

Opozorilo: Besedilo osnovnega predpisa

Na podlagi šestega odstavka 61. člena in 152.a člena Zakona o kmetijstvu (Uradni list RS, št. 45/08, 57/12, 90/12 – ZdZPVHVVR in 26/14), drugega, tretjega, četrtega in petega odstavka 8. člena, 76. člena ter 90. člena Zakona o veterinarskih merilih skladnosti (Uradni list RS, št. 93/05, 90/12 – ZdZPVHVVR, 23/13 – ZZZiv-C in 40/14 – ZIN-B) izdaja minister za kmetijstvo, gozdarstvo in prehrano

PRAVILNIK
o registraciji in odobritvi obratov na področju živil

I. SPLOŠNE DOLOČBE

1. člen
(vsebina pravilnika)

(1) Ta pravilnik podrobneje določa postopke registracije in odobritev obratov na področju živil (v nadaljnjem besedilu: obrati) razen obratov, ki delujejo na področju prehranskih dopolnil in živil za posebne prehranske namene, za izvajanje:

- Uredbe Evropskega parlamenta in Sveta (ES) št. 852/2004 z dne 29. aprila 2004 o higieni živil (UL L št. 165 z dne 30. 4. 2004, str. 1),

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Pursuant to paragraph six of Article 61 and Article 152a of the Agriculture Act (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 45/08, 57/12, 90/12 – ZdZPVHVVR and 26/14), paragraphs two, three, four and five of Article 8, Article 76 and Article 90 of the Veterinary Compliance Criteria Act (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 93/05, 90/12 – ZdZPVHVVR, 23/13 – ZZZiv-C and 40/14 – ZIN-B) the Minister of Agriculture, Forestry and Food hereby issues the following

RULES
on the registration and approval of food-processing establishments

I. GENERAL PROVISIONS

Article 1
(Subject of the Rules)

(1) These Rules shall specify the procedures for the registration and approval of food-processing establishments (hereinafter: establishments), with the exception of establishments operating in the field of food supplements and food for particular nutritional uses, for the implementation of:

- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139,

zadnjič spremenjene z Uredbo Komisije (EU) št. 579/2014 z dne 28. maja 2014 o odobritvi odstopanja od nekaterih določb Priloge II k Uredbi (ES) št. 852/2004 v zvezi s prevozom tekočih olj in maščob po morju (UL L št. 160 z dne 29. 5. 2014, str. 14), (v nadaljnjem besedilu: Uredba 852/2004/ES)

in

- Uredbe (ES) št. 853/2004 Evropskega parlamenta in Sveta z dne 29. aprila 2004 o posebnih higienskih pravilih za živila živalskega izvora (UL L št. 139 z dne 30. 4. 2004, str. 55), zadnjič spremenjene z Uredbo (EU) Komisije št. 1137/2014 št. 1137/2014 z dne 27. oktobra 2014 o spremembi Priloge III k Uredbi (ES) št. 853/2004 Evropskega parlamenta in Sveta v zvezi z obdelavo nekaterih vrst drobovine živali, namenjenih za prehrano ljudi (UL L št. 307 z dne 28. 10. 2014, str. 28), (v nadaljnjem besedilu: Uredba 853/2004/ES).

(2) S tem pravilnikom se določa tudi uporaba smernic dobre prakse za higieno oziroma za uporabo načel HACCP v skladu s tretjim odstavkom 8. člena Uredbe 852/2004/ES.

2. člen (izrazi)

Izrazi, uporabljeni v tem pravilniku, pomenijo naslednje:

1. obrat je obrat, kot je opredeljen v 2. členu Uredbe 852/2004/ES;
2. živilska dejavnost je dejavnost, kot je opredeljena v Uredbi (ES) št. 178/2002 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 spremenjeni z Uredbo (EU) št. 652/2014 Evropskega parlamenta in Sveta z dne 15. maja 2014 o določbah za upravljanje odhodkov v zvezi s prehransko verigo, zdravjem in dobrobitjo živali ter v zvezi z zdravjem rastlin in rastlinskimi razmnoževalnim materialom, spremembi direktiv Sveta 98/56/ES, 2000/29/ES in 2008/90/ES, uredb (ES) št. 178/2002, (ES) št. 882/2004 in (ES) št. 396/2005 Evropskega parlamenta in Sveta, Direktive 2009/128/ES Evropskega parlamenta in Sveta in Uredbe (ES) št. 1107/2009 Evropskega parlamenta in Sveta ter

30.4.2004, p. 1), as last amended by the Commission Regulation (EU) No 579/2014 of 28 May 2014 granting derogation from certain provisions of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council as regards the transport of liquid oils and fats by sea (OJ L 160, 29.5.2014, p. 14), (hereinafter: Regulation 852/2004/EC)

and

- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55), as last amended by the Commission Regulation (EU) No 1137/2014 of 27 October 2014 amending Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the handling of certain offal from animals intended for human consumption (OJ L 307, 28.10.2014, p. 28), (hereinafter: Regulation 853/2004/EC).

(2) These Rules also define the application of guides to good practice for hygiene and/or for the application of the HACCP principles in accordance with paragraph three of Article 8 of Regulation 852/2004 / EC.

Article 2 (Definitions)

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

1. establishment shall mean an establishment as defined in Article 2 of Regulation (EC) No 852/2004;
2. food business shall be a business as defined in 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 last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament

razveljavitvi sklepov Sveta 66/399/EGS in 76/894/EGS ter Odločbe Sveta 2009/470/ES (UL L št. 189 z dne 27. 6. 2014, str. 1), (v nadaljnjem besedilu: Uredba 178/2002/ES);

3. nosilec živilske dejavnosti je nosilec, kot je opredeljen v 3. členu Uredbe 178/2002/ES.

3. člen (registracija obrata in izjeme)

(1) Nosilec živilske dejavnosti mora skladno z drugim odstavkom 6. člena Uredbe 852/2004/ES vsak obrat, v katerem izvaja živilsko dejavnost, registrirati pri Upravi Republike Slovenije za varno hrano, veterinarstvo in varstvo rastlin (v nadaljnjem besedilu: uprava).

(2) Ne glede na določbe prejšnjega odstavka ni treba registrirati obratov tistim nosilcem živilske dejavnosti, katerih proizvodi so namenjeni dajanju na trg in so:

- vpisani v evidence rejnih živali v skladu s predpisi, ki urejajo evidence rejnih živali,
- vpisani v centralni register akvakulture v skladu s predpisi, ki urejajo centralni register akvakulture,
- vpisani v register čebelnjakov v skladu s predpisi, ki urejajo register čebelnjakov, ali
- oddali zbirno vlogo v skladu s predpisom, ki ureja izvedbo ukrepov kmetijske politike za področje pridelave kmetijskih rastlin, in je na podlagi njihove izjave iz vloge razvidno, da kmetijske pridelke dajejo na trg, z izjemo trženja majhnih količin primarnih proizvodov.

(3) Obrate iz prejšnjega odstavka uprava po uradni dolžnosti vpiše v register obratov iz četrtega odstavka 4. člena tega pravilnika.

(4) Ne glede na določbo prvega odstavka tega člena ni treba registrirati:

- obratov, ki so pri upravi odobreni v skladu s 6. členom tega pravilnika,

and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1), (hereinafter: Regulation 178/2002/EC);

3. food business operator shall be an operator as defined in Article 3 of Regulation 178/2002/EC.

Article 3 (Registration of establishment and exemptions)

(1) A food business operator shall register in accordance with paragraph two of Article 6 of Regulation 852/2004/EC each establishment in which it carries out a food business, with the Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection (hereinafter: the Administration).

(2) Notwithstanding the provisions of the preceding paragraph, it shall not be mandatory to register establishments for those food business operators whose products are intended to be placed on the market and which:

- are entered in the livestock records in accordance with the regulations governing livestock records;
- are entered in the central register of aquaculture in accordance with the regulations governing the central register of aquaculture;
- are entered in the register of apiaries in accordance with the regulations governing the register of apiaries;
- have submitted a summary application in accordance with the regulation governing the implementation of agricultural policy measures in the field of growing of crops, and on the basis of their statement in the application it is evident that crops are being placed on the market, with the exception of marketing small quantities of primary products.

(3) The Administration shall *ex officio* enter the establishments referred to in the preceding paragraph in the register of establishments referred to in paragraph four of Article 4 of these Rules.

(4) Notwithstanding the provision of paragraph one of this Article, it shall not be mandatory to register:

- establishments that are approved by the Administration in

- obratov na področju primarne pridelave živil, ki dajejo na trg majhne količine primarnih proizvodov in izpolnjujejo pogoje za majhne količine v skladu s predpisom, ki določa majhne količine živil.

II. REGISTRACIJA OBRATA

4. člen (postopek registracije obrata)

(1) Nosilec živilske dejavnosti mora pred začetkom obratovanja oddati vlogo za registracijo obrata.

(2) Vloga iz prejšnjega odstavka se vloži elektronsko na spletni strani uprave najpozneje 24 ur pred začetkom obratovanja ali pisno najpozneje 15 dni pred začetkom obratovanja pri pristojnem območnem uradu uprave. Vloga se lahko vloži na obrazcu, ki je dostopen na spletni strani uprave.

(3) Vloga za registracijo obrata vsebuje najmanj podatke o imenu in naslovu obrata, osebno ime in naslov oziroma firmo in sedež nosilca živilske dejavnosti, davčno številko, EMŠO ali matično številko poslovnega subjekta, podatke o dejavnostih, ki jih izvaja obrat, ter opis živil in postopkov dejavnosti obrata, v primerih kmetijskih gospodarstev pa tudi KMG-MID.

(4) Uprava obrat vpiše v register obratov, ki se vodi v skladu z zakonom, ki ureja kmetijstvo, za živila živalskega izvora pa v skladu z zakonom, ki ureja veterinarska merila skladnosti.

(5) Uprava ob registraciji obrata nosilcu živilske dejavnosti po uradni dolžnosti izda izpis iz registra živilskih obratov. Od načina vložitve vloge za registracijo obrata je odvisno, ali se izpis izda elektronsko ali

- accordance with Article 6 of these Rules, establishments in the field of primary production of foods which place on the market small quantities of primary products and meet the requirements for small quantities in accordance with the regulation determining small quantities of foods.

II. REGISTRATION OF ESTABLISHMENT

Article 4 (Procedure of registration of establishment)

(1) A food business operator shall submit an application for registration of an establishment prior to the commencement of operation.

(2) The application referred to in the preceding paragraph shall be submitted electronically on the website of the Administration no later than 24 hours prior to commencement of operation or in writing no later than 15 days prior to commencement of operation to the competent regional office of the Administration. The application may be submitted using a form available on the website of the Administration.

(3) The application for registration of an establishment shall contain at least information on the name and address of the establishment, the personal name and address and/or company name and registered office of the food business operator, tax ID number, personal registration number (PRN) or registration number of the business entity, information on the activities carried out by the establishment, and a description of the food and the operational procedures of the establishment, and in the case of agricultural holdings also the KMG-MID.

(4) The Administration shall enter the establishment in the register of establishments that is kept in accordance with the Act governing agriculture and for food of animal origin in accordance with the Act governing veterinary compliance criteria.

(5) Upon registration of the establishment, the Administration shall *ex officio* issue to the food business operator an extract from the register of food establishments. The manner in which an application for

pisno. Izpis iz registra se lahko izda tudi na zahtevo nosilca živilske dejavnosti.

(6) Seznam registriranih obratov se objavi na spletnih straneh uprave.

5. člen (spremembe podatkov o obratu)

(1) Nosilec živilske dejavnosti je dolžan upravi sporočiti vse spremembe, ki so nastale v zvezi z dejavnostmi, ki se izvajajo v obratu, vključno z informacijo o začasem ali trajnem prenehanju dejavnosti najpozneje 15 dni po vsakršni spremembi teh podatkov.

(2) Ne glede na določbo prejšnjega odstavka se šteje, da je nosilec živilske dejavnosti sporočil spremembo podatkov po tem pravilniku, če je te podatke že sporočil ministrstvu, pristojnemu za kmetijstvo, gozdarstvo in prehrano, na podlagi:

- predpisa, ki ureja evidenco rejnih živali, za dejavnost reje živali,
- predpisa, ki ureja označevanje čebelnjakov in stojšč, za dejavnost, povezano s čebelarstvom,
- predpisa, ki ureja centralni register objektov akvakulture in komercialnih ribnikov ter o zbiranju podatkov o staležu in proizvodnji akvakulture, za dejavnosti pridelave ribiških proizvodov, ali
- predpisa, ki ureja izvedbo ukrepov kmetijske politike, za dejavnost pridelave kmetijskih rastlin.

III. ODOBRITEV OBRATA

6. člen (odobreni obrati)

(1) Nosilec živilske dejavnosti mora pri upravi skladno s tretjim odstavkom 6. člena Uredbe 852/2004/ES oziroma tretjim odstavkom 4.

the registration of an establishment is submitted shall determine whether the extract is issued electronically or in writing. The extract from the register may also be issued at the request of the food business operator.

(6) The list of registered establishments shall be published on the website of the Administration.

Article 5 (Changes of data on the establishment)

(1) The food business operator shall notify the Administration of any changes that have occurred regarding the activities being carried out at the establishment, including information on the temporary or permanent cessation of activities at the latest 15 days after any change of these data.

(2) Notwithstanding the provision of the preceding paragraph, food business operator shall be deemed to have communicated the change of data pursuant to these Rules, if it has already communicated such data to the ministry responsible for agriculture, forestry and food, on the basis of:

- the regulation governing livestock records for the activity of animal production;
- the regulation governing the labelling of apiaries and stalls for beekeeping-related activities;
- the regulation governing the central register of aquaculture facilities and commercial ponds and the collection of data on livestock and production from aquaculture, for the activities of production of fishery products, or
- the regulation governing the implementation of agricultural policy measures in the area of crop production.

III. APPROVAL OF ESTABLISHMENT

Article 6 (Approved establishments)

(1) A food business operator shall initiate at the Administration the procedure for approval of an establishment in which it carries out food

člena Uredbe 853/2004/ES začeti postopek odobritve obrata, v katerem izvaja živilsko dejavnost.

(2) Odobritev je obvezna za obrate, ki izvajajo dejavnosti:

- a) na podlagi odločitve, ki jo sprejme Evropska komisija;
- b) za katere so določene zahteve v Prilogi III Uredbe 853/2004/ES, razen v primeru zahtev, ki veljajo za primarno proizvodnjo prodajo na drobno;
- c) iz priloge III Uredbe 853/2004/ES, če obrat prodaje na drobno odda več kot 25 odstotkov živil živalskega izvora, ki so predmet njegovega poslovanja, drugim obratom prodaje na drobno, ki neposredno oskrbujejo končnega potrošnika.

7. člen (postopek odobritve)

(1) Vlogo za odobritev obrata nosilec živilske dejavnosti vložijo pri pristojnem območnem uradu uprave. Vloga za odobritev obrata vsebuje najmanj podatke o imenu in naslovu obrata, osebno ime in naslov oziroma firmo in sedež nosilca živilske dejavnosti, podatke o dejavnostih, ki jih izvaja obrat ter opis živil in postopkov dejavnosti obrata. Obrazec vloge za odobritev obrata je dostopen na spletnih straneh uprave.

(2) Vlogi iz prejšnjega odstavka mora biti priložen tloris obrata z vrisano opremo in tehnološkimi potmi proizvodnje.

(3) Pred odločitvijo o odobritvi je obvezen pregled obrata, ki ga opravi eden ali več uradnih veterinarjev. V primeru obratov iz točke a) drugega odstavka prejšnjega člena pregled obrata opravi eden ali več inšpektorjev za hrano območnega urada uprave.

(4) O odobritvi, neodobritvi ali pogojni odobritvi obrata odloči

business, in accordance with paragraph three of Article 6 of Regulation 852/2004/EC or paragraph three of Article 4 of Regulation 853/2004/EC.

(2) Approval shall be mandatory for establishments carrying out activities:

- a) on the basis of a decision taken by the European Commission;
- b) for which the requirements are set out in Annex III of Regulation 853/2004/EC, except in the case of requirements applicable to primary retail production;
- c) referred to in Annex III of Regulation 853/2004/EC, provided that a retail establishment supplies more than 25 percent of the food of animal origin that is the subject of its business, to other retail establishments which are directly supplying end consumers.

Article 7 (Procedure of approval)

(1) The food business operator shall submit an application for approval of the establishment to the competent regional office of the Administration. The application for approval of the establishment shall contain at least information on the name and address of the establishment, the personal name and address and/or company name and registered office of the food business operator, information on the activities being carried out by the establishment, and a description of the foods and operational procedures of the establishment. The application form for approval of the establishment shall be available on the website of the Administration.

(2) The application referred to in the preceding paragraph shall be accompanied by a floor plan of the establishment with plotted equipment and technological production routes.

(3) Prior to the decision on approval, an inspection of the establishment carried out by one or more official veterinarians shall be mandatory. In the case of establishments referred to in point (a) of paragraph two of the preceding Article, the inspection of the establishment shall be carried out by one or more food inspectors of the regional office of the Administration.

(4) The director of the regional office of the Administration shall

direktor območnega urada uprave. Odobreni in pogojno odobreni obrati se vpišejo v register obratov, ki se vodi v skladu z zakonom, ki ureja kmetijstvo, za živila živalskega izvora pa v skladu z zakonom, ki ureja veterinarska merila skladnosti. Obrat se lahko pogojno odobri za največ tri mesece. Uprava po uradni dolžnosti pogojno odobritev podaljša še za tri mesece, če se pri pregledu ugotovi, da je bil dosežen napredek, vendar obrat še ne izpolnjuje vseh predpisanih zahtev.

(5) Nosilec živilske dejavnosti, ki mu ob pregledu po preteku prvega trimesečnega obdobja uprava ugotovi, da v obratu ni bil dosežen napredek ali da tudi po preteku drugega trimesečnega roka pogojne odobritve ne izpolnjuje pogojev za odobritev obrata, lahko ponovno zaprosi za odobritev obrata za isto vrsto ali vrste dejavnosti šele po preteku 6 mesecev od izteka roka zadnje pogojne odobritve.

(6) Seznam odobrenih obratov se vodi v skladu z 31. členom Uredbe (ES) št. 882/2004 Evropskega parlamenta in Sveta z dne 29. aprila 2004 o izvajanju uradnega nadzora, da se zagotovi preverjanje skladnosti z zakonodajo o krmi in živilih ter s pravili o zdravstvenem varstvu živali in zaščiti živali (UL L št. 165 z dne 30. 4. 2004, str. 1), zadnjič spremenjene z Uredbo (EU) št. 652/2014 Evropskega parlamenta in Sveta z dne 15. maja 2014 o določbah za upravljanje odhodkov v zvezi s prehransko verigo, zdravjem in dobrobitjo živali ter v zvezi z zdravjem rastlin in rastlinskimi razmnoževalnim materialom, spremembi direktiv Sveta 98/56/ES, 2000/29/ES in 2008/90/ES, uredb (ES) št. 178/2002, (ES) št. 882/2004 in (ES) št. 396/2005 Evropskega parlamenta in Sveta, Direktive 2009/128/ES Evropskega parlamenta in Sveta in Uredbe (ES) št. 1107/2009 Evropskega parlamenta in Sveta ter razveljavitvi sklepov Sveta 66/399/EGS in 76/894/EGS ter Odločbe Sveta 2009/470/ES (UL L št. 189 z dne 27. 6. 2014, str. 1), (v nadaljnjem besedilu: Uredba 882/2004/ES) in je objavljen na spletnih straneh uprave in Evropske komisije.

(7) Iz odločbe o odobritvi morajo biti razvidni naslednji podatki:

decide on the approval, disapproval or conditional approval of the establishment. Approved and conditionally approved establishments shall be entered in the register of establishments kept in accordance with the Act governing agriculture, and for food of animal origin in accordance with the Act governing veterinary compliance criteria. The establishment may be conditionally approved for a maximum of three months. The Administration shall *ex officio* extend the conditional approval for an additional period of three months, provided that it is concluded upon inspection that progress has been made although the establishment does not yet meet all the prescribed requirements.

(5) A food business operator for which upon inspection after the expiry of the first three-month period the Administration has concluded that the establishment has not made progress, or that even after the second three-month conditional approval period it does not meet the conditions for approval of the establishment, may re-apply for approval of the establishment for the same type or types of activity only after six months have elapsed since the expiry of the period of the last conditional approval.

(6) The list of approved establishments shall be kept in accordance with Article 31 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p.1), as last amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p.1) (hereinafter: Regulation 882/2004/EC) and shall be published on the website of the Administration and of the European Commission.

(7) The following data shall be evident from the approval decision:

- a) osebno ime ali firma in naslov ali sedež nosilca živilske dejavnosti;
- b) ime in naslov odobrenega obrata;
- c) številka odobritve in
- č) odobrene dejavnosti.

(8) Nosilec živilske dejavnosti mora za spremembo podatkov iz prejšnjega odstavka vložiti vlogo na območni urad uprave. V vlogi mora biti navedeno, katere podatke želi nosilec živilske dejavnosti spremeniti in razlog za njihovo spremembo.

(9) Če obrat začasno ne izvaja ene ali več odobrenih dejavnosti in je to obdobje daljše od šestih mesecev, mora nosilec živilske dejavnosti najmanj 15 dni pred nameranim ponovnim začetkom izvajanja dejavnosti o tem obvestiti območni urad uprave. Na podlagi tega obvestila opravi uradni veterinar ali inšpektor za hrano ponovni pregled obrata, da se preveri izpolnjevanje predpisanih pogojev. Ponovni pregled obrata ni potreben, če obrat svojo dejavnost izvaja sezonsko in je obdobje, ko obrat ne izvaja nobene dejavnosti, daljše od šestih mesecev.

8. člen (pregled obrata)

(1) V postopku odobritve obrata pregled obrata obsega:

- a) ugotavljanje izpolnjevanja zahtev glede infrastrukture in opreme v obratu, ki mora biti skladna z Uredbo 852/2004/ES in Uredbo 853/2004/ES;
- b) ugotavljanje ustreznosti sistema notranjih kontrol glede na tehnološke postopke, ki se bodo izvajali v obratu.

(2) Za ugotavljanje ustreznosti sistema notranjih kontrol mora nosilec živilske dejavnosti predložiti dokumentacijo, ki obsega najmanj:

- a) program čiščenja in razkuževanja obrata in izvajanja osebne higiene;
- b) program zaščite pred škodljivci;

- a) name or company name and address or registered office of the food business operator;
- b) name and address of the approved establishment;
- c) approval number and
- č) approved activities.

(8) In order to change the data referred to in the preceding paragraph, the food business operator must submit an application to the regional office of the Administration. The application shall state which data the food business operator would like to change and the reason for the change.

(9) If the establishment temporarily does not carry out one or more of the approved activities and this period exceeds six months, the food business operator must notify the regional office of the Administration at least 15 days before the intended resumption of the activity. On the basis of this notification, the official veterinarian or food inspector shall carry out a re-inspection of the establishment to verify the fulfilment of the prescribed conditions. A re-inspection of the establishment shall not be necessary provided that the establishment is carrying out its activity on a seasonal basis and the period when the establishment is not carrying out any activity is longer than six months.

Article 8 (Inspection of establishment)

(1) In the procedure of approval of an establishment, an inspection of the establishment shall consist of:

- a) establishing fulfilment of the requirements regarding the infrastructure and equipment in the establishment, which shall be in compliance with Regulation 852/2004/EC and Regulation 853/2004/EC;
- b) establishing the adequacy of the internal control system regarding the technological procedures being carried out at the establishment.

(2) In order to establish the adequacy of the internal control system, the food business operator shall provide documentation, consisting at a minimum of:

- a) the programme of cleaning and disinfecting the establishment and performing personal hygiene;
- b) pest control programme;

- c) program nadzora pitne vode;
- č) dokaze o zdravju delavcev v skladu s predpisom, ki ureja zdravstvene zahteve za osebe, ki pri delu v proizvodnji in prometu z živili prihajajo v stik z živili;
- d) program izobraževanja delavcev;
- e) program ugotavljanja izpolnjevanja mikrobioloških kriterijev, določenih z Uredbo Komisije (ES) št. 2073/2005 z dne 15. novembra 2005 o mikrobioloških merilih za živila (UL L št. 338 z dne 22. 12. 2005, str. 1), zadnjič spremenjene z Uredbo Komisije (EU) št. 217/2014 z dne 7. marca 2014 o spremembi Uredbe (ES) št. 2073/2005 v zvezi s salmonelo v klavnih trupih prašičev (UL L št. 69 z dne 8. 3. 2014, str. 93);
- f) program postopkov notranjega nadzora po sistemu oziroma po načelih ugotavljanja kritičnih točk v procesu proizvodnje (HACCP), v skladu s 5. členom Uredbe 852/2004/ES;
- g) program zagotavljanja sledljivosti surovin in živil;
- h) program ravnanja z ostanki živil, neužitnimi stranskimi produkti in drugimi odpadki, vključno z živalskimi stranskimi proizvodi.

(3) Programi iz prejšnjega odstavka morajo vsebovati opis del, postopkov in pogostnost izvajanja. Programi morajo vsebovati tudi korektivne ukrepe za primere ugotovljenih neskladij v procesu proizvodnje.

(4) Ne glede na določbo drugega odstavka tega člena nosilcu živilske dejavnosti ni treba predložiti dokumentacije o ustreznosti sistema notranjih kontrol, če izvaja sistem notranjih kontrol na podlagi smernic dobre prakse za higieno oziroma za uporabo načel HACCP iz 10. člena tega pravilnika.

9. člen **(začasen in trajen odvzem odobritve)**

(1) Če uradni veterinar ali inšpektor za hrano obratu v obdobju 12 mesecev trikrat izreče ukrep iz točke (e) drugega odstavka 54. člena Uredbe 882/2004/ES, direktor območnega urada uprave obratu z odločbo začasno odvzame odobritev za obdobje enega meseca.

- c) drinking water monitoring programme;
- č) evidence of the health of employees in accordance with the regulation governing the health requirements for persons coming into contact with foods during work in the production and marketing of foods;
- d) employment education programme;
- e) programme of establishing compliance with the microbiological criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p.1), as last amended by Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards Salmonella in pig carcasses (OJ L 69, 8.3.2014, p.93);
- f) programme of internal control procedures according to the system and/or according to the principles of identification of critical points in the production process (HACCP), in accordance with Article 5 of Regulation 852/2004 / EC;
- g) programme for ensuring traceability of raw materials and foodstuffs;
- h) programme of the management of food residues, non-edible by-products and other waste, including animal by-products.

(3) The programmes referred to in the preceding paragraph shall contain a description of the works, procedures and frequency of implementation. The programmes shall also contain corrective measures for cases of established discrepancies in the production process.

(4) Notwithstanding the provision of paragraph two of this Article, it shall not be mandatory for the food business operator to provide documentation on the adequacy of the internal control system provided that it implements the internal control system based on guides to good practice for hygiene and/or for the application of the HACCP principles referred to in Article 10 of these Rules.

Article 9 **(Temporary and permanent withdrawal of approval)**

(1) Where the official veterinarian or food inspector imposes on an establishment three times within 12 months the measure referred to in point (e) of paragraph two of Article 54 of Regulation 882/2004/EC, the director of the regional office of the Administration shall by decision

(2) Obratu, ki mu je bila v obdobju 24 mesecev trikrat začasno odzeta odobritev za obdobje enega meseca, direktor območnega urada uprave odobritev trajno odvzame.

(3) V primeru iz prejšnjega odstavka lahko obrat ponovno vloži vlogo za odobritev obrata po preteku šestih mesecev od dokončnosti odločbe o odvzemu odobritve.

IV. SMERNICE DOBRE HIGIENSKE PRAKSE

10. člen (smernice)

Nosilci živilske dejavnosti lahko vzpostavijo in izvajajo sisteme notranjih kontrol na podlagi smernic dobre prakse za higieno oziroma za uporabo načel HACCP, če jih je kot ustrezne za predvideno vrsto živilske dejavnosti ocenila uprava v skladu s tretjim odstavkom 8. člena Uredbe 852/2004/ES. Smernice dobre higienske prakse, ki niso posodobljene s trenutno veljavno nacionalno in evropsko zakonodajo, se lahko uporabljajo le v delu oziroma delih, v katerih je njihova vsebina skladna kljub spremembi zakonodaje.

V. PREHODNE IN KONČNE DOLOČBE

11. člen (prehodne določbe)

(1) Postopek odobritve obrata, ki se je začel pred uveljavitvijo tega pravilnika v skladu s Pravilnikom o obratih na področju živil živalskega izvora (Uradni list RS, št. 51/06, 66/07 in 27/09 – popr.), se nadaljuje v skladu s tem pravilnikom.

(2) Obrati, ki so na dan uveljavitve tega pravilnika registrirani

temporarily withdraw approval for a period of one month.

(2) An establishment that has its approval temporarily withdrawn three times within 24 months shall have its approval withdrawn permanently by the director of the regional office of the Administration.

(3) In the case referred to in the preceding paragraph, the establishment may re-apply for approval of the establishment after six months have elapsed from the finality of the decision withdrawing the approval.

IV. GUIDES TO GOOD PRACTICE FOR HYGIENE

Article 10 (Guides)

Food business operators may establish and implement internal control systems based on guides to good practice for hygiene and/or for the application of the HACCP principles, provided that they have been assessed by the Administration as appropriate for the intended type of food business in accordance with paragraph three of Article 8 of Regulation 852/2004/EC. Guides to good practice for hygiene which are not up to date with current national and European legislation, may only be applied within the scope in which their content is compliant, despite the amended legislation.

V. TRANSITIONAL AND FINAL PROVISIONS

Article 11 (Transitional provisions)

(1) The procedure for approval of an establishment initiated prior to the entry into force of these Rules in accordance with the Rules on establishments in the field of foods of animal origin (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 51/06, 66/07 and 27/09 – corr.) shall continue in accordance with these Rules.

(2) Establishments that are registered and/or approved in

oziroma odobreni skladno z določbami Pravilnika o obratih na področju živil živalskega izvora (Uradni list RS, št. 51/06, 66/07 in 27/09 – popr.) ali Pravilnika o registraciji obratov primarnih proizvajalcev živil in krme rastlinskega izvora (Uradni list RS, št. 79/06 in 45/08 – Zkme-1), se štejejo za registrirane oziroma odobrene po tem pravilniku.

(3) Ne glede na določbo drugega odstavka 4. člena tega pravilnika lahko nosilci živilske dejavnosti do 31. decembra 2015 vlogo za registracijo obratov oddajo le v pisni obliki.

(4) Izpis iz registra živilskih obratov se do datuma, določenega v prejšnjem odstavku, izdaja samo v pisni obliki.

12. člen (prenehanje uporabe)

(1) Z dnem uveljavitve tega pravilnika preneha veljati Pravilnik o obratih na področju živil živalskega izvora (Uradni list RS, št. 51/06, 66/07 in 27/09 – popr.).

(2) Z dnem uveljavitve tega pravilnika se prenehajo uporabljati določbe 1., 2., 3., 5. in 6. člena Pravilnika o registraciji obratov primarnih proizvajalcev živil in krme rastlinskega izvora (Uradni list RS, št. 79/06 in 45/08 – Zkme-1), v delih, ki se nanašajo na živila rastlinskega izvora.

13. člen (uveljavitev)

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

Št. 007-381/2014
Ljubljana, dne 24. decembra 2014

accordance with the provisions of the Rules on establishments in the field of foods of animal origin (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 51/06, 66/07 and 27/09 – corr.) or the Rules on registration of primary producers' establishments of foods and feed of plant origin (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 79/06 and 45/08 – Zkme-1) shall be considered as registered and/or approved under these Rules.

(3) Notwithstanding the provision of paragraph two of Article 4 of these Rules, up until 31 December 2015 food business operators may submit an application for registration of establishments in writing only.

(4) Up until the date specified in the preceding paragraph, an extract from the register of food-processing establishments shall be issued in writing only.

Article 12 (End of application)

(1) On the day these Rules enter into force, the Rules on establishments in the field of foods of animal origin (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 51/06, 66/07 and 27/09 – corr.) shall cease to be in force.

(2) On the day these Rules enter into force, the provisions of Articles 1, 2, 3, 5, and 6 of the Rules on registration of primary producers' establishments of foods and feed of plant origin (Official Gazette of the Republic of Slovenia [*Uradni list RS*], Nos 79/06 and 45/08 – Zkme-1) shall cease to apply as regards the parts relating to foods of plant origin.

Article 13 (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.

No. 007-381/2014
Ljubljana, 24 December 2014

EVA 2014-2330-0016

Mag. Dejan Židan l.r.
minister
za kmetijstvo, gozdarstvo in prehrano

EVA 2014-2330-0016

Mag. Dejan Židan m.p.
Minister
of Agriculture, Forestry and Food