

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance)

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 17

^{F1}...Register of Feed Additives

[^{F2}1 The Food Safety Authority must establish and keep up to date a Register of Feed Additives.]

2 The Register shall be made available to the public.

Textual Amendments

- F1** Word in [Art. 17](#) heading omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **25(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** [Art. 17\(1\)](#) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **25(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 18

Confidentiality

1 The applicant may indicate which information submitted under this Regulation he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be given in such cases.

2 The [^{F3}appropriate authority] shall determine, after consultation with the applicant, which information other than that specified in paragraph 3 should be kept confidential and shall inform the applicant of its decision.

3 The following information shall not be considered confidential:

- a name and composition of the feed additive and, where appropriate, indication of the production strain;
- b physico-chemical and biological characteristics of the feed additive;
- c the conclusions of the study results on effects of the feed additive on human and animal health and on the environment;
- d the conclusions of the study results on effects of the feed additive on the characteristics of animal products and its nutritional properties;
- e methods for detection and identification of the feed additive and, where applicable, monitoring requirements and a summary of the results of the monitoring.

[^{F4}4 The Food Safety Authority must, on request, supply the appropriate authority with all information in its possession, including any identified as confidential pursuant to paragraph 2.]

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[^{F6} The appropriate authority and the Food Safety Authority must keep confidential all the information identified as confidential under paragraph 2 except where it is appropriate for such information to be made public in order to protect human health, animal health or the environment.]

7 If an applicant withdraws or has withdrawn an application, the [^{F7}appropriate authority and the Food Safety Authority must] respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the [^{F8}appropriate authority] and the applicant disagree as to its confidentiality.

Textual Amendments

- F3** Words in Art. 18(2) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Art. 18(4) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 18(5) omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Art. 18(6) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 18(7) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(e)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 18(7) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **26(e)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

[^{F9}Article 18A

Regulations and devolved powers

1. Any power to make regulations under this Regulation—
 - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
 - b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
 - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
 - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
 - a in the case of England, of either House of Parliament;
 - b in the case of Wales, of Senedd Cymru;
 - c in the case of Scotland, of the Scottish Parliament;

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5. In this Regulation, any power—
- a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
 - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
 - c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;]

Textual Amendments

- F9** Art. 18A inserted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **27** (as amended by [S.I. 2020/1504](#), regs. 1(2), **12(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 19

Administrative review

Any decision taken under, or failure to exercise, the powers vested in the [^{F10}Food Safety Authority] by this Regulation may be reviewed by the [^{F11}appropriate authority] on its own initiative or in response to a request from ^{F12}... any person directly and individually concerned.

For that purpose, a request shall be submitted to the [^{F11}appropriate authority] within two months after the day on which the party concerned became aware of the act or omission in question.

The [^{F11}appropriate authority] shall take a decision within two months requiring, if appropriate, the [^{F10}Food Safety Authority] to withdraw its decision or to remedy its failure to act within a set time limit.

Textual Amendments

- F10** Words in Art. 19 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **28(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Words in Art. 19 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **28(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in Art. 19 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **28(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 20

Data protection

1 The scientific data and other information in the application dossier required under Article 7 may not be used for the benefit of another applicant for a period of 10 years from the date of authorisation, unless the other applicant has agreed with the previous applicant that such data and information may be used.

2 In order to stimulate efforts to obtain authorisations for minor species for additives whose use is authorised for other species, the 10-year data protection period shall be extended by one year for each minor species for which a use extension authorisation is granted.

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3 The applicant and the previous applicant shall take all necessary steps to reach agreement on sharing the use of information, in order not to repeat toxicological tests on vertebrates. If, however, no such agreement is reached on sharing the information, the [F13 appropriate authority] may decide to disclose information necessary to avoid repeating toxicological tests on vertebrates, while ensuring a reasonable balance between the interests of the parties concerned.

4 On the expiry of the 10-year period, the findings of all or part of the evaluation conducted on the basis of the scientific data and information contained in the application dossier may be used by the [F14 Food Safety Authority] for the benefit of another applicant.

Textual Amendments

- F13** Words in Art. 20(3) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **29(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Words in Art. 20(4) substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **29(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[F15 Article 21

Reference laboratory

1. The duties and tasks of the reference laboratory are laid down in Annex 2.
2. Applicants for the authorisation of additives must contribute to supporting the cost of the duties and tasks of the reference laboratory.
3. The appropriate authority may prescribe rules for implementing Annex 2.
4. The appropriate authority may prescribe amendments to Annex 2.]

Textual Amendments

- F15** Art. 21 substituted (31.12.2020) by [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

F16 Article 21a

Exercise of the delegation

Textual Amendments

- F16** Art. 21a omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **30A** (as inserted by S.I. 2020/1504, regs. 1(2), **12(6)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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^{F17}Article 22

Committee procedure

Textual Amendments

- F17** Art. 22 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

Article 23

Repeals

1 Directive 70/524/EEC shall be repealed with effect from the date of application of this Regulation. However, Article 16 of Directive 70/524/EEC shall remain in force until Directive 79/373/EEC has been revised to include rules concerning the labelling of feedingstuffs incorporating additives.

2 Points 2.1, 3 and 4 of the Annex to Directive 82/471/EEC shall be deleted with effect from the date of application of this Regulation.

3 Directive 87/153/EEC shall be repealed with effect from the date of application of this Regulation. However, the Annex to that Directive shall remain in force until the implementing rules provided for in Article 7(4) of this Regulation are adopted.

4 References to Directive 70/524/EEC shall be construed as references to this Regulation.

^{F18}Article 24

Penalties

Textual Amendments

- F18** Art. 24 omitted (31.12.2020) by virtue of [The Animal Feed \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/654\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

Article 25

Transitional measures

1 Applications submitted under Article 4 of Directive 70/524/EEC before the date of application of this Regulation shall be treated as applications under Article 7 of this Regulation where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have not yet been forwarded to the Commission. Any Member State selected as rapporteur in respect of any

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such application shall immediately forward the dossier submitted in support of that application to the Commission. Notwithstanding Article 23(1), such applications shall continue to be treated in accordance with Article 4 of Directive 70/524/EEC where the initial comments provided for under Article 4(4) of Directive 70/524/EEC have already been forwarded to the Commission.

2 The labelling requirements laid down in Chapter III shall not apply to products which have been lawfully manufactured and labelled in the Community or which have been lawfully imported into the Community and put into circulation, before the date of application of this Regulation.

Article 26

Entry into force

1 This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

2 It shall apply from 12 months after the date of publication of this Regulation.

Changes to legislation:

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Changes and effects yet to be applied to :

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 2(2)(o)-(t) inserted by [S.I. 2019/654 reg. 10\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 10(a)(ii) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 12(3))
- Art. 18A(4)(d) words substituted by [S.I. 2019/1013 reg. 32](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))