wyznaczonej przez drogę nr S22 w powiecie elbląskim,
- powiat miejski Elbląg,
- gminy Dobrze Miasto i Jeziorany w powiecie olsztyńskim.

w województwie podlaskim:

- gminy Brańsk z miastem Brańsk, Rudka i Wyszki w powiecie bielskim,
- gmina Perlejewo w powiecie siemiatyckim,
- gminy Kolno z miastem Kolno, Mały Płock i Turośl w powiecie kolneńskim,
- gmina Poświętne w powiecie białostockim,
- gminy Kołaki Kościelne, Rutki, Szumowo, część gminy Zambrów położona na południe od linii wyznaczonej przez drogę nr S8 i miasto Zambrów w powiecie zambrowskim,
- gminy Wiżajny i Przerośl w powiecie suwalskim,
- gminy Kulesze Kościelne, Nowe Piekuty, Szepietowo, Klukowo, Ciechanowiec, Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew w powiecie wysokomazowieckim,
- gminy Miastkowo, Nowogród i Zbójna w powiecie łomżyńskim.

w województwie mazowieckim:

- gminy Cerańów, Kosów Lacki, Sabnie, Sterdyń, część gminy Bielany położona na zachód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na zachód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
- gminy Grębków, Korytnica, Liw, Łochów, Miedzna, Sadowne, Stoczek, Wierzbno i miasto Węgrów w powiecie węgrowskim,

- część gminy Kotuń położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków w powiecie siedleckim,
  - gminy Rzekuń, Troszyn, Lelis, Czerwin i Goworowo w powiecie ostrołęckim,
  - powiat miejski Ostrołęka,
  - powiat ostrowski,
  - gminy Karniewo, Maków Mazowiecki, Rzewnie i Szelków w powiecie makowskim,
  - gmina Krasne w powiecie przasnyskim,
  - gminy Mała Wieś i Wyszogród w powiecie płońskim,
  - gminy Ciechanów z miastem Ciechanów, Głinojeck, Gołymin – Ośrodek, Ojrzeń, Opinogóra Górna i Sońsk w powiecie ciechanowskim,
  - gminy Baboszewo, Czerwińsk nad Wisłą, Naruszewo, Płońsk z miastem Płońsk, Sochocin i Załuski w powiecie płońskim,
  - gminy Gzy, Obryte, Zatory, Pułtusk i część gminy Winnica położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
  - gminy Brańszczyk, Długosiodło, Rząśnik, Wyszków, Zabrodzie i część gminy Somianka położona na północ od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,
  - gminy Jadów, Klembów, Poświętne, Strachówka i Tłuszcz w powiecie wołomińskim,
  - gminy Dobrze, Jakubów, Mrozy, Dębe Wielkie, Halinów, Kałuszyn, Stanisławów, część gminy Ceglów położona na północ od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Ceglów i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Ceglów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy, część gminy Mińsk Mazowiecki położona na północ od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy i miasto Mińsk Mazowiecki w powiecie mińskim,
  - gminy Garwolin z miastem Garwolin, Górzno, Łaskarzew z miastem Łaskarzew, Maciejowice, Miastków Kościelny, Sobolew, Trojanów, Wilga i Żelechów w powiecie garwolińskim,
  - gminy Garbatka Letnisko, Gniewoszów, Kozienice, Sieciechów i część gminy Głowaczów położona na południe od linii wyznaczonej przez drogę nr 48 w powiecie kozienickim,
  - gminy Baranów i Jaktorów w powiecie grodziskim,
  - powiat żyrardowski,
  - gminy Belsk Duży, Błędów, Goszczyn i Mogielnica w powiecie grójeckim,
  - gminy Białobrzegi, Promna, Stara Błotnica, Wyśmierzyce i część gminy Stromiec położona na południe od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
  - gminy Jedlińsk, Jastrzębia i Pionki z miastem Pionki w powiecie radomskim,
  - gminy Iłów, Młodzieszyn, Nowa Sucha, Rybno, Sochaczew z miastem Sochaczew i Teresin w powiecie sochaczewskim,
  - gmina Policzna w powiecie zwoleńskim.
- w województwie lubelskim:
- gminy Jabłonna, Krzczonów, Niemce, Garbów, Jastków, Konopnica, Wólka, Głusk w powiecie lubelskim,
  - gminy Łęczna i część gminy Spiczyn położona na wschód od linii wyznaczonej przez drogę nr 829 w powiecie łęczyńskim,
  - gminy Miączyn, Sitno, Skierbieszów, Stary Zamość, Komarów-Osada w powiecie zamojskim,
  - gminy Trzeszczany i Werbkowice w powiecie hrubieszowskim,
  - gminy Abramów, Kamionka i Lubartów z miastem Lubartów w powiecie lubartowskim,
  - gminy Kłoczew, Ryki, Dęblin i Stężyca w powiecie ryckim,

- gminy Puławy z miastem Puławy, Janowiec, Kazimierz Dolny, Końskowola, Kurów, Wąwolnica, Nałęczów, Markuszów, Żyrzyn w powiecie puławskim,
- gminy Mełgiew, Rybczewice, miasto Świdnik i część gminy Piaski położona na południe od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na zachód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
- gminy Kraśniczyn, Gorzków, Izbica, Żółkiewka, część gminy Krasnystaw położona na zachód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw i miasto Krasnystaw w powiecie krasnostawskim,
- gminy Bełżec, Jarczów, Lubycza Królewska, Łaszczów, Susiec, Tyszowce i Ułhówek w powiecie tomaszowskim,
- gminy Łukowa i Obsza w powiecie biłgorajskim,
- powiat miejski Lublin.

w województwie podkarpackim:

- gminy Horyniec-Zdrój, Narol, Stary Dzików i Wielkie Oczy i część gminy Oleszyce położona na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na zachód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz — na południe od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików – na zachód od tej drogi w powiecie lubaczowskim,
- gminy Laszki i Wiązownica w powiecie jarosławskim.

## 7. Romania

The following areas in Romania:

- Alba county with the following delimitation:
  - North of National Road no. 7
- Arad county with the following delimitation:
  - In the North side of the line described by following localities:
    - Macea,
    - Şiria,
    - Bârzava,
    - Toc, which is junction with National Road no. 7,
    - North of National Road no. 7,
- Bistriţa county,
- Braşov county with the following delimitation:
  - In the East side of the line described by National Road no. 1A from the entrance into the Braşov county and National Road no. 103B intersecting the Dălgău locality,
- Cluj county,
- Covasna county,
- Giurgiu county,
- Harghita county,
- Hunedoara county with the following delimitation:
  - North of the line described by following localities:
    - Brănişca,
    - Deva municipality,
    - Turdaş,
    - Zam and Aurel Vlaicu localities which are at junction with National Road no. 7,
    - North of National Road no. 7,

- Iasi county,
- Ilfov county,
- Maramureş county,
- Neamt county,
- Prahova county.

## PART II

**1. The Czech Republic**

The following areas in the Czech Republic:

- katastrální území obcí v okrese Zlín:

- Bohuslavice u Zlína,
- Bratřejov u Vizovic,
- Březnice u Zlína,
- Březová u Zlína,
- Březůvky,
- Dešná u Zlína,
- Dolní Ves,
- Doubravy,
- Držková,
- Fryšták,
- Horní Lhota u Luhačovic,
- Horní Ves u Fryštáku,
- Hostišová,
- Hrobice na Moravě,
- Hvozdná,
- Chrástěšov,
- Jaroslavice u Zlína,
- Jasenná na Moravě,
- Karlovice u Zlína,
- Kašava,
- Klečůvka,
- Kostelec u Zlína,
- Kudlov,
- Kvítkovice u Otrokovic,
- Lhota u Zlína,
- Lhotka u Zlína,
- Lhotsko,
- Lípa nad Dřevnicí,
- Loučka I,
- Loučka II,
- Louky nad Dřevnicí,
- Lukov u Zlína,
- Lukoveček,
- Lutonina,

- Lužkovice,
- Malenovice u Zlína,
- Mladcová,
- Neubuz,
- Oldřichovice u Napajedel,
- Ostrata,
- Podhradí u Luhačovic,
- Podkopná Lhota,
- Provodov na Moravě,
- Prštné,
- Příluky u Zlína,
- Racková,
- Raková,
- Salaš u Zlína,
- Sehradice,
- Slopné,
- Slušovice,
- Štípa,
- Tečovice,
- Trnava u Zlína,
- Ublo,
- Újezd u Valašských Klobouk,
- Velíková,
- Veselá u Zlína,
- Vítová,
- Vizovice,
- Vlčková,
- Všemina,
- Vysoké Pole,
- Zádveřice,
- Zlín,
- Želechovice nad Dřevnicí.

## 2. Estonia

The following areas in Estonia:

- Eesti Vabariik (välja arvatud Hiiu maakond).

## 3. Hungary

The following areas in Hungary:

- Heves megye 700860, 700950, 701050, 701111, 701150, 701250, 701350, 701550, 701560, 701650, 701750, 701850, 701950, 702050, 702150, 702250, 702260, 702950, 703050, 703150, 703250, 703370, 705150 és 705450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye 850950, 851050, 851150, 851250, 851350, 851450, 851550, 851560, 851650, 851660, 851751, 851752, 852850, 852860, 852950, 852960, 853050, 853150, 853160, 853250, 853260, 853350, 853360, 853450, 853550, 854450, 854550, 854560, 854650, 854660, 854750, 854850, 854860, 854870, 854950, 855050, 855150, 856350, 856360, 856450, 856550, 856650, 856750, 856760 és 857650 kódszámú vadgazdálkodási egységeinek teljes területe.

#### 4. Latvia

The following areas in Latvia:

- Ādažu novads,
- Aglonas novads,
- Aizkraukles novads,
- Aknīstes novads,
- Alojas novads,
- Alūksnes novads,
- Amatas novads,
- Apes novads,
- Auces novada Īles un Vecauces pagasts un Lielaucē pagasta daļa uz Austrumiem no autoceļa P104 un Vītiņu pagasta daļu uz Dienvidiem no autoceļa P96, Auces pilsēta,
- Babītes novads,
- Baldones novads,
- Baltinavas novads,
- Balvu novads,
- Bauskas novads,
- Beverīnas novads,
- Brocēnu novada Blīdenes pagasta daļa uz Ziemeļiem no autoceļa A9, Remtes pagasta daļa uz austrumiem no autoceļa 1154 un P109,
- Burtnieku novads,
- Carnikavas novads,
- Cēsu novads,
- Cesvaines novads,
- Ciblas novads,
- Dagdas novads,
- Daugavpils novads,
- Dobeles novada Annenieku, Auru, Bērzes, Bikstu, Dobeles, Jaunbērzes, Krimūnu un Naudītes pagasts un Zebrenes pagasta daļa uz Austrumiem no autoceļa P104, Dobeles pilsēta,
- Dundagas novads,
- Engures novads,
- Ērgļu novads,
- Garkalnes novads,
- Gulbenes novads,
- Iecavas novads,
- Ikšķiles novads,
- Ilūkstes novads,
- Inčukalna novads,
- Jaunjelgavas novads,
- Jaunpiebalgas novads,
- Jaunpils novads,
- Jēkabpils novads,
- Jelgavas novada, Glūdas, Svētes, Zaļenieku, Vilces, Lielplatones, Elejas, Sesavas, Platones un Vircavas pagasts,

- Kandavas novads,
- Kārsavas novads,
- Ķeguma novads,
- Ķekavas novads,
- Kocēnu novads,
- Kokneses novads,
- Krāslavas novads,
- Krimuldas novads,
- Krustpils novads,
- Kuldīgas novada Ēdoles, Īvandes, Padures, Rendas un Kabiles, pagasts, Rumbas pagasta daļa uz ziemeļiem no autoceļa P120, Kurmāles pagasta daļa uz rietumiem no autoceļa 1283 un 1290, un uz ziemeļaustrumiem no autoceļa P118, Kuldīgas pilsēta,
- Lielvārdes novads,
- Līgatnes novads,
- Limbažu novads,
- Līvānu novads,
- Lubānas novads,
- Ludzas novads,
- Madonas novads,
- Mālpils novads,
- Mārupes novads,
- Mazsalacas novads,
- Mērsraga novads,
- Naukšēnu novads,
- Neretas novads Zalves, Neretas un Pilskalnes pagasts,
- Ogres novads,
- Olaines novads,
- Ozolnieku novada Ozolnieku un Cenu pagasts,
- Pārgaujas novads,
- Pļaviņu novads,
- Preiļu novads,
- Priekule novads,
- Raunas novads,
- republikas pilsēta Daugavpils,
- republikas pilsēta Jelgava,
- republikas pilsēta Jēkabpils,
- republikas pilsēta Jūrmala,
- republikas pilsēta Rēzekne,
- republikas pilsēta Valmiera,
- Rēzeknes novads,
- Riebiņu novads,
- Rojas novads,
- Ropažu novads,

- Rugāju novads,
- Rundāles novads,
- Rūjienas novads,
- Salacgrīvas novads,
- Salas novads,
- Salaspils novads,
- Saldus novada Šķēdes, Nīgrandes, Jaunaucis, Rubas, Vadakstes, Zaņas, Ezeres un Pampāļu pagasts,
- Saulkrastu novads,
- Sējas novads,
- Siguldas novads,
- Skrīveru novads,
- Skrundas novada Raņķu pagasts un Skrundas pagasta daļa, kas atrodas uz Ziemeļiem no autoceļa A9
- Smiltenes novads,
- Stopiņu novada daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Strenču novads,
- Talsu novads,
- Tērvetes novada Tērvetes un Augstkalnes pagast,
- Tukuma novads,
- Valkas novads,
- Varakļānu novads,
- Vārkavas novads,
- Vecpiebalgas novads,
- Vecumnieku novads Vecumnieku, Stelpes, Bārbeles, Skaistkalnes, un Valles pagasts,
- Ventspils novada Ances, Tārgales, Popes, Vārves, Užavas, Piltēnes, Puzes, Ziru, Ugāles, Usmas un Zlēku pagasts, Piltēnes pilsēta,
- Viesītes novads,
- Viļakas novads,
- Viļānu novads,
- Zilupes novads.

## 5. Lithuania

The following areas in Lithuania:

- Alytaus rajono savivaldybė: Krokialaukio, Miroslavo ir Simno seniūnijos,
- Anykščių rajono savivaldybė,
- Biržų miesto savivaldybė,
- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Jurbarko rajono savivaldybė: Jurbarko miesto ir Jurbarkų, seniūnijos,
- Kaišiadorių miesto savivaldybė,
- Kaišiadorių rajono savivaldybė: Kaišiadorių apylinkės, Kruonio, Nemaitonių, Palomenės, Pravieniškių, Rumšiškių, Žiežmarių ir Žiežmarių apylinkės seniūnijos,

- Kalvarijos savivaldybė,
- Kauno miesto savivaldybė,
- Kauno rajono savivaldybė: Akademijos, Alšėnų, Babtų, Batniavos, Domeikavos, Ežerėlio, Garliavos, Garliavos apylinkių, Kačerginės, Karmėlavos, Kulautuvos, Lapių, Linksmakalnio, Neveronių, Raudondvario, Ringaudų, Rokų, Samylų, Taurakiemio, Užliedžių, Vandžiogalos ir Zapyškio seniūnijos,
- Kazlų Rūdos savivaldybė,
- Kėdainių rajono savivaldybė: Gudžiūnų, Surviliškio, Šėtos, Truskavos ir Vilainių seniūnijos,
- Kupiškio rajono savivaldybė,
- Marijampolės savivaldybė,
- Molėtų rajono savivaldybė,
- Pakruojo rajono savivaldybė: Klovainių seniūnijos dalis į šiaurę nuo kelio Nr. 150, Linkuvos seniūnijos dalis į rytus nuo kelio Nr. 151 ir kelio Nr. 211,
- Panevėžio rajono savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė: Aukštelkų seniūnija, Baisogalos seniūnijos dalis į vakarus nuo kelio Nr. 144, Radviliškio, Radviliškio miesto seniūnija, Šeduvos miesto seniūnijos dalis į pietus nuo kelio Nr. A9 ir į vakarus nuo kelio Nr. 3417 ir Tyrulių seniūnija,
- Prienų miesto savivaldybė,
- Prienų rajono savivaldybė: Ašmintos, Balbieriškio, Išlaužo, Naujosios Ūtos, Pakuonio, Šilavoto ir Veiverių seniūnijos,
- Rokiškio rajono savivaldybė,
- Šalčininkų rajono savivaldybė,
- Šilutės rajono savivaldybė: Rusnės seniūnija,
- Širvintų rajono savivaldybė,
- Švenčionių rajono savivaldybė,
- Telšių rajono savivaldybė: Degaičių, Gadūnavo, Luokės, Nevarėnų, Ryškėnų, Telšių miesto, Upynos, Varnių, Viešvėnų ir Žarėnų seniūnijos,
- Ukmergės rajono savivaldybė,
- Utenos rajono savivaldybė,
- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė,
- Vilkaviškio rajono savivaldybė,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

## 6. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Kalinowo, Prostki i gmina wiejska Elk w powiecie elckim,
- gmina Młynary i część gminy Milejewo położona na południe od linii wyznaczonej przez drogę nr S22 w powiecie elbląskim,
- powiat olecki,
- gminy Orzysz, Biała Piska i część gminy Pisz położona na północ od linii wyznaczonej przez drogę nr 58 w powiecie piskim,
- gmina Frombork, część gminy wiejskiej Braniewo położona na zachód od linii wyznaczonej przez drogę nr E28 i S22 i miasto Braniewo, część gminy Wilczęta położona na północ od linii wyznaczonej przez drogę 509 w powiecie braniewskim,

w województwie podlaskim:

- powiat grajewski,
- gminy Jasionówka, Jaświły, Knyszyn, Krypno, Mońki i Trzciannę w powiecie monieckim,
- gminy Łomża, Piątnica, Śniadowo, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,
- powiat miejski Łomża,
- gminy, Mielnik, Nurzec – Stacja, Grodzisk, Drohiczyn, Dziadkowice, Milejczyce i Siemiatycze z miastem Siemiatycze w powiecie siemiatyckim,
- gminy Białowieża, Czeremcha, Narew, Narewka, część gminy Dubicze Cerkiewne położona na wschód od linii wyznaczonej przez drogę nr 685, część gminy Kleszczewo położona na wschód od linii wyznaczonej przez drogi nr 685, a następnie nr 66 i nr 693, część gminy Hajnówka położona na północ od linii wyznaczonej przez drogę nr 689 i na wschód od linii wyznaczonej przez drogę nr 685 i miasto Hajnówka w powiecie hajnowskim,
- gminy Kobylin-Borzymy i Sokoły w powiecie wysokomazowieckim,
- część gminy Zambrów położona na północ od linii wyznaczonej przez drogę nr S8 w powiecie zambrowskim,
- gminy Grabowo i Stawiski w powiecie kolneńskim,
- gminy Czarna Białostocka, Dobrzyniewo Duże, Gródek, Juchnowiec Kościelny, Łapy, Michałowo, Supraśl, Suraz, Turośń Kościelna, Tykocin, Wasilków, Zabłudów, Zawady i Choroszcz w powiecie białostockim,
- gmina Boćki i część gminy Bielsk Podlaski położona na zachód od linii wyznaczonej przez drogę nr 19 i miasto Bielsk Podlaski w powiecie bielskim,
- gmina Puńsk, część gminy Krasnopol położona na północ od linii wyznaczonej przez drogę nr 653, część gminy Sejny położona na północ od linii wyznaczonej przez drogę nr 653 i na wschód od linii wyznaczonej przez drogę nr 663 i miasto Sejny w powiecie sejneńskim,
- gminy Bakalarzewo, Filipów, Jeleniewo, Raczek, Rutka-Tartak, Suwałki i Szypliszki w powiecie suwalskim,
- powiat miejski Suwałki,
- powiat augustowski,
- gminy Korycin, Krynk, Kuźnica, Sokółka, Szudziałowo, część gminy Nowy Dwór położona na północ od linii wyznaczonej przez drogę nr 670, część gminy Janów położona na południe od linii wyznaczonej przez drogę nr 671 biegnącą od wschodniej granicy gminy do miejscowości Janów i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Janów, Trofimówka i Kizielany i część gminy Suchowola położona na zachód od linii wyznaczonej przez drogę nr 8 biegnącą od północnej granicy gminy do miejscowości Suchowola, a następnie przedłużonej drogą łączącą miejscowości Suchowola i Dubasiewszczyzna biegnącą do południowo-wschodniej granicy gminy w powiecie sokólskim,
- powiat miejski Białystok.

w województwie mazowieckim:

- gminy Przesmyki, Wodynie, część gminy Mordy położona na południe od linii wyznaczonej przez drogę nr 698 biegnącą od zachodniej granicy gminy do północno – wschodniej granicy gminy i część gminy Zbuczyn położona na wschód od linii wyznaczonej przez drogę biegnącą od północno-wschodniej do południowej granicy gminy i łączącą miejscowości Tarcze, Chojna, Zbuczyn, Grodzisk, Dziewule i Smolanka w powiecie siedleckim,
- gminy Repki, Jabłonna Lacka, część gminy Bielany położona na wschód od linii wyznaczonej przez drogę nr 63 i część gminy wiejskiej Sokołów Podlaski położona na wschód od linii wyznaczonej przez drogę nr 63 w powiecie sokołowskim,
- powiat łosicki,
- gmina Brochów w powiecie sochaczewskim,
- gminy Czosnów, Leoncin, Pomiechówek, Zakroczym i miasto Nowy Dwór Mazowiecki w powiecie nowodworskim,
- gmina Joniec w powiecie płońskim,
- gmina Pokrzywnica w powiecie pułtuskim,
- gminy Dąbrówka, Kobyłka, Marki, Radzymin, Wołomin, Zielonka i Ząbki w powiecie wołomińskim,
- część gminy Somianka położona na południe od linii wyznaczonej przez drogę nr 62 w powiecie wyszkowskim,

- gmina Sulejówek i części gminy Latowicz położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Stawek do skrzyżowania z drogą nr 802 i na północ od linii wyznaczonej przez drogę nr 802 biegnącą od tego skrzyżowania do wschodniej granicy gminy w powiecie mińskim,
- gmina Borowie w powiecie garwolińskim,
- gminy Celestynów, Józefów, Karczew, Osieck, Otwock, Sobienie Jeziory i Wiązowna w powiecie otwockim
- powiat warszawski zachodni,
- powiat legionowski,
- powiat piaseczyński,
- powiat pruszkowski,
- gminy Chynów, Grójec, Jasieniec, Pniewy i Warka w powiecie grójeckim,
- gminy Milanówek, Grodzisk Mazowiecki, Podkowa Leśna i Żabia Wola w powiecie grodziskim,
- gminy Grabów nad Pilicą, Magnuszew i część gminy Głowaczów położona na północ od linii wyznaczonej przez drogę nr 48 w powiecie kozienickim,
- część gminy Stromiec położona na północ od linii wyznaczonej przez drogę nr 48 w powiecie białobrzeskim,
- powiat miejski Warszawa.

w województwie lubelskim:

- gminy Czemierniki, Kąkolewnica, Wołyń, część gminy Borki położona na południowy – wschód od linii wyznaczonej przez drogę nr 19, miasto Radzyń Podlaski, część gminy wiejskiej Radzyń Podlaski położona na wschód od linii wyznaczonej przez drogę biegnącą od północno-zachodniej granicy gminy i łącząca miejscowości Brzostowiec i Radowiec do jej przecięcia z granicą miasta Radzyń Podlaski, następnie na wschód od linii stanowiącej granicę miasta Radzyń Podlaski biegnącej do południowej granicy gminy i na południe od linii wyznaczonej przez drogę nr 19 biegnącą od południowo zachodniej granicy gminy do granicy miasta Radzyń Podlaski oraz na południe od południowej granicy miasta Radzyń Podlaski do granicy gminy w powiecie radzyńskim,
- gminy Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, część gminy Krzywda położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w kierunku południowym i łączącą miejscowości Kozuchówka, Krzywda i Adamów, część gminy Stanin położona na zachód od linii wyznaczonej przez drogę nr 807, i część gminy wiejskiej Łuków położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków i na północ od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków i część miasta Łuków położona na wschód od linii wyznaczonej przez drogę nr 63 biegnącą od północnej granicy miasta Łuków do skrzyżowania z drogą nr 806 i na północ od linii wyznaczonej przez drogę nr 806 biegnącą od tego skrzyżowania do wschodniej granicy miasta Łuków w powiecie łukowskim,
- gminy Leśna Podlaska, Rossosz, Łomazy, Konstantynów, Piszczac, Rokitno, Biała Podlaska, Zalesie, Terespol z miastem Terespol, Drelów, Międzyrzec Podlaski z miastem Międzyrzec Podlaski w powiecie białskim,
- powiat miejski Biała Podlaska,
- część gminy Siemień położona na zachód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na zachód od drogi nr 813 w powiecie parczewskim,
- gminy Niedźwiada, Ostrówek i część gminy Firlej położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie lubartowskim,
- gmina Trawniki i część gminy Piaski położona na północ od linii wyznaczonej przez drogę nr 17 biegnącą od wschodniej granicy gminy Piaski do skrzyżowania z drogą nr S12 i na wschód od linii wyznaczonej przez drogę biegnącą od skrzyżowania dróg nr 17 i nr S12 przez miejscowość Majdan Brzezicki do północnej granicy gminy w powiecie świdnickim;
- gmina Fajslawice i część gminy Łopiennik Górny położona na zachód od linii wyznaczonej przez drogę nr 17 w powiecie krasnostawskim,
- gminy Milejów, Puchaczów, część gminy Ludwin położona na wschód od linii wyznaczonej przez drogę nr 820 i część gminy Cyców położona na zachód od linii wyznaczonej przez drogi nr 82 i 838 w powiecie łęczyńskim,
- gminy Dołhobyczów, Mircze i część gminy wiejskiej Hrubieszów położona na południe od linii wyznaczonej przez drogę nr 844 oraz na południe od linii wyznaczonej przez drogę nr 74 i miasto Hrubieszów w powiecie hrubieszowskim,

- gmina Telatyn w powiecie tomaszowskim,
- część gminy Wojsławice położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wojsławice do południowej granicy gminy w powiecie chełmskim,
- gmina Grabowiec w powiecie zamojskim.

## PART III

## 1. Latvia

The following areas in Latvia:

- Auces novads Ukru un Bēnes pagasti un Lielaucē pagasta daļa uz Rietumiem no autoceļa P104 un Vītiņu pagasta daļa uz Ziemeļiem no autoceļa P96,
- Brocēnu novads Ciecēres un Gaiķu pagasts, Blīdēnes pagasta daļa uz Dienvidiem no autoceļa A9, Remtes pagasta daļa uz rietumiem no autoceļa 1154 un P109, Brocēnu pilsēta,
- Dobeles novads Penkules pagasts un Zebrenes pagasta daļa uz Rietumiem no autoceļa P104,
- Jelgavas novads Jaunsvirlaukas, Valgundes, Kalnciema, Līvberzes pagasts,
- Kuldīgas novads Pelču, Snēpeles un Vārmes pagasts, Rumbas pagasta daļa uz dienvidiem no autoceļa P120, Kurmāles pagasta daļa uz austrumiem no autoceļa 1283 un 1290, un uz dienvidrietumiem no autoceļa P118,
- Neretas novads Mazzalves pagasts,
- Ozolnieku novads Salgales pagasts,
- Saldus novads Novadnieku, Kursišu, Zvārdes, Saldus, Zirņu, Lutriņu un Jaunlutriņu pagasts, Saldus pilsēta,
- Tērvetes novads Bukaišu pagasts,
- Vecumnieku novads Kurmenes pagasts.

## 2. Lithuania

The following areas in Lithuania:

- Akmenės rajono savivaldybė,
- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė: Alytaus, Alovės, Butrimonių, Daugų, Nemunaičio, Pivašiūnų, Punios ir Raitininkų seniūnijos,
- Birštono savivaldybė,
- Jurbarko rajono savivaldybė: Girdžių, Juodaičių, Raudonės, Seredžiaus, Skirsnemunės, Šimkaičių ir Veliunos seniūnijos,
- Joniškio rajono savivaldybė,
- Kauno rajono savivaldybė: Babtų, Čekiškės, Vilkijos ir Vilkijos apylinkių seniūnijos,
- Kaišiadorių rajono savivaldybė: Paparčių ir Žaslių seniūnijos,
- Kėdainių rajono savivaldybė: Dotnuvos, Josvainių, Kėdainių miesto, Krakių, Pelėdnagių ir Pernaravos seniūnijos,
- Kelmės rajono savivaldybė: Tytyvėnų seniūnijos dalis į rytus ir pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105 ir Tytuvėnų apylinkių seniūnijos dalis į pietus nuo kelio Nr. 157 ir į rytus nuo kelio Nr. 2105,
- Lazdijų rajono savivaldybė,
- Mažeikių rajono savivaldybės: Laižuvos, Mažeikių apylinkės, Mažeikių, Reivyčių, Tirkšlių ir Viekšnių seniūnijos,
- Pakruojo rajono savivaldybė: Guostagalio seniūnija, Klovainių seniūnijos dalis į pietus nuo kelio Nr. 150, Linkuvos seniūnijos dalis į vakarus nuo kelio Nr. 151 ir kelio Nr. 211, Lygumų, Pakruojo, Pašvitinio, Rozalimo ir Žeimelio seniūnijos,
- Prienų rajono savivaldybė: Jiezno ir Stakliškių seniūnijos,
- Radviliškio rajono savivaldybė: Baisogalos seniūnijos dalis į rytus nuo kelio Nr. 144, Grinkiškio, Pakalniškių, Sidabravo, Skėmių seniūnijos, Šeduvos miesto seniūnijos dalis į šiaurę nuo kelio Nr. A9 ir į rytus nuo kelio Nr. 3417, Šaukoto ir Šiaulėnų seniūnijos,
- Raseinių rajono savivaldybė: Ariogalos, Betygalos, Pajūjū Šiluvos, Kalnų seniūnijos ir Girkalnio seniūnijos dalis į pietus nuo kelio Nr. A1,

- Šakių rajono savivaldybė: Gelgaudiškio, Kidulių, Plokščių ir Šakių seniūnijos,
- Šiaulių miesto savivaldybė,
- Šiaulių rajono savivaldybė,
- Telšių rajono savivaldybė: Tryškių seniūnija,
- Trakų rajono savivaldybė,
- Varėnos rajono savivaldybė.

### 3. Poland

The following areas in Poland:

w województwie warmińsko-mazurskim:

- gminy Lelkowo, Pieniężno, Płoskinia i część gminy wiejskiej Braniewo położona na wschód od linii wyznaczonej przez drogę nr E28 i S22 w powiecie braniewskim,
- gminy Bartoszyce z miastem Bartoszyce, Górowo Iławeckie z miastem Górowo Iławeckie i Sępól w powiecie bartoszyckim,
- część gminy Kiwity położona na północ od linii wyznaczonej przez drogę nr 513 i część gminy Lidzbark Warmiński położona na północ od linii wyznaczonej przez drogę nr 513 biegnącą od wschodniej granicy gminy do wschodniej granicy miasta Lidzbark Warmiński i na wschód od linii wyznaczonej przez drogę nr 511 w powiecie lidzbarskim,
- gminy Srokowo, Barciany i część gminy Korsze położona na północ od linii wyznaczonej przez drogę biegnącą od zachodniej granicy łączącą miejscowości Krelikiejmy i Sątoczno i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Sątoczno, Sajna Wielka biegnącą do skrzyżowania z drogą nr 590 w miejscowości Glitajny, a następnie na zachód od drogi nr 590 do skrzyżowania z drogą nr 592 i na północ od linii wyznaczonej przez drogę nr 592 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 590 w powiecie kętrzyńskim,
- gmina Budry i część gminy Węgorzewo położona na wschód od linii wyznaczonej przez drogę nr 63 biegnącą od południowo-wschodniej granicy gminy do skrzyżowania z drogą nr 650, a następnie na północ od linii wyznaczonej przez drogę nr 650 biegnącą od skrzyżowania z drogą nr 63 do skrzyżowania z drogą biegnącą do miejscowości Przysań i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Przysań, Pniewo, Kamionek Wielki, Radziej, Dłużec w powiecie węgorzewskim,
- część gminy Banie Mazurskie położona na północ od linii wyznaczonej przez drogę nr 650 w powiecie gołdapskim,

w województwie podlaskim:

- gminy Dąbrowa Białostocka, Sidra, część gminy Nowy Dwór położona na południe od linii wyznaczonej przez drogę nr 670, część gminy Janów położona na północ od linii wyznaczonej przez drogę nr 671 biegnącą od wschodniej granicy gminy do miejscowości Janów i na wschód od linii wyznaczonej przez drogę łączącą miejscowości Janów, Trofimówka i Kizielany i część gminy Suchowola położona na wschód od linii wyznaczonej przez drogę nr 8 biegnącą od północnej granicy gminy do miejscowości Suchowola, a następnie przedłużonej drogą łączącą miejscowości Suchowola i Dubasiewszczyzna biegnącą do południowo-wschodniej granicy gminy w powiecie sokólskim,
- gmina Giby, część gminy Krasnopol położona na południe od linii wyznaczonej przez drogę nr 653 i część gminy Sejny położona na południe od linii wyznaczonej przez drogę nr 653 oraz południowo — zachodnią granicę miasta Sejny i na zachód od linii wyznaczonej przez drogę nr 663 w powiecie sejneńskim,
- gmina Orla, część gminy Bielsk Podlaski położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie bielskim,
- gminy Czyże, część gminy Dubicze Cerkiewne położona na zachód od linii wyznaczonej przez drogę nr 685, część gminy Kleszczewo położona na zachód od linii wyznaczonej przez drogi nr 685, a następnie nr 66 i nr 693 i część gminy Hajnówka położona na południe od linii wyznaczonej przez drogę nr 689 i na zachód od linii wyznaczonej przez drogę nr 685 w powiecie hajnowskim,
- gmina Goniądz w powiecie monieckim

w województwie mazowieckim:

- gmina Nasielsk w powiecie nowodworskim,
- gmina Świercze i część gminy Winnica położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,

- gmina Nowe Miasto w powiecie płońskim,
- gminy Domanice, Korczew, Paprotnia, Skórzec, Wiśniew, Mokobody, Siedlce, Suchożebry, część gminy Kotuń położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Nowa Dąbrówka, Pieróg, Kotuń wzdłuż ulicy Gorzkowskiego i Kolejowej do przejazdu kolejowego łączącego się z ulicą Siedlecką, Broszków, Żuków, część gminy Mordy położona na północ od linii wyznaczonej przez drogę nr 698 biegnącą od zachodniej granicy gminy do północno – wschodniej granicy gminy i część gminy Zbuczyn położona na zachód od linii wyznaczonej przez drogę biegnącą od północnowschodniej do południowej granicy gminy i łączącą miejscowości: Tarcze, Choja, Zbuczyn, Grodzisk, Dziewule i Smolanka w powiecie siedleckim,
- powiat miejski Siedlce,
- gmina Siennica, część gminy Mińsk Mazowiecki położona na południe od linii wyznaczonej przez drogę nr 92 biegnącą od zachodniej granicy gminy do granicy miasta Mińsk Mazowiecki i na południe od linii wyznaczonej przez drogę biegnącą od wschodniej granicy miasta Mińsk Mazowiecki łączącą miejscowości Targówka, Budy Barczackie do wschodniej granicy gminy, część gminy Ceglów położona na południe od linii wyznaczonej przez drogę biegnącą od zachodniej granicy gminy łączącą miejscowości Wiciejów, Mienia, Ceglów i na zachód od linii wyznaczonej przez drogę łączącą miejscowości Ceglów, Skwarne i Podskwarne biegnącą do wschodniej granicy gminy i części gminy Latowicz położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Stawek do skrzyżowania z drogą nr 802 i na południe od linii wyznaczonej przez drogę nr 802 biegnącą od tego skrzyżowania do wschodniej granicy gminy w powiecie mińskim,
- gmina Kołbiel w powiecie otwockim,
- gminy Parysów i Pilawa w powiecie garwolińskim,

w województwie lubelskim:

- gminy Białopole, Dubienka, Chełm, Leśniowice, Wierzbica, Sawin, Ruda Huta, Dorohusk, Kamień, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze, Żmudź i część gminy Wojsławice położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy do miejscowości Wojsławice do południowej granicy gminy w powiecie chełmskim,
- powiat miejski Chełm,
- gmina Siennica Różana część gminy Łopiennik Górny położona na wschód od linii wyznaczonej przez drogę nr 17 i część gminy Krasnystaw położona na wschód od linii wyznaczonej przez drogę nr 17 biegnącą od północno – wschodniej granicy gminy do granicy miasta Krasnystaw w powiecie krasnostawskim,
- gminy Hanna, Hańsk, Wola Uhruska, Urszulín, Stary Brus, Wiryki i gmina wiejska Włodawa w powiecie włodawskim,
- część gminy Cyców położona na wschód od linii wyznaczonej przez drogi nr 82 i 838 części gminy Ludwin położona na zachód od linii wyznaczonej przez drogę nr 820 i część gminy Spiczyn położona na wschód od linii wyznaczonej przez drogę nr 829 w powiecie łęczyńskim,
- gminy Jabłoń, Podedwórze, Dębowa Kłoda, Parczew, Sosnowica, część gminy Siemień położona na wschód od linii wyznaczonej przez drogę nr 815 i część gminy Milanów położona na wschód od drogi nr 813 w powiecie parczewskim,
- gminy Janów Podlaski, Kodeń, Sławatycze, Sosnowka, Tuczná i Wisznice w powiecie białskim,
- gmina Ulan Majorat, część gminy wiejskiej Radzyń Podlaski położona na zachód od linii wyznaczonej przez drogę biegnącą od północno-zachodniej granicy gminy i łączącą miejscowości Brzostówiec i Radowiec do jej przecięcia z granicą miasta Radzyń Podlaski, a następnie na zachód od linii stanowiącej granicę miasta Radzyń Podlaski do jej przecięcia z drogą nr 19 i na północ od linii wyznaczonej przez drogę nr 19 biegnącą od południowo zachodniej granicy gminy do granicy miasta Radzyń Podlaski, część gminy Borki położona na północny – zachód od linii wyznaczonej przez drogę nr 19 w powiecie radzyńskim,
- gminy Jeziorzany, Michów, Kock, Ostrów Lubelski, Serniki, Uścimów i część gminy Firlej położona na zachód od linii wyznaczonej przez drogę nr 19 w powiecie lubartowskim,
- gminy Adamów, Serokomla Wojcieszków, część gminy wiejskiej Łuków położona na zachód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy przez miejscowość Wólka Świątkowa do północnej granicy miasta Łuków, a następnie na północ, zachód, południe i wschód od linii stanowiącej północną, zachodnią, południową i wschodnią granicę miasta Łuków do jej przecięcia się z drogą nr 806 i na południe od linii wyznaczonej przez drogę nr 806 biegnącą od wschodniej granicy miasta Łuków do wschodniej granicy gminy wiejskiej Łuków, część miasta Łuków położona na zachód i na południe od linii wyznaczonej przez drogę nr 63 biegnącą od północnej granicy miasta Łuków do skrzyżowania z drogą nr 806 i na południe od linii wyznaczonej przez drogę nr 806 biegnącą do wschodniej granicy miasta Łuków, część gminy Stanin położona na wschód od linii wyznaczonej przez drogę nr 807 i część gminy Krzywda położona na wschód od linii wyznaczonej przez drogę biegnącą od północnej granicy gminy w kierunku południowym i łączącą miejscowości Kożuchówka, Krzywda i Adamów w powiecie łukowskim;

- gminy Horodło, Uchanie i część gminy wiejskiej Hrubieszów położona na północ od linii wyznaczonej przez drogę nr 844 biegnącą od zachodniej granicy gminy wiejskiej Hrubieszów do granicy miasta Hrubieszów oraz na północ od linii wyznaczonej przez drogę nr 74 biegnącą od wschodniej granicy miasta Hrubieszów do wschodniej granicy gminy wiejskiej Hrubieszów w powiecie hrubieszowskim,
- gmina Baranów w powiecie puławskim,
- gminy Nowodwór i Ułęż w powiecie ryckim,

w województwie podkarpackim:

- gminy Cieszanów, Lubaczów z miastem Lubaczów i część gminy Oleszyce położona na północ od linii wyznaczonej przez drogę biegnącą od wschodniej granicy gminy przez miejscowość Borchów do skrzyżowania z drogą nr 865 w miejscowości Oleszyce, a następnie na wschód od linii wyznaczonej przez drogę nr 865 biegnącą w kierunku północno-wschodnim do skrzyżowania z drogą biegnącą w kierunku północno-zachodnim przez miejscowość Lubomierz — na północ od linii wyznaczonej przez tę drogę do skrzyżowania z drogą łączącą miejscowości Uszkowce i Nowy Dzików – na wschód od tej drogi w powiecie lubaczowskim.

#### 4. Romania

The following areas in Romania:

- Constanța county,
- Satu Mare county,
- Tulcea county,
- Bacau county,
- Bihor county,
- Brăila county,
- Buzău county,
- Călărași county.
- Galați county,
- Ialomița county,
- Salaj county,
- Vaslui county,
- Vrancea county.

#### PART IV

#### Italy

The following areas in Italy:

- tutto il territorio della Sardegna.'
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