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#### COVER NOTE

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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	18 October 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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No. Cion doc.:	C(2021) 7376 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 18.10.2021 supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the issuance of complementary certificates certifying the non-use of antibiotics in organic production of animal products for the purpose of export

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Delegations will find attached document C(2021) 7376 final.

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Encl.: C(2021) 7376 final



Brussels, 18.10.2021  
C(2021) 7376 final

**COMMISSION DELEGATED REGULATION (EU) .../...**

**of 18.10.2021**

**supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the issuance of complementary certificates certifying the non-use of antibiotics in organic production of animal products for the purpose of export**

(Text with EEA relevance)

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE DELEGATED ACT**

Following the adoption of Regulation (EU) 2018/848, which will apply from 1 January 2022, it is necessary to adopt a delegated regulation supplementing that Regulation by laying down the model of a complementary certificate, which certifies that organic animal products are produced without the use of antibiotics. This is necessary to facilitate the access of EU organic operators to markets in certain third countries, which require that organic animal products are produced without the use of antibiotics. EU organic operators need to have legal certainty on the rules that will apply for this issue.

### **2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT**

The act was discussed thoroughly with Member States at the Group of Experts on Organic Production, as well with the main organisations representing the organic sector. WTO partners were notified and general public consultations were carried out.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

This delegated act lays down the model of a complementary certificate, which certifies that organic animal products are produced without the use of antibiotics for the purpose of export.

COMMISSION DELEGATED REGULATION (EU) .../...

of 18.10.2021

**supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council with rules on the issuance of complementary certificates certifying the non-use of antibiotics in organic production of animal products for the purpose of export**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007<sup>1</sup>, and in particular Article 44(2) thereof,

Whereas:

- (1) Certain third countries require that organic animal products are produced without the use of antibiotics. In order to facilitate access to markets in those countries, operators or groups of operators in the Union wanting to export such products should be able to prove the non-use of antibiotics by means of an official document.
- (2) Pursuant to Article 35 of Regulation (EU) 2018/848, competent authorities or, where appropriate, control authorities or control bodies, are to provide a certificate to any operator or group of operators that has notified its activity and complies with that Regulation. In order to certify that the organic animal products are produced without the use of antibiotics, the operator or group of operators should have the possibility to request those competent authorities or, where appropriate, control authorities or control bodies, to issue a complementary certificate. The model for that complementary certificate should be established.
- (3) In the interest of clarity and legal certainty, this Regulation should apply from the date of application of Regulation (EU) 2018/848,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Complementary certificate certifying the non-use of antibiotics in organic production of animal products for the purpose of export**

At the request of an operator or group of operators that is already in possession of a certificate as referred to in Article 35 of Regulation (EU) 2018/848, the relevant competent authority or, where appropriate, the relevant control authority or control body, shall issue a complementary certificate certifying that the operator or group of operators produced organic animal products without the use of antibiotics if such certificate is needed for the purpose of export of those products from the Union. The model for that complementary certificate is set out in the Annex to this Regulation.

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<sup>1</sup> OJ L 150, 14.6.2018, p. 1.

*Article 2*

**Entry into force an application**

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

It shall apply from 1 January 2022.

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

Done at Brussels, 18.10.2021

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*