

Council of the European Union

> Brussels, 13 July 2021 (OR. en)

10752/21

VETER 60 AGRILEG 145 SAN 459 DENLEG 54 PHYTOSAN 26 SEMENCES 35 DELACT 152

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 July 2021
То:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 383 final
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('Official Controls Regulation')

Delegations will find attached document COM(2021) 383 final.

Encl.: COM(2021) 383 final



EUROPEAN COMMISSION

> Brussels, 9.7.2021 COM(2021) 383 final

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('Official Controls Regulation')

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products ('Official Controls Regulation')

1. INTRODUCTION

Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products¹ was adopted on 15 March 2017 and entered into force on 27 April 2017. It has applied from 14 December 2019, except as provided for in Article 167(2) to (4) thereof.

Regulation (EU) 2017/625 constitutes the basic act governing the performance of official controls for the verification of compliance with the Union's agri-food chain rules, including where those rules apply to animals and goods entering the Union from third countries. It repealed and replaced Regulation (EC) No 882/2004² on official controls and other legislation that previously governed official controls and enforcement action along the Union's agri-food chain, including Council Directive 97/78/EC³ and Regulation (EC) 854/2004⁴. The aim of Regulation (EU) 2017/625 is to provide for a single and harmonised legislative framework for the organisation of official controls.

In this regard, Regulation (EU) 2017/625 significantly simplified and codified at EU level, the law on administrative enforcement of the EU's agri-food chain legislation in the Member States. Moreover, the scope of the Regulation is broad and covers the verification of compliance with food and food safety and feed and feed safety rules, animal health and welfare requirements, plant health requirements, animal-by products rules, rules on organic production and labelling of organic products, rules on plant protection products, protected

¹ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095 7.4.2017, p. 1).

² Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

³ Council Directive <u>97/78/EC</u> of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

⁴ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

designations and deliberate release into the environment of Genetically Modified Organisms (GMOs) for the purpose of food and feed production.

Additionally, Regulation (EU) 2017/625 establishes a common framework for the performance of border controls on animals and goods entering the EU, a uniform and harmonised framework for official certification, and strengthens cooperation and administrative assistance among Member States. It also empowers the Commission to adopt a number of measures where there is evidence that the system of controls in a Member State faces serious disruption, reinforces rules on financial penalties for fraudulent or deceptive practices, and introduces provisions on the protection of whistle-blowers of those practices.

Regulation (EU) 2017/625 empowers the Commission to adopt many implementing and delegated acts.

2. LEGAL BASIS

Article 144(2) of Regulation (EU) 2017/625 empowers the Commission to adopt delegated acts referred to in the provisions set out in that article (see section 3, below). Pursuant to Article 144(2) of Regulation (EU) 2017/625, the power to adopt delegated acts concerning the matters listed therein is conferred on the Commission for a period of five years from 28 April 2017. The Commission is required to draw up a report to the European Parliament and the Council in respect of that delegation of power not later than nine months before the end of the five-year period. The delegation of power is to be tacitly extended for periods of identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. EXERCISE OF THE DELEGATION

According to Article 144(2) of Regulation (EU) 2017/625, the Commission is empowered to adopt the delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) of that Regulation.

3.1. EMPOWERMENTS USED DURING THE REPORTING PERIOD

During the reporting period⁵, the Commission exercised its delegated powers, by adopting the following delegated acts⁶:

- Commission Delegated Regulation (EU) 2018/631 of 7 February 2018 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by establishing European Union reference laboratories for pests of plants⁷. This act entered into force on 15 May 2018 and entered into application on the same date.
- Commission Delegated Regulation (EU) 2019/478 of 14 January 2019 amending Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the

⁵ The cut-off date for the inclusion in this section of delegated acts adopted during the reporting period is 15 June 2021.

⁶ The delegated acts are listed in the chronological order of their date of adoption.

⁷ OJ L 105, 25.4.2018, p. 1.

categories of consignments to be subjected to official controls at border control posts⁸. This act entered into force on 14 April 2019 and it entered into application on 14 December 2019.

- Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council⁹. This act entered into force on 6 June 2019 and it entered into application on 14 December 2019.
- Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption¹⁰. This act entered into force on 6 June 2019 and it entered into application on 14 December 2019. However, the requirements laid down in Article 12, and Article (14)(1) and (2) entered into application on 21 April 2021.
- Commission Delegated Regulation (EU) 2019/1012 of 12 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by derogating from the rules on the designation of control points and from the minimum requirements for border control posts¹¹. This act entered into force on 11 July 2019 and it entered into application on 14 December 2019.
- Commission Delegated Regulation (EU) 2019/1602 of 23 April 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council concerning the Common Health Entry Document accompanying consignments of animals and goods to their destination¹². This act entered into force on 20 October 2019 and it entered into application on 14 December 2019. However, certain provisions enter into application in each Member State from the date on which the customs electronic data-processing techniques referred to in Article 6(1) of Regulation (EU) No 952/2013¹³ become operational in that Member State or from 1 March 2023, whichever is the earlier.
- Commission Delegated Regulation (EU) 2019/1666 of 24 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards conditions for monitoring the transport and arrival of consignments of certain goods from the border control post of arrival to the establishment at the place of destination in the Union¹⁴. This act entered into force on 24 October 2019 and it entered into application on 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2074 of 23 September 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules on specific official controls on consignments of certain animals and goods originating

⁸ OJ L 82, 25.3.2019, p. 4.

⁹ OJ L 131, 17.5.2019, p. 1. ¹⁰ OJ L 131, 17.5.2019, p. 18.

¹¹ OJ L 165, 21.6.2019, p. 4.

¹² OJ L 250, 30.9.2019, p. 6.

¹³ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast) (OJ L 269, 10.10.2013, p. 1).

¹⁴ OJ L 255, 4.10.2019, p. 1.

from, and returning to the Union following a refusal of entry by a third country¹⁵. This act entered into force on 26 December 2019 and applied from 14 December 2019.

- Commission Delegated Regulation (EU) 2019/2122 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No 142/2011¹⁶. This Regulation entered into force on 1 January 2020 and applied from 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2123 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts¹⁷. This act entered into force on 1 January 2020 and applied from 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2124 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for official controls of consignments of animals and goods in transit, transhipment and onward transportation through the Union, and amending Commission Regulations (EC) No 798/2008, (EC) No 1251/2008, (EC) No 119/2009, (EU) No 206/2010, (EU) No 605/2010, (EU) No 142/2011, (EU) No 28/2012, Commission Implementing Regulation (EU) 2016/759 and Commission Decision 2007/777/EC¹⁸. This act entered into force on 1 January 2020 and applied from 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2125 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules concerning the performance of specific official controls of wood packaging material, notification of certain consignments and measures to be taken in cases of noncompliance¹⁹. This act entered into force on 1 January 2020 and applied from 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2126 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for specific official controls for certain categories of animals and goods, measures to be taken following the performance of such controls and certain categories of animals and goods exempted from official controls at border control posts²⁰. This act entered into force on 1 January 2020 and applied from 14 December 2019.
- Commission Delegated Regulation (EU) 2019/2127 of 10 October 2019 amending Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the date of application of certain provisions of Council Directives 91/496/EEC, 97/78/EC and

¹⁵ OJ L 316, 6.12.2019, p. 6.

¹⁶ OJ L 321, 12.12.2019, p. 45.

¹⁷ OJ L 321, 12.12.2019, p. 64.

¹⁸ OJ L 321, 12.12.2019, p. 73.

¹⁹ OJ L 321, 12.12.2019, p. 99.

²⁰ OJ L 321, 12.12.2019, p. 104.

 $2000/29/EC^{21}$. This act entered into force on 1 January 2020 and applied from 14 December 2019.

- Commission Delegated Regulation (EU) 2020/2190 of 29 October 2020 amending Delegated Regulation (EU) 2019/2124 as regards official controls at the border control post where goods leave the Union and certain provisions on transit and transhipment²². This act entered into force on 12 January 2021 and applied from 1 January 2021.
- Commission Delegated Regulation (EU) 2021/573 of 1 February 2021 amending Delegated Regulation (EU) 2019/625 as regards import conditions for live snails, for composite products and for casings placed on the market for human consumption²³. This act entered into force on 28 April 2021 and applied from the same date. However, certain provisions applied from 21 April 2021.
- Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC²⁴. This act entered into force on 9 May 2021 and applied from 21 April 2021.
- Commission Delegated Regulation (EU) 2021/... supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to the cases and conditions under which competent authorities may designate official laboratories which do not fulfil the conditions in relation to all the methods they use for official controls or other official activities (C(2021) 3285). This act was adopted on 17 May 2021.

The Commission has notified each of the aforementioned delegated acts to the European Parliament and to the Council, in accordance with Article 144(5) of Regulation (EU) 2017/625. Neither the European Parliament nor the Council extended the objection period referred to in Article 144(6) of Regulation (EU) 2017/625 in relation to any of these acts. Similarly, neither the European Parliament nor the Council objected to any of these acts in accordance with Article 144(6) of Regulation (EU) 2017/625²⁵.

The Commission has so far used 17 out of the 26 empowerments in Article 144(2) of Regulation (EU) 2017/625 and which are therefore in the scope of this report. Out of the 17 empowerments used, 4 have been partially used. Some of these delegated powers were bundled in a single delegated act where the rules are substantively linked, in accordance with Section V, point (31) of the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making²⁶.

²¹ OJ L 321, 12.12.2019, p. 111.

²² OJ L 434, 23.12.2020, p. 3.

²³ OJ L 120, 8.4.2021, p. 6.

²⁴ OJ L 132, 19.4.2021, p. 17.

 $^{^{25}}$ In relation to Commission Delegated Regulation (EU) 2021/... supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to the cases and conditions under which competent authorities may designate official laboratories which do not fulfil the conditions in relation to all the methods they use for official controls or other official activities (C(2021) 3285), the objection period referred to in Article 144(6) of Regulation (EU) 2017/625, expires on 18 July 2021.

²⁶ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making of 13 April 2016 (OJ L 123, 12.5.2016, p. 1).

3.2. EMPOWERMENTS NOT USED DURING THE REPORTING PERIOD

Certain empowerments of Regulation (EU) 2017/625 have not been used during the reporting period for the reasons explained below.

• Article 21(8)

The Commission is continuously assessing the need to lay down specific rules on official controls, in addition to the general requirements in Regulation (EU) 2017/625, to address noncompliance and possible divergent enforcement practices across Member States. In particular, the Commission has identified the need, further emphasised by recent incidents in the Mediterranean Sea, to use Article 21(8), points (a) and (c), to lay down specific requirements for the performance of official controls to respond to risks associated with livestock vessels, as well as rules for the verification of animal welfare requirements at exit points. This act is expected to be adopted in 2022. In addition, in the framework of the revision of the EU animal welfare legislation by 2023 under the Farm to Fork Strategy²⁷, the possible future use of Article 21(8) is currently being considered. For instance, if necessary, new rules on the welfare of cats and dogs during transport could be complemented later by specific official controls requirements, in accordance with Article 21(8), point (a). Also, specific criteria and conditions for the activation of the mechanism of administrative assistance provided for in Articles 102 to 108 of Regulation (EU) 2017/625 could be established in accordance with Article 21(8), point (d), to help address for example the problem of illegal puppy trade. However, no such decision on the further use of the empowerment in Article 21(8) has yet been taken

Similarly, Article 154(3) has not been used. However, this empowerment is linked to the adoption of delegated and implementing acts provided for in Article 21.

• Article 48, points (a) and (g)

As regards Article 48, point (a), Commission Regulation (EU) No $142/2011^{28}$ already establishes such rules as regards certain samples and items which qualify as animal by-products and derived products not intended for human consumption, as provided for in Article 16(1), points (e) and (f) of Council Directive $97/78/EC^{29}$, now replaced by Article 48, points (a) and (b) of Regulation (EU) $2017/625^{30}$. However, this empowerment and the empowerment of point (g), are still needed to lay down rules in addition to those laid down in Delegated Regulations (EU) 2019/2122 and (EU) 2019/2126.

• Article 51(1), point (e) and Article 51(2)

When adopting Delegated Regulation (EU) 2019/2124, which lays down rules referred to in Article 51(1) points (b), (c) and (d) of Regulation (EU) 2017/625, neither the Commission, nor the experts from Member States consulted in the framework of Commission Expert Group

²⁷ COM/2020/381 final.

²⁸ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 054 26.2.2011, p. 1).

²⁹ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

³⁰ Cf. Annex V, point 4 of Regulation (EU) 2017/625.

"official controls", saw a need to provide for derogations from the said rules. In addition, Delegated Regulation (EU) 2019/2123 lays down rules on the cases where and the conditions under which competent authorities may perform documentary checks at distance from a border control post on consignments of plants, plant products, and other objects referred to in Article 47(1), point (c). The Commission is continuously assessing the need to establish such derogations, in light of the experience gained in the implementation of Delegated Regulations (EU) 2019/2124 and (EU) 2019/2123.

• Article 53(1), points (b) and (c) and Article 53(1), point (d)(i), (iii) and (iv)

The Commission is continuously assessing the need to establish such rules, in light of the experience gained in the implementation of Regulation (EU) 2017/625. As regards the empowerments of Article 53(1), point (d)(i), (iii) and (iv), such assessment also takes into account whether such goods are exempted or not from official controls at border control posts, as well as responsibilities in relation to official controls already conferred on customs authorities, by other Union acts, such as Regulation (EU) 952/2013³¹. Moreover, such empowerments could be used in the future, for example as part of the development of a specific policy, including rules on official controls, on internet sales.

• Article 77(1), points (e), (f), (g) and (i)

The Commission is continuously assessing the need to establish the specific rules in accordance with these empowerments, in particular in light of the experience gained in the implementation of the general rules on official controls on animals and goods entering the Union from third countries established in Regulation (EU) 2017/625 and related acts. In this regard, in relation to Article 77(1), point (e), such assessment takes into account the applicable animal health requirements, as well as certain exemptions from official controls at border control posts referred to in Annex III, point 3, of Delegated Regulation (EU) 2019/2122 in relation to petfood required for health-related reasons. Article 77(1), point (f) could be used in the future, as part of the development of a specific policy, including rules on official controls, on internet sales. In relation to plant products referred to in Article 77(1), point (g), such assessment takes into account the fact that hay and straw are currently subject to official controls at border control posts by virtue of Article 47(1)(b), following the entry into force of Delegated Regulation (EU) 2019/478. As regards the empowerment of Article 77(1), point (i), the Commission will assess the need to act in this respect in the light of experience on the practical application of Regulation (EU) 2017/625.

• Article 99(2)

The rules referred to in this empowerment should be limited to situations of new or emerging risks, new or emerging animal diseases or pests of plants or where new legal requirements so warrant. However, such situations or requirements have not yet occurred but may arise in the future.

• Article 100(6) and 101(2)

Pursuant to Articles 100(6) and 101(2), the rules referred to in those empowerments shall be limited to ensuring coherence with any additional responsibilities and tasks adopted in

³¹ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast)(OJ L 269, 10.10.2013, p. 1).

accordance with Article 99(2). The need may thus arise in the future to adopt such rules to ensure coherence with any additional responsibilities and tasks established in accordance with Article 99(2).

• Article 142(1)

In this respect, there is currently no change in the rules referred to in Article 1(2) of Regulation (EU) 2017/625 and no technological and scientific developments reported regarding the areas covered by Annexes II and III to that Regulation. However, future changes and developments may require proceeding with the preparation of a delegated act pursuant to Article 142(1).

• Article 142(2)

In this respect, there is currently no amendment by the CEN of the standards to which this empowerment refers. However, future amendments by the CEN may require proceeding with the preparation of a delegated act pursuant to Article 142(2).

• Article 150(3)

The Commission is currently preparing two implementing acts based on Article 19(3), points (a) and (b) of Regulation (EU) 2017/625, to apply from 15 December 2022. At the same time, it is not excluded that those acts are adopted after 28 April 2022 and that they are amended to apply before 14 December 2022.

• Article 155(3)

The Commission is currently preparing a delegated act, in accordance with Article 19(2) of Regulation (EU) 2017/625 and an implementing act pursuant to Article 19(3)(b) of that Regulation. These acts will reinstate the provisions in Article 27(1) and Article 30 of Regulation (EC) No $396/2005^{32}$. Consequently, both these acts are to apply from 15 December 2022. At the same time, it is not excluded that those acts are adopted after 28 April 2022 and that they are amended to apply before 14 December 2022.

CONCLUSION

The Commission sees the need for a tacit extension of the delegation of power provided for in Article 144(2) of Regulation (EU) 2017/625 for a period of five years, in accordance with that Article. This is due to the fact that the need to develop rules based on the empowerments granted by Article 144(2) of Regulation (EU) 2017/625 will remain in the future. This will be particularly important to provide the necessary flexibility in the new legal framework, to complement and adjust it regularly to the latest scientific standards and to allow the Commission to act in the areas where it did not act to this moment, but may need to do so in the future.

With this report, the Commission complies with the reporting requirements established in Article 144(2) of Regulation (EU) 2017/625.

³² Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

The Commission invites the European Parliament and the Council to take note of this report.