

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)

TITLE II

SPECIFIC REQUIREMENTS FOR THE PERFORMANCE OF OFFICIAL CONTROLS AND THE UNIFORM MINIMUM FREQUENCY FOR OFFICIAL CONTROLS ON PRODUCTS OF ANIMAL ORIGIN

CHAPTER I

Specific requirements for audits by the competent authorities in establishments handling products of animal origin

Article 3

Requirements subject to auditing

1 When auditing good hygiene practices in establishments, the competent authorities shall verify that food business operators handling products of animal origin apply procedures continuously and properly concerning at least the following:

- a the design and maintenance of premises and equipment;
- b pre-operational, operational and post-operational hygiene;
- c personal hygiene;
- d training in hygiene and in work procedures;
- e pest control;
- f water quality;
- g temperature control;
- h controls on animals or food entering and leaving the establishment, and any accompanying documentation.

2 When auditing procedures based on hazard analysis and critical control points (HACCP), as laid down in Article 5 of Regulation (EC) No 852/2004, the competent authorities shall verify that food business operators handling products of animal origin apply such procedures continuously and properly.

3 They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

- a comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria;
- b comply with Union legislation on:
 - the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC⁽¹⁾;

- maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010⁽²⁾ and Commission Implementing Regulation (EU) 2018/470⁽³⁾;
 - prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC⁽⁴⁾, Commission Decision 2005/34/EC⁽⁵⁾;
 - contaminants, in accordance with Regulations (EC) No 1881/2006 and (EC) No 124/2009 setting maximum levels for certain contaminants in food;
 - pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council⁽⁶⁾;
- c do not contain physical hazards, such as foreign bodies.
- 4 Where a food business operator uses procedures set out in guides to the application of HACCP-based principles, in accordance with Article 5(5) of Regulation (EC) No 852/2004, the audit shall cover the correct use of those guides.
- 5 When carrying out auditing tasks, the competent authorities shall take special care:
- a to determine whether staff and staff activities in the establishment at all stages of the production process comply with the requirements, as regards hygienic practices and HACCP laid down in Article 3 of Regulation (EC) No 2073/2005, Articles 4 and 5 of Regulation (EC) No 852/2004 and Article 3(1) of Regulation (EC) No 853/2004. To complement the audit, the competent authorities may carry out performance tests, in order to ascertain that staff are sufficiently skilled;
 - b to verify the food business operator's relevant records;
 - c to take samples for laboratory analysis where necessary;
 - d to document elements taken into account and the findings of the audit.

Article 4

Nature and frequency of auditing

- 1 The nature and frequency of auditing tasks in respect of individual establishments shall depend on the assessed risk. To this end, the competent authorities shall regularly assess:
- a human and, where appropriate, animal health risks;
 - b in the case of slaughterhouses, animal welfare aspects;
 - c the type and throughput of the processes carried out;
 - d the food business operator's past record as regards compliance with food law.
- 2 Where food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems or independent third-party certification, or by other means, and where these measures are documented and animals covered by such schemes are clearly identifiable, the competent authorities may take such measures into account when carrying out audits to review good hygiene practices and the HACCP-based procedures.

- (1) Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products ([OJ L 303, 6.11.1997, p. 12](#)).
- (2) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin ([OJ L 15, 20.1.2010, p. 1](#)).
- (3) Commission Implementing Regulation (EU) 2018/470 of 21 March 2018 on detailed rules on the maximum residue limit to be considered for control purposes for foodstuffs derived from animals which have been treated in the EU under Article 11 of Directive 2001/82/EC ([OJ L 79, 22.3.2018, p. 16](#)).
- (4) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC ([OJ L 125, 23.5.1996, p. 3](#)).
- (5) 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 ([OJ L 16, 20.1.2005, p. 61](#)).
- (6) 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](#)).