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Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, within the Sanitary and Phytosanitary Sub-Committee established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other, as regards the modification of Annex XI-B to that Agreement

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Reasons for and objectives of the proposal

The proposal concerns the decision establishing the position to be taken on the Union's behalf within the Sanitary and Phytosanitary Sub-Committee ('the SPS Sub-Committee') established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part¹ ('the Agreement') on the modification of Annex XI-B to the Agreement.

The Agreement entered into force on 1 July 2016. Its Article 55(1) establishes that Georgia is to gradually approximate its sanitary and phytosanitary, animal welfare and other legislative measures to those of the Union. Annex XI-B to the Agreement lists the relevant Union legislation to which Georgia is to align. The currently applicable Annex XI-B was adopted on 7 March 2017 by Decision No 1/2017 of the SPS Sub-Committee².

Since then, a number of acts present on the list has been repealed by the Union and replaced by newly established acts, while other acts have exhausted their legal effect. In addition, parties to the Agreement consider that a limited number of acts are not applicable to Georgia and they should not have been added in the first place. The proposed modification of Annex XI-B has the purpose of adding a number of acts that replace the acts listed therein that have been repealed and deleting a number of acts whose legal effect has been exhausted or that are considered no longer relevant to Georgia.

- Consistency with existing policy provisions in the policy area

This proposal implements the Union's common commercial policy towards Georgia, an Eastern Neighbourhood Partner country, on the basis of the provisions of the Agreement and in particular its objective to create a free-trade area. This proposal implements the Agreement's provisions that aim to boost agricultural trade and in particular improve the agricultural export capacity of Georgia, on the basis of the Union *acquis*.

- Consistency with other Union policies

This proposal is consistent with and contributes to the implementation of other external policies of the Union, notably the European Neighbourhood Policy and the development cooperation policy in relation to Georgia.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Procedural legal basis

2.1.1. Principles

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for the Council, on a proposal from the Commission, to adopt decisions establishing 'the positions to be adopted on the Union's behalf in a body set up by an

¹ OJ L 261, 30.08.2014, p. 4.

² OJ L 98, 11.04.2017, p. 22.

agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement.’

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement³.

The concept of ‘acts having legal effects’ includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are ‘capable of decisively influencing the content of the legislation adopted by the EU legislature’⁴.

2.1.2. Application to the present case

The SPS Sub-Committee is a body set up by an agreement, namely the Agreement, signed on 16 of June 2014 and entered into force on 1 July 2016.

The Union, together with its Member States, and the European Atomic Energy Community are Parties to the Agreement.

The envisaged act, which the SPS Sub-Committee is called upon to adopt, constitutes an act having legal effects. The envisaged act will be binding on the Parties under international law in accordance with Articles 408 and 409 of the Agreement.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

2.2. Substantive legal basis

2.2.1. Principles

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf. If the envisaged act pursues two aims or has two components and if one of those aims or components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(9) TFEU must be founded on a single substantive legal basis, namely that required by the main or predominant aim or component.

With regard to an envisaged act that simultaneously pursues a number of objectives, or that has several components, which are inseparably linked without one being incidental to the other, the substantive legal basis of a decision under Article 218(9) TFEU will have to include, exceptionally, the various corresponding legal bases.

2.2.2. Application to the present case

The envisaged act pursues the addition of a number of acts that replace the acts listed in Annex XI-B that have been repealed and the deletion of a number of acts whose legal effect has been exhausted or that are considered no longer relevant to Georgia. It has components falling within the areas of the common commercial policy.

³ Judgment of the Court of Justice of 7 October 2014, *Germany v Council*, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

⁴ Id. at paragraphs 61 to 64.

Therefore, the substantive legal basis of the proposed decision is Article 207(4) TFEU.

2.3. Conclusion

The legal bases of the proposed decision should be Article 207(4) in conjunction with Article 218(9) TFEU.

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

The common commercial policy, in accordance with Article 3 of the TFEU, is defined as an exclusive Union competence. Therefore, the subsidiarity principle does not apply.

- **Proportionality**

This proposal is necessary in order to implement the Union's international commitments set out in the Agreement with Georgia.

- **Choice of the instrument**

This proposal is in accordance with Article 218(9) of the TFEU, which envisages the adoption by the Council, on a proposal from the Commission, of a decision establishing the position to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects.

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

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

Not applicable.

- **Stakeholder consultations**

Georgia prepared the list of Union *acquis* to which it is to approximate its domestic legislation, in line with appropriate domestic procedures. EU stakeholder consultations are not applicable to this proposal.

- **Collection and use of expertise**

The Union made its expertise in sanitary, phytosanitary and animal welfare matters available to the authorities of Georgia for the purpose of preparing the list of the Union *acquis* intended for approximation by that partner country.

- **Impact assessment**

Not applicable.

- **Regulatory fitness and simplification**

Not applicable.

- **Fundamental rights**

The proposal does not have consequences for the protection of fundamental rights in the Union.

4. BUDGETARY IMPLICATIONS

Not applicable.

5. OTHER ELEMENTS

• **Implementation plans and monitoring, evaluation and reporting arrangements**

The implementation of the Agreement is reviewed regularly by the EU-Georgia Association Council and its subordinate bodies established by the Agreement. The SPS Sub-committee oversees the implementation of Chapter 4 on sanitary and phytosanitary measures of the Agreement and its Annex XI-B.

• **Explanatory documents (for directives)**

Not applicable.

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

The proposal aims to adopt a Union position in relation to the modification of Annex XI-B to the Agreement. In accordance with Article 55(1) of the Agreement, Annex XI-B lists the Union *acquis* to which Georgia is to approximate its legislation in the area of sanitary, phytosanitary and animal welfare measures, for the purpose of achieving a status of equivalence for a product or a group of products, as provided for in Article 57 of the Agreement.

Georgia prepared such a list of the Union *acquis* in accordance with its domestic procedures, submitted the proposal to the Commission in February 2015 and finalised it, in consultation with the Commission, in December 2015. The Sub-Committee modified Annex XI-B by Decision No 1/2017⁵. Since then, a number of acts present in Annex XI-B were repealed by the Union and replaced by newly established acts, while other acts had exhausted their legal effect. In addition, the parties consider a limited number of acts not applicable to Georgia.

The proposal therefore aims to update Annex XI-B by adding a number of acts that replace the measures listed therein that have been repealed and by deleting a number of acts that have exhausted their legal effect or have been considered no longer applicable to Georgia since the adoption of Annex XI-B by Decision No 1/2017 of the SPS Sub-Committee.

The SPS Sub-Committee is empowered to take a decision on the modification of Annex XI-B in accordance with Article 65 of the Agreement. In line with the provisions of that article, the SPS Sub-Committee monitors the implementation of Chapter 4 (Sanitary and Phytosanitary Measures) of Title IV (Trade and trade-related matters) of the Agreement and takes decisions, as appropriate, on the modification of Annexes IV-XII to the Agreement.

The following sections set out the modifications to be made to Annex XI-B.

1. ACTS TO BE REPLACED

Repealing act	Repealed act(s)
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	Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC.
	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions

⁵ OJ L 98, 11.4.2017, p. 22.

the area of animal health ('Animal Health Law').	89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC.
	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever.
	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease.
	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs.
	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC.
	Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals.
	Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.
	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine.
	Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue.
	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.
	Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC.
	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease.
	Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae.
	Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae.
Council Directive 92/35/EEC of 29 April 1992 laying down	

	control rules and measures to combat African horse sickness.
	Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species.
Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases.	Commission Decision 2010/367/EU of 25 June 2010 on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds.
	Commission Decision 2002/106/EC of 1 February 2002 approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever.
	Commission Decision 2003/422/EC of 26 May 2003 approving an African swine fever diagnostic manual.
	Commission Decision 2006/437/EC of 4 August 2006 approving a Diagnostic Manual for avian influenza as provided for in Council Directive 2005/94/EC.
	Commission Decision 2001/183/EC of 22 February 2001 laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases and repealing Decision 92/532/EEC.
	Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue.
	Commission Decision 2000/428/EC of 4 July 2000 establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease.
Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and	Council Directive 98/57/EC of 20 July 1998 on the control of <i>Ralstonia solanacearum</i> (Smith) <i>Yabuuchi et al.</i>
	Council Directive 2006/91/EC of 7 November 2006 on control of San José Scale.
	Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers.
	Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community.
	Council Directive 2007/33/EC of 11 June 2007 on the control of potato cyst nematodes and repealing Directive 69/465/EEC.
	Council Directive 93/85/EC of 4 October 1993 on control of Potato Ring Rot.

2007/33/EC.	
Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation').	Council Directive 90/427/EEC of 26 June 1990 on the zootechnical and genealogical conditions governing intra-Community trade in equidae.
	Council Directive 2009/157/EC of 30 November 2009 on pure-bred breeding animals of the bovine species.
	Council Directive 87/328/EEC of 18 June 1987 on the acceptance for breeding purposes of pure-bred breeding animals of the bovine species.
	Council Directive 94/28/EC of 23 June 1994 laying down the principles relating to the zootechnical and genealogical conditions applicable to imports from third countries of animals, their semen, ova and embryos, and amending Directive 77/504/EEC on pure-bred breeding animals of the bovine species.
	Council Directive 88/661/EEC of 19 December 1988 on the zoo technical standards applicable to breeding animals of the porcine species.
Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases.	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC.
	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease.
	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever.
	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC.
Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin.	Commission Implementing Regulation (EU) No 139/2013 of 7 January 2013 laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof.
	Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption.
	Commission Regulation (EU) No 28/2012 of 11 January 2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products and amending Decision 2007/275/EC and Regulation (EC) No 1162/2009.
Regulation (EU) 2017/625 of the European	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls

<p>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, OCR).</p>	<p>performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.</p>
	<p>Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.</p>
	<p>Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.</p>
<p>Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation).</p>	<p>Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed.</p>
	<p>Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger.</p>

Commission Implementing Regulation (EU) 2022/160 of 4 February 2022 laying down uniform minimum frequencies of certain official controls to verify compliance with Union animal health requirements in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and repealing Regulations (EC) No 1082/2003 and (EC) No 1505/2006.	Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals.
	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals.
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.	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.
	Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.
Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections.	Commission Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC.
	Commission Directive 93/64/EEC of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/34/EEC on the marketing of fruit plant propagating material and fruit plants intended for fruit production.
Commission Implementing Regulation (EU) 2020/1201 of 14 August 2020 as regards measures to prevent the introduction into and the spread within the Union of <i>Xylella fastidiosa</i> .	Commission Implementing Decision 2014/87/EU of 13 February 2014 as regards measures to prevent the spread within the Union of <i>Xylella fastidiosa</i> (Well and Raju).
	Commission Implementing Decision 2014/497/EU of 23 July 2014 as regards measures to prevent the introduction into and the spread within the Union of <i>Xylella fastidiosa</i> .
Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down	Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for <i>Trichinella</i> in meat.

specific rules on official controls for Trichinella in meat.	
Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feeding stuffs in the Community.
Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs.	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards ear tags, passports and holding registers.
Commission Implementing Regulation (EU) 2021/620 of 15 April 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of the disease-free and non-vaccination status of certain Member States or zones or compartments thereof as regards certain listed diseases and the approval of eradication programmes for those listed diseases.	Commission Regulation (EC) No 616/2009 of 13 July 2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments.
Commission Implementing Regulation	Commission Regulation (EC) No 1251/2008 of 12 December 2008 implementing Council Directive

<p>(EU) 2020/2236 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008.</p>	<p>2006/88/EC as regards conditions and certification requirements for the placing on the market and the import into the Community of aquaculture animals and products thereof and laying down a list of vector species.</p>
<p>Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC.</p>	<p>Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feeding stuffs for particular nutritional purposes.</p>
<p>Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae.</p>	<p>Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae.</p>
<p>Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed.</p>	<p>Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management.</p>
<p>Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying</p>	<p>Commission Regulation (EU) No 211/2013 of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts.</p>

<p>down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC.</p>	
<p>Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council.</p>	<p>Commission Implementing Decision 2012/137/EU of 1 March 2012 on imports into the Union of semen of domestic animals of the porcine species.</p>
<p>Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on</p>	<p>Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results.</p>

<p>the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC.</p>	
<p>Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660.</p>	<p>Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC.</p>
<p>Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.</p>	<p>Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.</p>
<p>Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food</p>	<p>Commission Decision 2005/34/EC of 11 January 2005 laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries.</p>

of animal origin and repealing Decision 2005/34/EC.	
Commission Recommendation 2013/711/EU of 3 December 2013 on the reduction of the presence of dioxins, furans and PCBs in feed and food.	Commission Recommendation 2011/516/EU of 23 August 2011 on the reduction of the presence of ioxins, furans and PCBs in feed and food.
Commission Regulation (EU) 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014.	Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012.
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 posts.	Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks.
Commission Implementing Regulation (EU) 2019/1014 of 12 June 2019 to lay down detailed rules on minimum requirements for border control posts, including inspection centres, and for the format, categories and abbreviations to use for listing border control posts and control points.	Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries.

<p>Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.</p>	<p>Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.</p>
<p>Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012.</p>	<p>Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.</p>
<p>Commission Implementing Directive 2014/97/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards the registration of suppliers and of varieties and the common list of varieties.</p>	<p>Commission Directive 93/79/EEC of 21 September 1993 setting out additional implementing provisions for lists of varieties of fruit plant propagating material and fruit plants, as kept by suppliers under Council Directive 92/34/EEC.</p>
<p>Commission Delegated Regulation (EU) 2019/829 of 14 March 2019 supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council on protective measures against pests of plants, authorising Member States to provide for temporary derogations in view of</p>	<p>Commission Directive 2008/61/EC of 17 June 2008 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 2000/29/EC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections.</p>

official testing, scientific or educational purposes, trials, varietal selections, or breeding.	
Commission Delegated Regulation (EU) 2022/671 of 4 February 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards specific rules on official controls performed by the competent authorities on animals, products of animal origin and germinal products, follow-up action to be taken by the competent authority in case of non-compliance with identification and registration rules for bovine, ovine and caprine animals or of non-compliance during transit through the Union of certain bovine animals, and repealing Commission Regulation (EC) No 494/98.	Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals.
Commission Implementing Regulation (EU) 2021/2285 of 14 December 2021 amending Implementing Regulation (EU) 2019/2072 as regards the listing of pests, prohibitions and requirements for the introduction into, and movement within, the Union of plants, plant products and other objects, and repealing Decisions 98/109/EC and 2002/757/EC and Implementing Regulations (EU) 2020/885 and (EU) 2020/1292.	Commission Decision 2002/757/EC of 19 September 2002 on provisional emergency phytosanitary measures to prevent the introduction into and the spread within the Community of <i>Phytophthora ramorum</i> Werres, De Cock & Man in 't Veld sp. Nov.
Commission	Commission Regulation (EC) No 637/2009 of 22 July 2009

<p>Implementing Regulation (EU) 2021/384 of 3 March 2021 on the suitability of the denominations of varieties of agricultural plant species and vegetable species and repealing Regulation (EC) No 637/2009.</p>	<p>establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species.</p>
<p>Commission Implementing Regulation (EU) 2020/1770 of 26 November 2020 on types and species of plants for planting not exempted from the traceability code requirement for plant passports under Regulation (EU) 2016/2031 of the European Parliament and of the Council and repealing Commission Directive 92/105/EEC.</p>	<p>Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement.</p>

2. ACTS NO LONGER IN FORCE TO BE REMOVED

- Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC.
- Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules.
- Commission Implementing Regulation (EU) No 750/2014 of 10 July 2014 on protection measures in relation to porcine epidemic diarrhoea as regards the animal health requirements for the introduction into the Union of porcine animals.
- Commission Recommendation 2004/704/EC of 11 October 2004 on the monitoring of background levels of dioxins and dioxin-like PCBs in feeding stuffs.
- Commission Decision 84/247/EEC of 27 April 1984 laying down the criteria for the recognition of breeders organizations and associations which maintain or establish herd-books for pure-bred breeding animals of the bovine species.

- Commission Decision 94/360/EC of 20 May 1994 on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries, under Council Directive 90/675/EEC.
- Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council.
- Commission Implementing Decision 2012/756/EU of 5 December 2012 as regards measures to prevent the introduction into and the spread within the Union of *Pseudomonas syringae* pv. *actinidiae* Takikawa, Serizawa, Ichikawa, Tsuyumu & Goto.
- Commission Decision 2007/365/EC of 25 May 2007 on emergency measures to prevent the introduction into and the spread within the Community of *Rhynchophorus ferrugineus* (Olivier).
- Commission Implementing Decision 2012/340/EU of 25 June 2012 on the organisation of a temporary experiment under Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards field inspection under official supervision for basic seed and bred seed of generations prior to basic seed.
- Commission Decision 2009/109/EC of 9 February 2009 on the organization of a temporary experiment providing for certain derogations for the marketing of seed mixtures intended for use as fodder plants pursuant to Council Directive 66/401/EEC to determine whether certain species not listed in Council Directives 66/401/EEC, 66/402/EEC, 2002/55/EC or 2002/57/EC fulfil the requirements for being included in Article 2 (1) (A) of Directive 66/401/EEC.
- Commission Decision 2007/433/EC of 18 June 2007 on provisional emergency measures to prevent the introduction into and the spread within the Community of *Gibberella circinata* Nirenberg & O'Donnell.
- Commission Decision 90/639/EEC of 12 November 1990 determining the names to be borne by the varieties derived from the varieties of vegetable species listed in Decision 89/7/EEC.
- Commission Decision 2004/200/EC of 27 February 2004 on measures to prevent the introduction into and the spread within the Community of Pepino mosaic virus.
- Commission Decision 2006/464/EC of 27 June 2006 on provisional emergency measures to prevent the introduction into and the spread within the Community of *Dryocosmus kuriphilus* Yasumatsu.
- Commission Decision 2007/410/EC of 12 June 2007 on measures to prevent the introduction into and the spread within the Community of Potato spindle tuber viroid.

3. ACTS NOT APPLICABLE TO GEORGIA TO BE REMOVED

N/A act	Motivation
Commission Regulation (EC) No 1662/95 of 7 July 1995 laying	Relevant to EU Member States only.

<p>down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use.</p>	
<p>Commission Delegated Regulation (EU) 2018/772 of 21 November 2017 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to preventive health measures for the control of <i>Echinococcus multilocularis</i> infection in dogs <i>repealing</i> Commission Delegated Regulation (EU) No 1152/2011 of 14 July 2011 supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of <i>Echinococcus multilocularis</i> infection in dogs.</p>	<p>Relevant to certain EU Member States only as specified in Commission Delegated Regulation (EU) 2018/772.</p>
<p>Commission Decision 2007/843/EC of 11 December 2007 concerning approval of Salmonella control programmes in breeding flocks of <i>Gallus gallus</i> in certain third countries in accordance with Regulation (EC) No 2160/2003 of the European Parliament and of the Council and amending Decision 2006/696/EC, as regards certain public health requirements at import of poultry and hatching eggs.</p>	<p>Decision establishes Salmonella control programmes in breeding flocks of <i>Gallus gallus</i> in certain third countries. Not relevant to Georgia.</p>
<p>Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives.</p>	<p>Regulates issues related to the Community Reference Laboratory, hence not relevant to Georgia.</p>
<p>Commission Implementing Regulation (EU) 2019/723 of 2 May 2019 laying down rules for the application of Regulation (EU)</p>	<p>Relevant to EU Member States only.</p>

<p>2017/625 of the European Parliament and of the Council as regards the standard model form to be used in the annual reports submitted by Member States <i>repealing</i> Commission Decision 2006/778/EC of 14 November 2006 concerning minimum requirements for the collection of information during the inspections of production sites on which certain animals are kept for farming purposes.</p>	
<p>Commission Implementing Regulation (EU) No 489/2012 of 8 June 2012 establishing implementing rules for the application of Article 16 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.</p>	<p>Relevant to EU Member States only.</p>
<p>Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.</p>	<p>Regulation 1333/2008 of European Parliament and of the Council was approximated in 2021 by Georgia and it does not foresee Georgian authorisation of other food additives that are not included in the lists. The Georgian government deemed not necessary to create an internal <i>ad hoc</i> authorisation process because it will automatically include those additives added to the lists by the EU in light of a dynamic approximation.</p>
<p>Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.</p>	
<p>Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.</p>	<p>Georgian legislation prohibits introducing into the Georgian territory and placing on the market living genetically modified organisms (GMOs) for further</p>

<p>and coordination of information concerning coexistence of genetically modified, conventional and organic crops.</p>	<p>cultivation, hence not relevant to Georgia.</p>
<p>Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council.</p>	
<p>Commission Recommendation 2010/C 200/01 of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops.</p>	
<p>Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products.</p>	
<p>Council Decision 2003/17/EC of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries.</p>	<p>Decision refers to the equivalence of field inspections carried out in specified third countries on seed-producing crops and on the equivalence of seed produced in specified third countries. Not relevant to Georgia.</p>

Proposal for a

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, within the Sanitary and Phytosanitary Sub-Committee established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other, as regards the modification of Annex XI-B to that Agreement

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first paragraph of Article 207(4), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part ('the Agreement') was concluded by Council Decision 2014/494/EU⁶ and entered into force on 1 July 2016.
- (2) Pursuant to Article 65 of the Agreement, the Sanitary and Phytosanitary Sub-Committee ('the SPS Sub-Committee') may adopt decisions on any matter relating to Chapter 4 (Sanitary and phytosanitary measures) of Title IV (Trade and Trade-related Matters), including its implementation, and is empowered to review and modify Annex XI-B to the Agreement.
- (3) The SPS Sub-Committee during its [...] meeting on [...] is to adopt a decision on the modification of Annex XI-B to the Agreement, which contains an approximation list of Union acts in the sanitary and phytosanitary as well as animal welfare areas to which Georgia is to gradually approximate its legislation pursuant to Article 55(1) of the Agreement.
- (4) Decision No 1/2017⁷ of the EU-Georgia Sanitary and Phytosanitary Sub-Committee of 7 March 2017 finalised the approximation list set out in Annex XI-B to the Agreement.
- (5) At seven yearly meetings of the SPS Sub-Committee, Georgia has informed the Commission on the progress made regarding the approximation to Union legislation. Similarly, Georgia has informed the Commission of what acts should be removed from Annex XI-B on the consideration that these acts are not relevant for Georgia given that they are only applicable to EU Member States.
- (6) Several Union acts listed in Annex XI-B to the Agreement have been repealed by the EU and a subset of these have been replaced by newly established acts since the

⁶ OJ L 261, 30.8.2014, p. 1.

⁷ OJ L 98, 11.04.2017, p. 22.

adoption of Decision No 1/2017 of the SPS Sub-Committee of 7 March 2017. Other acts have exhausted their legal effect in the meantime.

- (7) It is thus necessary to modify Annex XI-B to the Agreement in order to reflect the evolution of the Union *acquis* listed in that Annex and to replace it.
- (8) It is therefore appropriate to establish the position to be adopted on the Union's behalf within the SPS Sub-Committee with regard to the modification of Annex XI-B to the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf in the [...] meeting of the Sanitary and Phytosanitary Sub-Committee established by Article 65 of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part, as regards the modification of Annex XI-B to the Agreement, shall be in accordance with the draft decision of the Sanitary and Phytosanitary Sub-Committee attached as Annex to this Decision.

Minor technical changes to the wording of the draft decision attached as Annex to this Decision, which do not jeopardise the attainment of the objective of said modifications, may be agreed by the representatives of the Union within the Sanitary and Phytosanitary Sub-Committee without further decision of the Council.

Article 2

This Decision is addressed to the Commission.

Done at Brussels,

*For the Council
The President*