Council of the European Union

Brussels, 3 March 2026
(OR. en)

6877/26

Interinstitutional File: 2025/0409 (COD)

LIMITE

SIMPL 23	**DENLEG 10**
ANTICI 28	**MI 196**
AGRI 151	**FOOD 17**
AGRILEG 38	**FEED 4**
ENV 182	**SEMENCES 1**
PESTICIDE 8	**SAN 121**
PHYTOSAN 10	**CHIMIE 22**
VETER 27	**CODEC 350**

NOTE

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	17055/25
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 98/58/EC and Directive 2009/128/EC of the European Parliament and of the Council as regards the simplification and strengthening of food and feed safety requirements, and repealing Council Directives 82/711/EC and 85/572/EC - Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal.

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~.

ANNEX

2025/0409 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Directive 98/58/EC and Directive 2009/128/EC of the European Parliament and of the Council as regards the simplification and strengthening of food and feed safety requirements, and repealing Council Directives 82/711/EEC and 85/572/EEC

PUBLIC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 114 and Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Directive 2009/128/EC of the European Parliament and of the Council[1] lays down the legal framework for the sustainable use of pesticides (plant protection products). Article 9(1) of Directive 2009/128/EC provides for a prohibition of aerial spraying of pesticides by an aircraft. Article 9(2) to (6) thereof allows individual derogations from that prohibition, under certain conditions.

(2) Since the entry into force of Directive 2009/128/EC, experience has shown that the procedure for individual derogations from the prohibition of aerial spraying of pesticides entails considerable administrative burden for professional users and it slows down and restricts the

[1] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, pp. 71–86, ELI: http://data.europa.eu/eli/dir/2009/128/oj).

development of technologies that could allow for safer choices for human health and the environment. Certain types of unmanned aircraft systems (commonly referred to as drones) under particular conditions are capable of minimising the exposure of the operator to the use of pesticides in the field and could allow professional users to apply pesticides in more targeted ways. Such unmanned aircraft systems are likely to help reduce the use of pesticides and consequently help reduce the risks to human health and the environment compared to the use of land-based application equipment. It is therefore appropriate to enable Member States to exempt such types of unmanned aircraft systems from the prohibition of aerial spraying provided for in Directive 2009/128/EC under certain conditions.

(3) In order to ensure protection of human health and the environment, it is appropriate to require that such exemption can only apply if the pesticides are explicitly authorised for aerial use by unmanned aircraft systems. Such explicit authorisation of pesticides for aerial use by unmanned aircraft systems would ensure that any potential risks to human health and the environment from exposure to such pesticides are thoroughly assessed as part of the authorisation process. As the authorisations of pesticides are regulated under Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2], the Commission should mandate the European Food Safety Authority (EFSA) to develop a guidance document on risk assessment of pesticides for application by unmanned aircraft systems under Regulation (EC) No 1107/2009 in order to ensure that a robust framework of safeguards is in place.

(4) The legislative framework governing the operation of unmanned aircraft systems includes such acts as Regulation (EU) 2018/1139 of the European Parliament of the Council[3] and Commission Implementing Regulation (EU) 2019/947[4]. This legislative framework does not identify the types of unmanned aircraft systems that could be appropriate for use for aerial application of pesticides by professional users. Therefore, complementary to the development of specific guidance on the risk assessment of pesticides that could be used for application by unmanned aircraft systems, it is necessary to identify the types of unmanned aircraft systems that have lower or equal risks as regards human health and the environment compared to the risks arising from land-based application equipment for the same use.

(5) In order to identify the types of unmanned aircraft systems that may be used for application of pesticides, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of

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[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, pp. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

[3] Regulation (EU) 2018/1139 of the European Parliament of the Council on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, pp. 1, ELI: http://data.europa.eu/eli/reg/2018/1139/oj).

[4] Commission Implementing Regulation (EU) 2019/947 of 24 May 2019 on the rules and procedures for the operation of unmanned aircraft (OJ L 152, 11.6.2019, ELI: http://data.europa.eu/eli/reg_impl/2019/947/oj).

supplementing Directive 2009/128/EC to identify the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and those experts should systematically have access to meetings of Commission expert groups dealing with the preparation of such delegated acts.

(6) Given the need to address perceived remaining knowledge and data gaps before the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use can be identified, it is appropriate to allow time for the Commission to consult EFSA and the Member States in preparation of a delegated act identifying those types of unmanned aircraft systems that may be exempted from the prohibition of aerial spraying. The Commission should be empowered to adopt a delegated act in accordance with Article 20a to identify types of unmanned aircraft systems for which it can be established that the risks from exposure to pesticides to human health and the environment is equal to or lower than from the use of land-based application equipment for the same use. Adoption of this delegated act should be a precondition for the possibility for Member States to exempt such types of unmanned aircraft systems from the prohibition of aerial spraying. Pending the identification of the types of unmanned aircraft systems that may be exempted and the decision by a Member State to exempt those identified unmanned aircraft systems from the prohibition on aerial spraying, it is appropriate to continue to require a professional user to submit requests for approval of aerial spraying by all unmanned aircraft systems.

(7) Directive No 98/58/EC sets minimum requirements for the protection of animals kept for farming purposes. Owners or keepers of animals kept for farming purposes are currently required to keep records of medicinal treatments given to animals and of the number of mortalities in accordance with points 5 and 6 of the Annex to Directive 98/58/EC. Article 108 of Regulation (EU) 2019/6 of the European Parliament and of the Council[5] contains more detailed record keeping requirements on the use of medicinal products for owners or keepers of food producing animals. At the same time Article 102(1)(d) and Article 186(1)(d) of Regulation No 2016/429 of the European Parliament and of the Council[6] require operators to keep and maintain records containing information on the mortality of animals in their establishments. Thus, parallel reporting obligations exist for both points 5 and 6 of the Annex to Directive 98/58/EC. The obligations imposed should be simplified to avoid duplication of record keeping requirements for farmers. Therefore, points 5 and 6 of the Annex to Directive 98/58/EC should be deleted.

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5 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

6 Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1, ELI: : http://data.europa.eu/eli/reg/2016/429/oj).

(8) Regulation (EC) No 1935/2004 provides the legal framework applicable to materials and articles intended to come into contact with food. Article 5(1) of Regulation (EC) No 1935/2004 empowers the Commission to adopt specific measures for the materials and articles listed in Annex I of that Regulation. Pending the adoption by the Commission of a specific measure on plastic food contact materials, Regulation No 1935/2004 did not repeal Council Directives 82/711/EEC[7] and 85/572/EEC[8], which laid down the rules necessary for testing the migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, including the list of simulants to be used to that end for specific food categories. Commission Regulation (EU) No 10/2011[9] was adopted as a specific measure for plastic materials and articles intended to come into contact with food. Since Commission Regulation covers the matters regulated by Directives 82/711/EEC and 85/572/EEC, it is therefore appropriate to repeal Directives 82/711/EEC and 85/572/EEC for reasons of legal certainty.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2009/128/EC

Directive 2009/128/EC is amended as follows:

(1) Article 3 is amended as follows:

(a) point 5 is replaced by the following:

‘5. ‘aerial spraying’ means application of pesticides from a manned aircraft or an unmanned aircraft system;’;

(b) the following point 5a is inserted:

‘5a. ‘unmanned aircraft system’ means any aircraft with equipment for aerial application of pesticides, operating autonomously or piloted remotely without a pilot on board;’;

(2) Article 9 is amended as follows:

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7 Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, (OJ L 297, 23.10.1982, pp. 26–30, ELI: http://data.europa.eu/eli/dir/1982/711/oj).

8 Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs, (OJ L 372, 31.12.1985, pp. 14–21, ELI: http://data.europa.eu/eli/dir/1985/572/oj).

9 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance, (OJ L 12, 15.1.2011, pp. 1–89, ELI: http://data.europa.eu/eli/reg/2011/10/oj).

(a) in paragraph 1, the following new subparagraph is added:

'The prohibition provided for in the first subparagraph may only be derogated from in accordance with paragraphs 2 to 6 of this Article or with Article 9a.'

(b) in paragraph 2, the first sentence of the first subparagraph is replaced by the following:

'2. By way of derogation from paragraph 1, aerial spraying may be allowed in special cases provided the following conditions are met:';

(c) in paragraph 4, the first subparagraph is replaced by the following:

'A professional user wishing to apply pesticides by aerial spraying shall submit a request for approval of an application plan to the competent authority accompanied by evidence to show that the conditions referred to in paragraphs 2 and 3 are fulfilled. The request shall be submitted in due time to the competent authority. It shall contain information about the provisional time of spraying and the amounts and the type of pesticides applied. ';

(3) the following new Article 9a is inserted:

'Article 9a

Aerial spraying of pesticides by unmanned aircraft systems

1. By way of further derogation from Article 9(1), Member States may, in the case of professional users, exempt from the prohibition laid down in that Article, the aerial spraying of pesticides by unmanned aircraft systems identified pursuant to paragraph 2.

   Pesticides to be used for aerial spraying by such unmanned aircraft systems shall be explicitly authorised for that use by the Member State under Regulation (EC) No 1107/2009 following a specific assessment addressing risks from aerial spraying.

2. The Commission shall adopt a delegated act by [*OP: please insert the date = **3** ~~4~~ years after the entry into force of this Directive]* in accordance with Article 20a supplementing this Directive to identify the types of unmanned aircraft systems that have lower or equal risks compared to the risks arising from land-based application equipment for the same use.';

(4) Article 20a is replaced by the following:

'Article 20a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) shall be conferred on the Commission for a period of *[OP: please insert the date = five years after the date of entry into force of this Directive]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([6]).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 5(3), Article 8(7), Article 9a(2), Article 14(4) and Article 15(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'.

Article 2

Amendment to Directive 98/58/EC

Points 5 and 6 of Annex I to Directive 98/58/EC are deleted.

Article 3

Repeal of Directives 82/711/EEC and 85/572/EEC

1. Directive 82/711/EEC and Directive 85/572/EEC are repealed ~~with effect from [*OP: please insert the date = date of entry into force of this Directive*]~~.

2. References to the repealed Directives shall be construed as references to Commission Regulation (EU) No 10/2011.

Article 4

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 1 of this Directive by [*OP: please insert the date = 5 years after the entry into force of this Directive.*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

2. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Articles 2 and 3 of this Directive by [*OP: please insert the date = two years after the entry into force of this Directive.*] at the latest. When Member States adopt the provisions referred to in paragraphs 1 and 2, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 5

Entry into force

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

Article 6

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	The President

PUBLIC