

Opozorilo: Neuradno prečiščeno besedilo predpisa predstavlja zgolj informativni delovni pripomoček, glede katerega organ ne jamči odškodninsko ali kako drugače.

Neuradno prečiščeno besedilo Pravilnika o krmnih dodatkih obsega:

- Pravilnik o krmnih dodatkih (Uradni list RS, št. 110/09 z dne 29. 12. 2009),
- Pravilnik o spremembah Pravilnika o krmnih dodatkih (Uradni list RS, št. 69/10 z dne 27. 8. 2010),
- Pravilnik o spremembah Pravilnika o krmnih dodatkih (Uradni list RS, št. 43/11 z dne 3. 6. 2011).

PRAVILNIK o krmnih dodatkih

(neuradno prečiščeno besedilo št. 2)

1. člen (vsebina pravilnika)

Ta pravilnik ureja:

- **(črtana)**,
- proizvodnjo, skladiščenje, dajanje na trg za namen izvoza in izvoz krmnih dodatkov, predmešanic in krmnih mešanic, ki vsebujejo krmne dodatke, ki nimajo dovoljenja za dajanje na trg in uporabo v Skupnosti, ter
- izjemno uporabo snovi kot krmnega dodatka, ki nima dovoljenja Skupnosti, za namen znanstvenega poskusa za izvajanje drugega

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The unofficial consolidated version of the Rules on feed additives comprises:

- Rules on feed additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 110/09 of 29 December 2009),
- Rules amending the Rules on feed additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 69/10 of 27 August 2010),
- Rules amending the Rules on feed additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 43/11 of 3 June 2011).

RULES on feed additives

(Unofficial consolidated version No. 2)

Article 1 (Subject of the Rules)

These Rules shall regulate:

- **(Deleted)**,
- the manufacture, storage, placing on the market for the purposes of the export and import of feed additives, premixtures and compound feed containing feed additives that have no authorisation to be placed on the market and used within the Community, and
- exceptional use, as additives, of substances that are not authorised by the Community, for scientific experiments for the purpose of

odstavka 3. člena Uredbe (ES) št. 1831/2003 Evropskega parlamenta in Sveta z dne 22. septembra 2003 o dodatkih za uporabo v prehrani živali (UL L št. 268 z dne 18. 10. 2003, str. 29), zadnjič spremenjene z Uredbo Komisije (ES) št. 386/2009 z dne 12. maja 2009 o spremembi Uredbe Evropskega parlamenta in Sveta (ES) št. 1831/2003 glede uvedbe nove funkcionalne skupine krmnih dodatkov (UL L št. 118 z dne 13. 5. 2009, str. 66), (v nadaljnjem besedilu: Uredba 1831/2003/ES).

2. člen (pomen izrazov)

Za potrebe tega pravilnika imajo uporabljeni izrazi naslednji pomen:

1. dovoljeni krmni proizvodi so krmni dodatki, ki imajo dovoljenje iz točke (a) prvega odstavka 3. člena Uredbe 1831/2003/ES (v nadaljnjem besedilu: dovoljenje Skupnosti), ter predmešanice in krmne mešanice, ki vsebujejo krmne dodatke, ki imajo dovoljenje Skupnosti;
2. nedovoljeni krmni proizvodi so krmni dodatki, ki nimajo dovoljenja Skupnosti, ter predmešanice in krmne mešanice, ki vsebujejo krmne dodatke, ki nimajo dovoljenja Skupnosti;
3. direktni izvoz je izvoz nedovoljenih krmnih proizvodov v tretjo državo direktno iz proizvodnega obrata nosilca dejavnosti poslovanja s krmo;
4. indirektni izvoz je dajanje nedovoljenih krmnih proizvodov na trg Skupnosti za namen kasnejšega izvoza v tretjo državo.

3. člen (črtan)

4. člen (proizvodnja in skladiščenje nedovoljenih krmnih proizvodov)

(1) Če nosilec dejavnosti poslovanja s krmo proizvaja tako dovoljene kot nedovoljene krmne proizvode, se mora proizvodnja odvijati

implementation of paragraph two of Article 3 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10. 2003, p. 29), as amended most recently by Commission Regulation (EC) No 386/2009 of 12 May 2009 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the establishment of a new functional group of feed additives (OJ L 118, 13.5.2009, p. 66) (hereinafter: Regulation 1831/2003/EC).

Article 2 (Definitions)

For the purposes of these Rules, the following definitions shall apply:

1. authorised animal feed products shall mean feed additives that have the authorisation referred to in point (a) of paragraph one of Article 3 of Regulation 1831/2003/EC (hereinafter Community authorisation) as well as premixtures and compound feed that contain feed additives that have Community authorisation;
2. unauthorised animal feed products shall mean feed additives that have no Community authorisation as well as premixtures and compound feed that contain feed additives that have no Community authorisation;
3. direct export shall mean the export of unauthorised animal feed products to a third country directly from a manufacturing establishment of an animal feed business operator;
4. indirect export shall mean placing unauthorised animal feed products on the Community market for the purpose of future export to a third country.

Article 3 (Deleted)

Article 4 (Manufacture and storage of unauthorised feed additives)

(1) If an animal feed business operator manufactures authorised as well as unauthorised animal feed products, manufacture

na ločenih linijah. Zagotovljeni morajo biti ločeni skladiščni prostori za nedovoljene in dovoljene krmne proizvode, ki se skladiščijo v razsutem stanju. Nedovoljeni in dovoljeni krmni proizvodi, ki so pakirani, se lahko skladiščijo v istem prostoru, če je mesto skladiščenja nedovoljenih krmnih proizvodov jasno ločeno od mesta skladiščenja dovoljenih krmnih proizvodov. V obratu mora biti zagotovljena notranja sledljivost in izvajati se morajo ukrepi za preprečevanje navzkrižne kontaminacije.

(2) Nedovoljeni krmni proizvodi, ki se dajo na trg Skupnosti za namen kasnejšega izvoza, morajo imeti na označbi proizvoda oznako, iz katere je razvidno, da so namenjeni za izvoz.

(3) Za izvajanje dejavnosti proizvodnje nedovoljenih krmnih proizvodov in dovoljenih krmnih proizvodov v istem obratu in na isti proizvodni liniji mora nosilec dejavnosti v skladu z drugim odstavkom 10. člena Uredbe 183/2005/ES Evropskega parlamenta in Sveta z dne 12. januarja 2005 o zahtevah glede higiene krme (UL L št. 35 z dne 8. 2. 2005, str. 1), zadnjič spremenjene z Uredbo Komisije (ES) št. 141/2007 z dne 14. februarja 2007 o zahtevi za odobritev v skladu z uredbo Evropskega Parlamenta in Sveta (ES) št. 183/2005 obratov za proizvodnjo krme, ki proizvajajo ali dajejo v promet krmne dodatke vrste »kokcidiostatiki in histomonostatiki« (UL L št. 43 z dne 15. 2. 2007, str. 9), (v nadaljnjem besedilu: Uredba 183/2005/ES) pridobiti dovoljenje Veterinarske uprave Republike Slovenije.

(4) Obrat nosilca dejavnosti poslovanja s krmo, ki proizvaja tudi nedovoljene krmne proizvode, mora poleg evidenc, predpisanih v Uredbi 183/2005/ES voditi tudi posebno evidenco o:

- dobaviteljnih, količinah in datumih nabave nedovoljenih krmnih proizvodov,
- datumih in količinah proizvedenih krmnih proizvodov,
- kupcih v državah članicah EU in
- kupcih iz tretjih držav.

5. člen

must take place on separate lines. Separate storage facilities must be provided for unauthorised and authorised animal feed products that are stored in bulk form. Packed unauthorised and authorised animal feed products may be stored in the same room if the place for the storage of unauthorised animal feed products is clearly separated from the place for the storage of authorised animal feed products. In the establishment, traceability must be ensured and measures to prevent cross-contamination must be carried out.

(2) Unauthorised animal feed products that are being placed on the Community market for the purpose of future export must be labelled on their designation in a manner that clearly indicates that they are intended for export.

(3) In order to carry out the manufacture of unauthorised and authorised animal feed products at the same establishment and on the same production line, an animal feed business operator must obtain approval from the Veterinary Administration of the Republic of Slovenia (hereinafter: VARS) pursuant to paragraph two of Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1), as amended most recently by Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category coccidiostats and histomonostats (OJ L 43, 15.2.2007, p. 9) (hereinafter: Regulation 183/2005/EC).

(4) In addition to the records prescribed by Regulation 183/2005/EC, the establishment of an animal feed business operator who also manufactures unauthorised animal feed products must keep a special register of:

- suppliers, quantities and dates of purchase of unauthorised animal feed products,
- dates and quantities of manufactured animal feed products,
- buyers in EU Member States, and
- buyers from third countries.

Article 5

(dajanje na trg za namen izvoza in izvoz nedovoljenih krmnih proizvodov)

(1) Nedovoljene krmne proizvode je dovoljeno direktno izvoziti v tretje države.

(2) Nosilci dejavnosti poslovanja s krmo morajo za namen direktnega izvoza nedovoljenih krmnih proizvodov vsaj en delovni dan pred pričakovanim izvozom pošiljke nedovoljenih krmnih proizvodov o tem obvestiti krajevno pristojni območni urad VURS, v kolikor je za izvoz potrebno veterinarsko spričevalo. Najavo o namenu izvoza poda nosilec dejavnosti na obrazcu 2, ki je objavljen na spletni strani VURS.

(3) Izvoz nedovoljenih krmnih proizvodov je dovoljen:

- če so izpolnjeni pogoji iz 12. člena Uredbe 178/2002/ES Evropskega parlamenta in Sveta z dne 28. januarja 2002 o določitvi splošnih načel in zahtevah živilske zakonodaje, ustanovitvi Evropske agencije za varnost hrane in postopkih, ki zadevajo varnost hrane (UL L št. 31 z dne 1. 2. 2002, str. 1), zadnjič spremenjene z Uredbo Komisije (ES) št. 202/2008 z dne 4. marca 2008 o spremembi Uredbe (ES) št. 178/2002 Evropskega Parlamenta in Sveta glede števila in poimenovanja znanstvenih svetov Evropske agencije za varnost hrane (UL L št. 60 z dne 5. 3. 2008, str. 17),
- če pristojni organ tretje države za pošiljko zahteva veterinarsko spričevalo, ki ga potrdi VURS ali
- če pristojni organ tretje države poda pisno izjavo, da je uporaba določenega nedovoljenega krmnega proizvoda v tretji državi dovoljena.

(4) Indirektni izvoz nedovoljenih krmnih proizvodov je dovoljen, če nosilec dejavnosti poslovanja s krmo za to dejavnost pridobi dovoljenje VURS.

(5) Nosilci dejavnosti, ki imajo dovoljenje iz prejšnjega odstavka, morajo o pošiljkah, danih na trg, do 10. dne v januarju in juliju obveščati pristojni območni urad VURS.

(6) Glavni urad VURS obvesti pristojni organ države članice o

(Placing on the market for the purpose of export, and the export of unauthorised animal feed products)

(1) It shall be permitted to directly export unauthorised animal feed products to third countries.

(2) For the purpose of the direct export of unauthorised animal feed products, animal feed business operators must notify thereof a locally competent regional office of the VARS at least one workday before the anticipated export of a consignment of unauthorised feed products if a veterinary certificate is required for the export. Animal feed business operators shall notify the VARS of their intended export on Form 2, which is published on the VARS website.

(3) Export of unauthorised animal feed products shall be permitted:

- if the conditions referred to in Article 12 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), as amended most recently by Commission Regulation (EC) No 202/2008 of 4 March 2008 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the Scientific Panels of the European Food Safety Authority (OJ L 60, 5.3.2008, p. 17) are met,
- if a competent authority of a third country requests a veterinary certificate approved by the VARS, or
- if a competent authority of a third country submits a written statement that the use of a certain unauthorised animal feed product is permitted in the third country in question.

(4) Indirect export of unauthorised animal feed products shall be permitted if an animal feed business operator obtains approval from the VARS for such activity.

(5) Animal feed business operators that have obtained the approval referred to in the preceding paragraph must notify the VARS by the 10th day of January and July of consignments placed on the market.

(6) The VARS main office shall notify a competent authority of

dajanju na trg krmnega proizvoda, ki izvira iz Slovenije, za namen indirektnega izvoza.

6. člen

(izjemna uporaba snovi kot krmnega dodatka, ki še nima dovoljenja Skupnosti, za namen znanstvenega poskusa)

(1) Za izvedbo znanstvenega poskusa, v katerem se želi uporabiti snov kot krmni dodatek, ki še nima dovoljenja Skupnosti, mora izvajalec v skladu z drugim odstavkom 3. člena Uredbe 1831/2003/ES predhodno pridobiti dovoljenje VURS.

(2) Zahtevek za izjemno uporabo snovi kot krmnega dodatka, ki še nima dovoljenja Skupnosti poda vodja poskusa, v katerem navede kraj poskusa, čas in trajanje poskusa, obseg poskusa, namen poskusa, oznako krme, vsebnost snovi, ki jo želijo v poskusu uporabiti v krmi, način proizvodnje krme, pri proizvodnji krmnih mešanicah sestavo predmešanice in druge podatke, ki so pomembni za obravnavo zahtevka. Zahtevku je treba predložiti dokumentacijo iz katere je razvidna ustrezna izobrazba in usposobljenost osebja za izvedbo poskusa in da ima organizacija, ki izvaja poskus, za ta namen odobritev pristojnega organa ter mnenje inštitucije, ki izdeluje ocene tveganja na področju krme, da je krma iz poskusa primerna za predvideni namen uporabe.

(3) VURS dovoli izjemno uporabo snovi kot krmnega dodatka, ki še nima dovoljenja Skupnosti, v skladu z načeli in pogoji iz drugega odstavka 3. člena Uredbe 1831/2003/ES.

(4) V dovoljenju iz prejšnjega odstavka se določi:

- kje in koliko krmnega dodatka, ki še nima dovoljenja, se lahko nabavi za namen poskusa,

a third country of the placing on the market of an animal feed product originating from Slovenia for the purpose of indirect export.

Article 6

(Exceptional use of a substance as a feed additive that has not yet been granted Community authorisation for the purpose of a scientific experiment)

(1) In order to carry out a scientific experiment in which a substance is intended to be used as a feed additive that has not yet been granted Community authorisation, the experimenter must obtain approval from the VARS pursuant to paragraph two of Article 3 of Regulation 1831/2003/EC.

(2) A request for exceptional use of a substance as a feed additive that has not yet been granted Community authorisation shall be submitted by the lead experimenter. In the request, the lead experimenter shall indicate the place of the experiment, the time and duration of the experiment, the scope of the experiment, the purpose of the experiment, the animal feed designation, the content of the substance intended to be used in animal feed, the manner of animal feed manufacture, the composition of premixtures in the case of compound feed manufacture and other data important for processing the request. The request shall be accompanied by documentation showing that the staff is appropriately educated and qualified to conduct the experiment and that the organisation conducting the experiment has obtained for this purpose approval from the competent authority and the opinion of an institution conducting risk assessments in the field of animal feed stating that the animal feed used in the experiment is appropriate for the intended purpose of use.

(3) The VARS shall approve an exceptional use of a substance as an animal feed additive that has not yet been granted Community authorisation in accordance with the principles and conditions referred to in paragraph two of Article 3 of Regulation 1831/2003/EC.

(4) The following shall be specified in the approval referred to in the preceding paragraph:

- where and how much animal feed additive that has not yet been granted Community authorisation for the purpose of the experiment,

- krajevne in časovne omejitve proizvodnje,
- obrat nosilca dejavnosti v katerem se bo izdelovala predmešanica oziroma krmna mešanica, ki bo vsebovala snov kot krmni dodatek, ki še nima dovoljenja Skupnosti,
- vsebnost snovi kot krmnega dodatek, ki še nima dovoljenja Skupnosti, v predmešanici in v krmni mešanici,
- krajevne in časovne omejitve uporabe poskusne krme in
- omejitve v krmljenju.

(5) Krmni proizvodi, ki bodo uporabljeni v poskusu iz tega člena, morajo imeti na oznaki jasno navedbo »UPORABA SAMO ZA NAMEN POSKUSA« (z velikimi tiskanimi črkami).

(6) Na oznaki krmnega dodatka, ki nima dovoljenja Skupnosti in je namenjen za uporabo v poskusa iz tega člena, morajo biti navedeni naslednji podatki: ime dodatka, ime proizvajalca, številka odobritve obrata, neto masa oziroma neto volumen, številka serije in datum proizvodnje.

(7) Iz deklaracije predmešanice in krmne mešanice mora biti razvidno, da vsebujeta krmni dodatek, ki nima dovoljenja Skupnosti.

(8) Zgoraj navedene krmne proizvode je treba ločeno skladiščiti na način, da ne pride do zamenjave ali navzkrižne kontaminacije z ostalo krmo. Na trg se jih lahko da le v sklopu izdanega dovoljenja iz četrtega odstavka tega člena.

(9) Če se želi rejne živali, na katerih so se izvajali poskusi, uporabiti za proizvodnjo živil, mora vodja poskusa v skladu z drugim odstavkom 3. člena Uredbe 1831/2003/ES za ta namen pridobiti dovoljenje VURS.

(10) Živali iz poskusne skupine se lahko uporabi za proizvodnjo živil, če se ugotovi, da na podlagi predložene dokumentacije o varnostnih

may be purchased,

- place and time restrictions regarding manufacture,
- the animal feed business operator establishment manufacturing the premixture or compound feed that will contain the substance as an animal feed additive that has not yet been granted Community authorisation,
- the content of the substance as an animal feed additive that has not yet been granted Community authorisation in a premixture and a compound feed,
- place and time restrictions regarding the use of experimental animal feed, and
- feeding restrictions.

(5) On the designation of animal feed products that will be used in an experiment referred to in this Article it must be clearly indicated "USE EXCLUSIVELY FOR EXPERIMENTAL PURPOSES" (in upper-case printed letters).

(6) The designation of a feed additive without Community authorisation that is intended to be used in an experiment referred to in this Article must contain the following data: the name of the additive, the name of the manufacturer, the approval number of the establishment, the net mass or net volume, the series number and the date of manufacture.

(7) It must be clearly indicated in the declaration of a premixture and compound feed that they contain a feed additive without Community authorisation.

(8) The above-mentioned animal feed products must be stored separately in a manner that prevents animal feed products from being mistaken for one another or cross-contamination with other animal feed. They may be placed on the market only under the issued approval referred to in paragraph four of this Article.

(9) If farm animals on which experiments have been conducted are to be used for food production, the lead experimenter must obtain approval from the VARS for this purpose pursuant to paragraph two of Article 3 of Regulation 1831/2003/EC.

(10) Animals from a test group may be used for food production if it is established, based on documentation on safety studies referred to

študijah iz Uredbe Komisije 429/2008/ES o podrobnih pravilih za izvajanje Uredbe Evropskega Parlamenta in Sveta 1831/2003/ES v zvezi s pripravo in predložitvijo vlog ter oceno krmnih dodatkov za izdajo dovoljenj zanje (UL L št. 133 z dne 25. 4. 2008, str. 1) s strani organizacije, ki izvaja poskus, to ne bo škodljivo vplivalo na zdravje ljudi in živali ter okolje.

7. člen (vloga)

(1) Vlogo za izdajo dovoljenja iz tretjega odstavka 4. člena in četrtega odstavka 5. člena tega pravilnika vložijo nosilec dejavnosti poslovanja s krmo na krajevno pristojni območni urad VURS, na obrazcu 1, ki je objavljen na spletni strani VURS.

(2) V dovoljenju iz prejšnjega odstavka se določi vrsta dejavnosti, za katero se dovoljenje izda.

(3) Nosilci dejavnosti morajo o vsaki spremembi podatkov iz vloge v roku 30 dni obvestiti območni urad VURS.

(4) Vlogo za izdajo dovoljenja iz 6. člena tega pravilnika vložijo organizacija, ki izvaja poskus, na glavni urad VURS, na obrazcu 3, ki je objavljen na spletni strani VURS.

(5) Vloga iz prvega in četrtega odstavka tega člena, kot tudi najava o namenu izvoza iz drugega odstavka 5. člena tega pravilnika, se lahko odda na VURS v pisni ali elektronski obliki.

8. člen (prehodna določba)

Postopki, začeti na podlagi Pravilnika o krmnih dodatkih (Uradni list RS, št. 47/05), se dokončajo po postopku, ki ga določa Pravilnik o krmnih dodatkih (Uradni list RS, št. 47/05).

in Commission Regulation (EC) No. 429/2008 on detailed rules for the implementation of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 25.4.2008, p. 1), submitted by the organisation conducting an experiment, that this will not adversely affect the health of people, animals, or the environment.

Article 7 (Application)

(1) An application for the issuance of the approval referred to in paragraph three of Article 4 and paragraph four of Article 5 of these Rules shall be submitted by an animal feed business operator to a locally competent regional office of the VARS on Form 1, which is published on the VARS website.

(2) In the approval referred to in the preceding paragraph, the type of activity shall be specified for which the approval is to be issued.

(3) Animal feed business operators must notify a regional office of the VARS of any change of the data in the application within 30 days.

(4) An application for the issuance of the approval referred to in Article 6 of these rules shall be submitted by the organisation conducting the experiment to the VARS main office on Form 3, which is published on the VARS website.

(5) The application referred to in paragraphs one and four of this Article as well as the notification of the intended export referred to in paragraph two of Article 5 of these Rules may be submitted to the VARS in written or electronic form.

Article 8 (Special provision)

Procedures initiated pursuant to the Rules on Feed Additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 47/05) shall be completed following the procedure set out by the Rules on Feed

Additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 47/05).

9. člen
(prenehanje veljavnosti)

Z dnem uveljavitve tega pravilnika preneha veljati Pravilnik o krmnih dodatkih (Uradni list RS, št. 47/05).

10. člen
(uveljavitev)

Ta pravilnik začne veljati petnajsti dan po objavi v Uradnem listu Republike Slovenije.

Article 9
(End of validity)

On the day these Rules enter into force, the Rules on feed additives (Official Gazette of the Republic of Slovenia [*Uradni list RS*], No. 47/05) shall cease to be in force.

Article 10
(Entry into force)

These Rules shall enter into force on the fifteenth day following their publication in the Official Gazette of the Republic of Slovenia.