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Simplification Omnibus Package

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The proposal is part of the cross-cutting legislative simplification package announced in the European Commission's Vision for Agriculture and Food¹, which aims to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, and for the protection of human and animal health, and the environment. More specifically, this initiative is aiming at simplification of certain provisions and procedures of the following acts:

Directive 2009/128/EC²: Drones³ have the potential to be used for more targeted application of pesticides and, in certain situations may present a lower risk to the operator and environment than land-based application technologies. However, currently they are covered by the general prohibition of aerial spraying under Directive 2009/128/EC, and granting and obtaining individual derogations for their use gives rise to a considerable administrative burden on professional users and competent authorities of the Member States. This was identified as the most significant burden in the evaluation of the Directive conducted in 2022.⁴ The impact of this burden is growing as opportunities increase to apply pesticides using drones, hampering the development and uptake of this innovative technology in the EU. In the meeting of the AGRIFISH Council in December 2024, several Member States supported a paper⁵ requesting the inclusion in the Directive of certain criteria to facilitate use of drones such as those that had already been identified in a previous Commission proposal⁶ (since withdrawn⁷). A possibility for Member States to grant a general derogation from the ban on aerial spraying for certain types of drones identified by the Commission in delegated act is therefore proposed to be introduced in the Directive. The application of pesticides by drones would be subject to the condition that the respective plant protection products have to be explicitly authorised under Regulation (EC) No 1107/2009 for application by drones. Therefore, the Commission will mandate the European Food Safety Authority (EFSA) to develop a guidance document on the risk assessment for authorising plant protection products for aerial application under Regulation (EC) No 1107/2009 and will consult EFSA and the Member States in the preparation of the delegated act listing the types of drones that could be used for aerial spraying. The application of pesticides by drones would also continue to be subject to other requirements of the Directive, including those regulating training and equipment inspection. In addition, they would continue to be subject to detailed requirements in

¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075>.

² 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>).

³ Drones are referred to as 'unmanned aircraft systems' in this proposal.

⁴ Study Supporting the Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides and Impact Assessment of its possible revision: [Final Report of the Evaluation](#), pp. 78-79.

⁵ AOB item for the meeting of the "Agriculture and Fisheries" Council on 9 and 10 December 2024: The need to establish appropriate legislation for the use of drones to contribute to the resilience of agricultural systems, <https://data.consilium.europa.eu/doc/document/ST-16521-2024-INIT/en/pdf>

⁶ [Proposal for a regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation \(EU\) 2021/2115](#) (2022/0196 (COD)).

⁷ Withdrawal of Commission Proposals, OJ C, C/2024/3117, 6.5.2024, <http://data.europa.eu/eli/C/2024/3117/oj>.

other EU legislation⁸, including on the competence of remote pilots, the operational limitations to reduce the risk posed to people and to other aircraft and the technical parameters applicable to the types of drone used.

Directive 98/58/EC⁹: 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 as part of the horizontal directive for the welfare of animals kept in farms. Similar record keeping is required by Regulation on the veterinary medicinal products and by the animal health Regulation respectively. While the potential for further simplification for farmers in general will be considered in the process of modernising EU animal welfare legislation under the *Vision for Agriculture and Food*.¹⁰, this omnibus will already avoid the duplication of record keeping requirements for farmers by amending Directive 98/58/EC in this respect.

Directive 82/711/EEC¹¹ and Directive 85/572/EEC¹²: Regulation (EC) No 1935/2004¹³ provides the legal framework applicable to materials and articles intended to come into contact with food. It replaced and repealed Council Directive 89/109/EEC.

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 and 85/572/EEC, 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 10/2011¹⁴ of 14 January 2011 was adopted as a specific measure for plastic materials and articles intended to come into contact with food. Regulation No 10/2011 covers the matters regulated by Directives 82/711/EEC and 85/572/EEC. Therefore, it is appropriate to repeal Directives 82/711/EEC and 85/572/EEC for reasons of legal certainty.

⁸ See for example [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, p. 45); [Commission Delegated Regulation \(EU\) 2019/945 of 12 March 2019 on unmanned aircraft systems and on third-country operators of unmanned aircraft systems](#) (OJ L 152, 11.6.2019, p. 1).

⁹ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, (OJ L 221, 8.8.1998, pp. 23–27, ELI: <http://data.europa.eu/eli/dir/1998/58/oj>).

¹⁰ https://agriculture.ec.europa.eu/overview-vision-agriculture-food/vision-agriculture-and-food_en

¹¹ 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>).

¹² 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>).

¹³ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, (OJ L 338, 13.11.2004, pp. 4–17, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>).

¹⁴ 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>).

- **Consistency with existing policy provisions in the policy area**

The amendments to Directive 2009/128/EC are in line with the overall aims of that Directive, which is to reduce the risks and impacts of pesticide use on human health and the environment. Facilitating greater use of drones with the necessary safeguards would allow for the targeted aerial application of plant protection products, improve operator safety and reduce the overall use and risk of pesticides.

Since safeguards for animal health and welfare remain in place, the amendment to Directive 98/58/EC is in line with the overall objective of that Directive, i.e. to protect animal welfare at farms.

Since Regulation (EU) No 10/2011 covers the matters regulated by Directives 82/711/EEC and 85/572/EEC, those Directives are repealed for reasons of legal certainty.

- **Consistency with other Union policies**

The contribution of drones to pesticide reduction through more targeted application as part of precision agriculture is consistent with the European Green Deal's objective that all EU policies should contribute to preserving and restoring Europe's natural capital.¹⁵

The Commission adopted a *Drone Strategy 2.0* in November 2022. It notes that the digitalisation of the economy should strengthen the Union's competitiveness and empower people with a new generation of technologies, leaving no one behind, in line with the European Pillar of Social Rights. A viable drone eco-system will contribute to leverage European research, innovation, and entrepreneurship to achieve the objectives of the European Green Deal and Digital Europe, fully in line with the new growth strategy for Europe.¹⁶

The *Drone Strategy 2.0* sets out a clear vision for 2030 of large scale highly automated and digitally connected affordable, safe, secure, and environmentally friendly drone operations in several Member States. The vision aims for the EU drone industry to become viable and accessible to EU citizens and businesses with an active participation of actors of all sizes. The drone eco-system will provide jobs, promote and protect European technological know-how and allow for growth opportunities for the EU economy as a whole.¹⁷ Targeted amendments to Directive 2009/128/EC to allow drones to be used without the need to apply for an individual derogation would serve these wider aims of economic growth.

The proposed amendment to Directive 2009/128/EC is also in line with the Commission's ambition in its Communication on implementation and simplification to radically lighten the regulatory load for people, businesses and administrations, boost prosperity and resilience and unleash opportunities, innovation and growth.¹⁸

¹⁵ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, 'The European Green Deal' COM(2019/640 final, [EUR-Lex - 52019DC0640 - EN - EUR-Lex \(europa.eu\)](#).

¹⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Drone Strategy 2.0 for a Smart and Sustainable Unmanned Aircraft Eco-System in Europe, COM(2022) 652 final.

¹⁷ *Ibid.*

¹⁸ European Commission 2024-2029, [A simpler and faster Europe](#): Communication on implementation and simplification.

By eliminating parallel record keeping requirements, the amendment to Directive 98/58 provides for a more streamlined and coherent framework which simplifies compliance for farmers and ensures a clearer legal basis for enforcement by the competent authorities. This is in line with the Commission's overall approach to reduce administrative burden as well as with its ambition to ensure a better compliance and effective enforcement of the EU animal welfare rules.

By repealing Directives 82/711/EEC and 85/572/EEC, whose subject-matters are presently regulated by Regulation (EU) No 10/2011, the Commission takes into account better regulation principles and guarantees legal certainty for the operators in the field of plastic food contact materials.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Article 43(2), Article 114 and Article 192(1) of the Treaty on the Functioning of the European Union (TFEU).

- **Subsidiarity (for non-exclusive competence)**

In accordance with the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States. To address the difficulties arising from administrative burdens related to an individual application procedure for aerial application of pesticides, Directive 2009/128/EC needs to be amended, which can only be done at EU level. Similarly, to eliminate the duplication of record keeping requirements on mortalities and the use of veterinary medicines, Directive 98/58/EC must be amended, which also can only be done at EU level. Finally, the repeal of Directives 82/711/EEC and 85/572/EEC to guarantee legal certainty can only be achieved at EU level. The principle of subsidiarity is therefore respected.

- **Proportionality**

The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction, without lowering the protection of human health and environment.

The proposal amends Directive 2009/128/EC, Directive 98/58/EC only to the extent necessary to achieve the objectives outlined above.

Directives 82/711/EEC and 85/572/EEC are repealed but their subject-matters are currently regulated by Regulation (EU) No 10/2011.

- **Choice of the instrument**

The proposal for revision is a legislative proposal, as the relevant Directives to be amended/repealed were adopted by co-decision/ ordinary legislative procedure. As this omnibus legislative proposal amends two directives and repeals another two directives, a Directive is the most appropriate legal instrument.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

This proposal is accompanied by a Commission staff working document that includes a detailed overview of the positive impacts of the proposed amendments of Directives 2009/128/EC and 98/58/EC, based on existing data and information gathered during the call for evidence and previous analyses. This includes drawing on an ex-post evaluation of Directive 2009/128/EC that was conducted between May 2020 and June 2022¹⁹ as part of a combined evaluation and impact assessment for its possible revision.

The repeal of Directives 82/711/EEC and 85/572/EEC does not require either an impact assessment, or stakeholder consultation as the provisions of the directives are superseded by more recent legal acts.

- **Stakeholder consultations**

Following the Commission's fitness check, concluded in 2022, stakeholders have raised concerns regarding the administrative burden caused by the current EU animal welfare legislation. For instance, in the public consultation that supported the fitness check, 75% of companies and business organisations (495 of 660) considered the current rules on animal welfare to be too burdensome and/or costly for farmers. In the stakeholder interviews that also were performed in support of the fitness check, one business organisation specifically referred to problems related to record keeping at farm level in this respect.²⁰ As noted above, the administrative burden of individual derogations was identified as the most significant burden in the evaluation Directive 2009/128/EC conducted in 2022.²¹

This is not applicable for the repeal of Directives 82/711/EEC and 85/572/EEC for the reasons explained above.

- **Collection and use of expertise**

Different stakeholder suggestions for simplification have been made concerning the removal of excessive administrative burden stemming from the prohibition of aerial spraying under Directive 2009/128/EC, and parallel requirements for keeping records of medicinal treatments and animal mortalities under Directive 98/58/EC. In addition, the experience of implementing Directive 2009/128/EC and the findings of Commission audits in Member States and drawing on an ex-post evaluation of Directive 2009/128/EC conducted between May 2020 and June 2022²² have informed the Commission's understanding of this topic.

This is not applicable to the repeal of Directives 82/711/EEC and 85/572/EEC for the reasons explained above.

¹⁹ See Study Supporting the Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides and Impact Assessment of its possible revision: [Final Report of the Evaluation](#).

²⁰ Commission Staff Working Document, Fitness Check of the EU Animal Welfare Legislation (SWD(2022) 329 final), p 119.

²¹ Study Supporting the Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides and Impact Assessment of its possible revision: [Final Report of the Evaluation](#), pp. 78-79.

²² Study Supporting the Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides and Impact Assessment of its possible revision: [Final Report of the Evaluation](#).

- **Impact assessment**

The proposed simplification measures are highly technical in nature. There are no viable alternatives to achieve the objectives, and the proposed measures do not alter core policy objectives or introduce significant new obligations. For these reasons, a full impact assessment would not bring added value. Instead, the proposal is accompanied by an analytical staff working document. The document clearly explains the proposed measures and present the underlying evidence, analysis and stakeholders' views, as well as estimating the potential cost savings.

In addition, the proposed amendment to Directive 2009/128/EC is informed by a recent impact assessment²³ carried out between May 2020 and June 2022 by the Commission in relation to the now withdrawn proposal for a regulation on the sustainable use of plant protection products.²⁴

This is not applicable to the repeal of Directives 82/711/EEC and 85/572/EEC for the reasons explained above.

- **Regulatory fitness and simplification**

This proposal is part of the commitment of the European Commission to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU. The proposal is therefore aiming at simplifying provisions of food and feed safety legislation, reducing unnecessary burdens and costs for businesses and authorities, without undermining the protection of human and animal health and the environment.

- **Fundamental rights**

The proposal respects the fundamental rights and observes the principles enshrined in the Charter of Fundamental Rights of the European Union and adheres to the values recognised therein. The reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. At the same time, the proposal will not undermine the objective of ensuring a high level of protection of human health and of the environment.

4. BUDGETARY IMPLICATIONS

This initiative will not imply any additional costs for the Commission.

5. OTHER ELEMENTS

- **Explanatory documents (for directives)**

The amendments to Directive 98/58/EC do not require Explanatory Documents on the transposition as they constitute waiving of obligations for the Member States and do not create new provisions to be transposed in national laws.

²³ Study Supporting the Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides and Impact Assessment of its possible revision: [Final Impact Assessment Report](#).

²⁴ [Proposal for a regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation \(EU\) 2021/2115 \(2022/0196 \(COD\)\)](#).

The amendments to Directive 2009/128/EC do not require explanatory documents on the transposition either as the proposal empowers the Commission to adopt delegated act in future.

The repeal of Directives 82/711/EEC and 85/572/EEC does not require any explanatory documents on the transposition as their provisions were replaced by Regulation (EU) No 10/2011, which is directly applicable since its date of application.

- **Detailed explanation of the specific provisions of the proposal**

- Directive 98/58/EC

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) No 2019/6 contains more detailed record keeping requirements on the use of medicinal products for owners or keepers of food producing animals. Articles 102(1)(d) and 186(1)(d) of Regulation (EU) No 2016/429 require operators to keep and maintain records containing information on the mortality of animals in their establishments. 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

- Directive 2009/128/EC

The definition of "aerial spraying" in Article 3, point 5 of Directive 2009/128/EC is updated to include a specific reference to unmanned aircraft systems (drones), and a definition of unmanned aircraft systems is provided for in the new point 5a of Article 3.

A new Article 9a gives the possibility to Member States to exempt certain types of unmanned aircraft systems (drones) from the prohibition of aerial spraying provided for in Article 9(1) of Directive 2009/128/EC where an assessment has shown that the risks are equal or lower compared to the risks arising from the use of land-based application equipment for the same use. This exemption will become possible, once the Commission has adopted delegated acts identifying the types of drones fulfilling this requirement. The Commission will be empowered to adopt the delegated acts.

- Directives 82/711/EEC and 85/572/EEC

Directives 82/711/EEC and 85/572/EEC are repealed since Regulation (EU) No 10/2011 regulates their subject-matters since its date of application.

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

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 Council¹ 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 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

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>).

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 Council², 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 Council³ and Commission Implementing Regulation (EU) 2019/947⁴. 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 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

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).

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 Council⁵ 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 Council⁶ 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.
- (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/EEC⁷ and 85/572/EEC⁸, 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 10/2011⁹ was adopted as a specific measure for plastic materials

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>).

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>).

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:
 - (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:’;
- (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 = 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
The President

For the Council
The President