Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/627

of 15 March 2019

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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) 1107/2009, (EU) 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)[(1)], and in particular Article 18(8) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption. In addition, it repeals Regulation (EC) No 854/2004 of the European Parliament and of the Council[(2)] with effect from 14 December 2019. That Regulation currently lays down specific rules for official controls on products of animal origin intended for human consumption, including requirements on uniform practical arrangements for the performance of the controls.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/627. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(2) The rules laid down in this Regulation should ensure a continuation of the requirements to ensure the verification of food business operators' compliance with the rules for the safe handling of products of animal origin, in particular as laid down in:

— Council Directive 96/23/EC[(3)] as regards measures to monitor certain substances and residues;

— Regulation (EC) No 999/2001 of the European Parliament and of the Council[(4)] as regards controls on transmissible spongiform encephalopathies;

— Council Directive 2002/99/EC[(5)] as regards animal health rules on products of animal origin;

— Regulation (EC) No 178/2002 of the European Parliament and of the Council[(6)] as regards the general principles and requirements of food law;

— Directive 2003/99/EC of the European Parliament and of the Council[(7)] as regards the monitoring of zoonoses and zoonotic agents;

— Commission Decision 2003/467/EC[(8)] as regards control of tuberculosis, brucellosis and enzootic-bovine-leukosis;

— Regulation (EC) No 2160/2003 of the European Parliament and of the Council[(9)] as regards Salmonella controls;

— Regulation (EC) No 852/2004 of the European Parliament and of the Council[(10)] as regards the hygiene of foodstuffs;

— Regulation (EC) No 853/2004 of the European Parliament and of the Council[(11)] as regards the specific hygiene rules for food of animal origin;

— Council Regulation (EC) No 1/2005[(12)] as regards the protection of animals during transport and related operations;

— Commission Regulation (EC) No 2073/2005[(13)] as regards microbiological criteria in foodstuffs;

— Commission Regulations (EC) No 1881/2006[(14)] and (EC) No 124/2009[(15)] as regards maximum levels for certain contaminants in foodstuffs;

— Council Directive 2007/43/EC[(16)] as regards the protection of chickens;

— Regulation (EC) No 1069/2009 of the European Parliament and of the Council[(17)] as regards health rules on animal by-products;

— Council Regulation (EC) No 1099/2009[(18)] as regards the protection of animals at the time of killing;

— Directive 2010/63/EU of the European Parliament and of the Council[(19)] as regards the protection of animals used for scientific purposes;

— Commission Implementing Regulation (EU) No 636/2014[(20)] as regards trade in unskinned large wild game;

— Commission Implementing Regulation (EU) 2015/1375[(21)] as regards official controls for *Trichinella*; and

— Regulation (EU) 2016/429 of the European Parliament and of the Council[(22)] as regards animal health rules.

(3) The practical arrangements for the performance of official controls on products of animal origin should be considered where a minimum level of official controls is

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necessary to respond to recognised uniform hazards and risks that might be posed by products of animal origin, covering all aspects that are important for protecting human health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and scientific evidence from opinions of the European Food Safety Authority (EFSA).

(4) On 31 August 2011, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (swine)[(23)]. The recommendations of that opinion were taken into account in the requirements for pig meat inspections laid down in Regulation (EC) No 854/2004 and should be maintained in the requirements laid down in this Regulation.

(5) On 23 May 2012, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (poultry)[(24)]. That opinion identifies *Campylobacter* spp. and *Salmonella* spp. as the main hazards to be covered in poultry meat inspections through an integrated food safety assurance system, achievable through improved food chain information (FCI) and risk-based interventions.

(6) On 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (bovine animals)[(25)]. That opinion identifies *Salmonella* spp. and pathogenic verocytotoxin-producing *Escherichia coli* (*E. coli*) as the most relevant hazards for meat inspections in bovine animals. It recommends the omission of palpation and incision during the post-mortem inspection of animals subjected to routine slaughter, since it may reduce spreading and cross-contamination with the high-priority biological hazards. However, palpations and incisions during post-mortem inspection, necessary to survey the occurrence of tuberculosis and *Taenia saginata* (tapeworm) cysticercosis, should be maintained.

(7) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat from sheep and goats[(26)]. That opinion identifies pathogenic verocytotoxin-producing *E. coli* as the most relevant hazard for meat inspections in sheep and goats. It also recommends omitting palpation and incisions to the extent possible from the post-mortem inspection of sheep and goats subject to routine slaughter. However, palpation and incisions for the surveillance of tuberculosis and fascioliasis should be maintained in older animals for reasons of animal and human health surveillance.

(8) Also on 6 June 2013, EFSA adopted a scientific opinion on the human health hazards to be covered by the inspection of meat (solipeds)[(27)]. That opinion recommends the use of visual-only inspection in solipeds, which may have a significant favourable effect on the microbiological status of soliped carcase meat. Such inspection is considered unlikely to affect the overall surveillance of animal diseases.

(9) Also on 6 June 2013, EFSA adopted a scientific opinion on the meat inspection of farmed game. That opinion recommends omitting palpation and incision unless abnormalities are detected, while at the same time underlining that such omission might have consequences for the overall surveillance of tuberculosis.

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(10) The recommendations set out in these EFSA opinions should be taken into account when laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption. The possible impact on trade with third countries should also be taken into account. At the same time, a smooth transition from the current requirements, as laid down in Regulation (EC) No 854/2004, should be ensured.

(11) These practical arrangements should apply to official controls on products of animal origin laid down in Article 18 of Regulation (EU) 2017/625 and in Commission Delegated Regulation (EU) 2019/624[(28)]. These practical arrangements for the performance of official controls should be uniform and facilitate the application of the requirements for a minimum level of official controls, taking into account the size of small businesses as laid down in Article 16 of Regulation (EU) 2017/625 by the use of a threshold in a non-discriminatory way.

(12) Since the structure of slaughterhouses and game-handling establishments differs across Member States, a threshold should be based on the number of animals slaughtered or handled, or on the demonstration that it represents a limited and fixed percentage of the meat placed on the market. Article 17(6) of Regulation (EC) No 1099/2009 defines livestock units and lays down conversion rates to express the number of animals of a certain species in such livestock units. These provisions should be used to set thresholds and harmonise derogations from certain requirements based on the size of a slaughterhouse to the extent possible.

(13) Specific requirements for auditing by the competent authorities should also be maintained to ensure the uniform practical verification of compliance with Union requirements on products of animal origin. Auditing is of particular interest for the verification of general and specific hygiene requirements and the application of procedures based on hazard analysis and critical control points (HACCP).

(14) Verification of compliance with the requirements on identification marking in Section I of Annex II to Regulation (EC) No 853/2004, as currently laid down in Regulation (EC) No 854/2004, should be maintained to allow tracing back the animals.

(15) Ante-mortem and post-mortem inspections are essential to verify compliance with requirements on human and animal health and animal welfare. In order to ensure at least the same level of human and animal health and animal welfare protection as provided by Regulation (EC) No 854/2004 and fair trade in an open market, it is necessary to lay down uniform practical requirements for such inspections, including cases where official controls are performed under the responsibility of the official veterinarian. As regards official controls on fresh meat, these inspections should be supplemented by appropriate documentary checks, controls on the safe disposal of specified risk material, as defined in Article 3(1)(g) of Regulation (EC) No 999/2001, and other animal by-products, and laboratory testing where appropriate.

(16) It is important to identify cases of suspected and established non-compliance where competent authorities must take measures with respect to certain products of animal

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origin. Non-compliance with good hygiene practices should also result in corrective action by competent authorities.

(17) The health mark defined in point 51 in Article 3 of Regulation (EU) 2017/625 covers meat of certain species and attests that the meat is fit for human consumption. Technical requirements of the health mark and practical arrangements for its application should be laid down in a specific and uniform way in order to indicate the fitness of the meat for human consumption and to prevent any trade disruption.

(18) Commission Regulation (EC) No 2074/2005[(29)] lays down, inter alia, implementing measures for the organisation of official controls under Regulation (EC) No 854/2004 as regards recognised testing methods for marine biotoxins in live bivalve molluscs, testing methods for raw milk and heat-treated milk, official controls in fishery products and the inspection of meat. It is appropriate to merge all implementing measures for the organisation of official controls and include the ones from Regulation (EC) No 2074/2005 in this Regulation. They should be deleted in Regulation (EC) No 2074/2005.

(19) The current conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs have proven to be effective and ensure a high level of consumer protection. They should therefore be maintained.

(20) A reference method for the analysis of *E. coli* in live bivalve molluscs, as currently laid down in Regulation (EC) No 854/2004, should be maintained.

(21) The limits for marine biotoxins are laid down in Regulation (EC) No 853/2004. In particular, point 2 in Chapter V of Section VII of Annex III to that Regulation provides that live bivalve molluscs must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the limits established in that Chapter.

(22) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on raw milk and dairy products should be laid down to ensure a high level of consumer protection and fair competition between food business operators.

(23) Specific requirements for the performance of official controls and the uniform minimum frequency for such controls on fishery products should be laid down to ensure a high level of consumer protection and fair competition between food business operators. Those controls should include at least regular checks on the hygiene conditions of landing and first sale, regular inspections of vessels and establishments, including fish auctions and wholesale markets, and checks on storage and transport. Specific requirements for the control of vessels should also be established.

(24) Those controls should also include practical arrangements as regards organoleptic examinations, freshness indicators, controls on histamine, residues and contaminants, microbiological checks. Special attention should be paid to the controls of parasites and on poisonous fishery products. Fishery products not meeting those hygiene requirements should be declared as unfit for human consumption.