
Sistemi vodenja varnosti živil – Zahteve za vsako organizacijo v prehranski verigi (ISO 22000:2005)

Food safety management systems – Requirements for any organization in the food chain (ISO 22000:2005)

Systèmes de management de la sécurité des denrées alimentaires – Exigences pour tout organisme appartenant à la chaîne alimentaire (ISO 22000:2005)

Managementsysteme für die Lebensmittelsicherheit – Anforderungen an Organisationen in der gesamten Lebensmittelkette (ISO 22000:2005)

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NACIONALNI UVOD

Standard SIST EN ISO 22000 (sl,en), Sistemi vodenja varnosti živil – Zahteve za vsako organizacijo v prehranski verigi (ISO 22000:2005), 2005, ima status slovenskega standarda in je enakovreden evropskemu standardu EN ISO 22000 (en), Food safety management systems – Requirements for any organization in the food chain (ISO 22000:2005), 2005-09-01.

NACIONALNI PREDGOVOR

Evropski standard EN ISO 22000:2005 je pripravil tehnični odbor ISO/TC 34 Živilski proizvodi v sodelovanju s tehničnim odborom Evropskega komiteja za standardizacijo CEN/SS C01 Živilski proizvodi.

Slovenski standard SIST EN ISO 22000:2005 je prevod evropskega standarda EN ISO 22000:2005. Ob sporu zaradi besedila slovenskega prevoda v tem standardu je odločilen izvorni evropski standard v angleškem jeziku. Slovensko izdajo standarda je pripravil tehnični odbor SIST/TC KŽP Kmetijski pridelki in živilski proizvodi.

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SIST EN ISO 9000 (sl,en) Sistemi vodenja kakovosti – Osnove in slovar

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- Povsod, kjer se v besedilu standarda uporablja izraz »evropski standard« oziroma »mednarodni standard«, v SIST EN ISO 22000:2005 to pomeni »slovenski standard«.
- Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.
- Ta nacionalni dokument je enakovreden EN ISO 22000:2005 in je objavljen z dovoljenjem

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Slovenska izdaja

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European Committee for Standardization
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Centralni sekretariat: Rue de Stassart 36, B-1050 Bruselj

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Predgovor

Mednarodna organizacija za standardizacijo (ISO) je svetovna zveza nacionalnih organov za standarde (članov ISO). Mednarodne standarde ponavadi pripravljajo tehnični odbori ISO. Vsak član, ki želi delovati na določenem področju, za katero je bil ustanovljen tehnični odbor, ima pravico biti zastopan v tem odboru. Pri delu sodelujejo tudi vladne in nevladne mednarodne organizacije, povezane z ISO. V vseh zadevah, ki so povezane s standardizacijo na področju elektrotehnike, ISO tesno sodeluje z Mednarodno elektrotehniško komisijo (IEC).

Osnutki mednarodnih standardov so pripravljeni v skladu s pravili, podanimi v drugem delu Direktiv ISO/IEC.

Poglavitna naloga tehničnih odborov je priprava mednarodnih standardov. Osnutki mednarodnih standardov, ki jih sprejmejo tehnični odbori, se pošljejo vsem članom v glasovanje. Za objavo mednarodnega standarda je treba pridobiti soglasje najmanj 75 odstotkov članov, ki se udeležijo glasovanja.

Opozoriti je treba na možnost, da so nekateri elementi tega mednarodnega standarda lahko predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

ISO 22000 je pripravil tehnični odbor ISO/TC 34 Živilski proizvodi.

Uvod

Varnost živil je povezana s prisotnostjo dejavnikov tveganja v živilih v času, ko uporabnik to živilo zaužije. Ker se dejavniki tveganja lahko pojavijo na vsaki stopnji prehranske verige, je slednje treba v celoti ustrezno nadzirati. Varnost živil je torej zagotovljena, če so povezana prizadevanja vseh, ki sodelujejo v prehranski verigi.

V prehransko verigo so vključene najrazličnejše organizacije: proizvajalci krme in primarni proizvajalci, predelovalci živil, prevozniki in izvajalci pri skladiščenju, podizvajalci, trgovci, prodajalci (skupaj z drugimi vključenimi organizacijami, kot so izdelovalci opreme, proizvajalci embalaže in pakirnih materialov, čistil, aditivov in sestavin). Vključeni so tudi dobavitelji servisnih storitev.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22000 was prepared by Technical Committee ISO/TC 34, Food products.

Introduction

Food safety is related to the presence of food-borne hazards in food at the point of consumption (intake by the consumer). As the introduction of food safety hazards can occur at any stage of the food chain, adequate control throughout the food chain is essential. Thus, food safety is ensured through the combined efforts of all the parties participating in the food chain.

Organizations within the food chain range from feed producers and primary producers through food manufacturers, transport and storage operators and subcontractors to retail and food service outlets (together with inter-related organizations such as producers of equipment, packaging material, cleaning agents, additives and ingredients). Service providers are also included.

Ta mednarodni standard opredeljuje zahteve za sistem vodenja varnosti živil, ki s povezovanjem naslednjih splošno znanih ključnih elementov zagotovi varnost živil v vsej prehranski verigi, prav do končne točke potrošnje:

- vmesne povezave,
- vodenje sistema,
- prerekvizitni programi,
- načela HACCP.

Povezovanje v vsej prehranski verigi je nujno za zagotovitev, da so vsi pomembni dejavniki tveganja prepoznani in ustrezno nadzorovani prav na vsaki stopnji prehranske verige, kar vključuje povezave navzgor in navzdol v verigi. Povezave med odjemalci in dobavitelji zaradi prepoznanih dejavnikov tveganja in kontrolnih ukrepov pripomorejo k jasni opredelitvi uporabnikovih in dobaviteljevih zahtev (glede na možnost in potrebe po teh zahtevah in njihov vpliv na končni proizvod).

Nujno je tudi prepoznavanje vloge in položaja organizacije v prehranski verigi, saj lahko omogoči uspešne medsebojne povezave v vsej verigi, da so končnemu uporabniku dobavljeni varni živilski proizvodi. Na sliki 1 je prikazan primer komunikacijskih povezav med zainteresiranimi v prehranski verigi.

Najuspešnejši sistemi varnosti živil so vzpostavljeni, delujejo in se posodablajo v okviru strukturiranega sistema vodenja ter so vključeni v najširše vodstvene aktivnosti v organizaciji. To zagotavlja organizacijam in zainteresiranim udeležencem največjo korist. Ta mednarodni standard je usklajen z ISO 9001 prav zato, da se poveča vzajemno delovanje obeh standardov. Navzkrižni prikaz zahtev tega mednarodnega standarda in ISO 9001 je naveden v dodatku A.

Ta mednarodni standard se lahko uporablja neodvisno od drugih standardov vodenja. Njegovo izvajanje lahko poteka vzporedno ali pa tako, da je vključen v že obstoječe zahteve za vodenje. Organizacije pa lahko uporabijo obstoječe sisteme vodenja, da vzpostavijo sistem vodenja varnosti živil, ki je skladen z zahtevami tega mednarodnega standarda.

Ta mednarodni standard povezuje načela sistema analize tveganja in kritičnih kontrolnih točk (HACCP) in uporabo stopenj, ki jih je razvila komisija Codex Alimentarius

This International Standard specifies the requirements for a food safety management system that combines the following generally recognized key elements to ensure food safety along the food chain, up to the point of final consumption:

- interactive communication;
- system management;
- prerequisite programmes;
- HACCP principles.

Communication along the food chain is essential to ensure that all relevant food safety hazards are identified and adequately controlled at each step within the food chain. This implies communication between organizations both upstream and downstream in the food chain. Communication with customers and suppliers about identified hazards and control measures will assist in clarifying customer and supplier requirements (e.g. with regard to the feasibility and need for these requirements and their impact on the end product).

Recognition of the organization's role and position within the food chain is essential to ensure effective interactive communication throughout the chain in order to deliver safe food products to the final consumer. An example of the communication channels among interested parties of the food chain is shown in Figure 1.

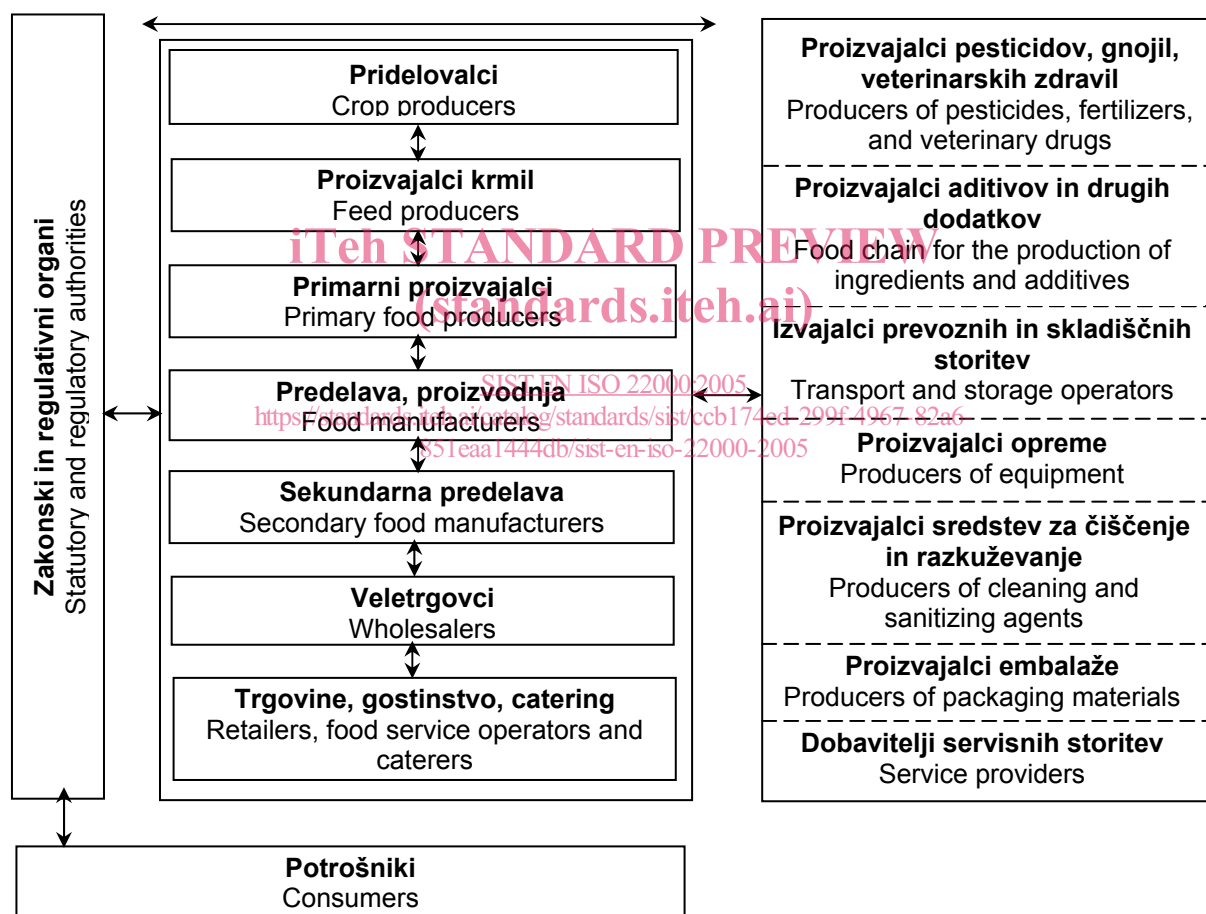
The most effective food safety systems are established, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties. This International Standard has been aligned with ISO 9001 in order to enhance the compatibility of the two standards. Cross-references between this International Standard and ISO 9001 are provided in Annex A.

This International Standard can be applied independently of other management system standards. Its implementation can be aligned or integrated with existing related management system requirements, while organizations may utilize existing management system(s) to establish a food safety management system that complies with the requirements of this International Standard.

This International Standard integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system and application steps developed by the Codex Alimentarius

Commission. S pomočjo zahtev presoje povezuje načrt HACCP s prerekvizitnimi programi. Analiza tveganja je ključ do uspešnega sistema vodenja varnosti živil, saj prav izvedba analize tveganja pomaga pri organiziranju znanja, potrebnega za vzpostavitev uspešne kombinacije kontrolnih ukrepov. Ta mednarodni standard zahteva, da so prepoznani in določeni vsi dejavniki tveganja, katerih pojav se v prehranski verigi upravičeno pričakuje, vključno s tistimi, ko so lahko povezani z vrsto procesa ali prostori. Na ta način zagotavlja orodje, s katerim se določi in dokumentira, zakaj mora organizacija nekatere prepoznane dejavnike tveganja nadzorovati, drugih pa ne.

Commission. By means of auditable requirements, it combines the HACCP plan with prerequisite programmes (PRPs). Hazard analysis is the key to an effective food safety management system, since conducting a hazard analysis assists in organizing the knowledge required to establish an effective combination of control measures. This International Standard requires that all hazards that may be reasonably expected to occur in the food chain, including hazards that may be associated with the type of process and facilities used, are identified and assessed. Thus it provides the means to determine and document why certain identified hazards need to be controlled by a particular organization and why others need not.



OPOMBA: Slika ne prikazuje medsebojnih komunikacij vzdolž in križem prehranske verige, ki obide neposredne dobavitelje in potrošnike.

NOTE The figure does not show the type of interactive communications along and across the food chain that by-pass immediate suppliers and customers.

Slika 1: Primer komunikacije znotraj prehranske verige
Figure 1 – Example of communication within the food chain

Med analizo tveganja organizacija določi strategijo, ki jo mora izvajati, da s kombinacijo prekrivnih programov, delujočih prekrivnih programov in načrtom HACCP zagotovi nadzor nad dejavniki tveganja.

Povezave med načeli HACCP komisije Codex Alimentarius in aplikacijskimi koraki (glej referenco 11) ter tem mednarodnim standardom so opredeljene v dodatku B.

Za lažjo uporabo je ta mednarodni standard pripravljen kot standard za presojo. Vendar pa se posamezne organizacije svobodno odločajo o potrebnih metodah in pristopih za izpolnitev zahtev tega mednarodnega standarda. Napotki za pomoč posameznim organizacijam pri izvajanju tega mednarodnega standarda in za njegovo uporabo so opredeljeni v ISO/TS 22004.

Ta mednarodni standard se nanaša samo na tiste vidike, ki zadevajo varnost živil. A enak pristop, kot je določen s tem mednarodnim standardom, se lahko uporabi pri oblikovanju in odzivanju na druge specifične vidike glede živil (npr. etični vidik in zavedanje potrošnika).

Ta mednarodni standard dovoljuje organizaciji (kot je majhna in/ali manj razvita organizacija), da izvaja kombinacijo kontrolnih ukrepov, ki je bila razvita zunaj organizacije.

Cilj tega mednarodnega standarda je na globalni ravni uskladiti zahteve sistemov vodenja za zagotavljanje varnih živil za podjetja znotraj prehranske verige. Posebej je namenjen temu, da ga uporabljajo organizacije, ki želijo bolj osredotočen, povezan in integriran sistem vodenja varnosti živil, kot to splošno zahteva zakonodaja. Zahteva, da se organizacija spozna z vsemi zakonskimi in regulativnimi zahtevami glede varnosti živil skozi lasten sistem vodenja za zagotavljanje varnih živil.

During hazard analysis, the organization determines the strategy to be used to ensure hazard control by combining the PRP(s), operational PRP(s) and the HACCP plan.

Cross-references between the Codex Alimentarius Commission HACCP principles and application steps (see Reference [11]) and this International Standard are provided in Annex B.

To facilitate the application of this International Standard, it has been developed as an auditable standard. However, individual organizations are free to choose the necessary methods and approaches to fulfil the requirements of this International Standard. To assist individual organizations with the implementation of this International Standard, guidance on its use is provided in ISO/TS 22004.

This International Standard is intended to address aspects of food safety concerns only. The same approach as provided by this International Standard can be used to organize and respond to other food specific aspects (e.g. ethical issues and consumer awareness).

This International Standard allows an organization (such as a small and/or less developed organization) to implement an externally developed combination of control measures.

The aim of this International Standard is to harmonize on a global level the requirements for food safety management for businesses within the food chain. It is particularly intended for application by organizations that seek a more focused, coherent and integrated food safety management system than is normally required by law. It requires an organization to meet any applicable food safety related statutory and regulatory requirements through its food safety management system.

Sistemi vodenja varnosti živil – Zahteve za vsako organizacijo v prehranski verigi

1 Predmet standarda

Ta mednarodni standard navaja zahteve za sistem vodenja varnosti živil, ko organizacija v prehranski verigi dokazuje, da je sposobna nadzorovati dejavnike tveganja in s tem zagotoviti varnost živila v času njegovega zaužitja.

Primeren je za vse organizacije ne glede na velikost, ki so kakorkoli vključene v prehransko verigo in želijo izvajati sisteme, ki stalno zagotavljajo varnost izdelkov. Pomen katerekoli zahteve tega mednarodnega standarda je lahko izpopolnjen z uporabo notranjih ali zunanjih virov.

Ta mednarodni standard določa zahteve, ki organizaciji omogočajo:

- a) načrtovati, izvajati, voditi, vzdrževati in posodabljeni sistem vodenja varnosti živil, s katerim zagotovi izdelke, ki so glede na namen uporabe varni za uživanje;
- b) prikazati skladnost z ustreznimi zakonskimi in regulativnimi zahtevami za varnost živil;
- c) vrednotiti in oceniti zahteve kupcev in prikazati skladnost z medsebojno usklajenimi zahtevami kupcev glede varnosti živil, da bi se povečalo njihovo zadovoljstvo;
- d) uspešno povezati vidike varnosti živil svojih dobaviteljev, odjemalcev in vključenih zainteresiranih strank v prehranski verigi;
- e) zagotavljati, da usklajuje določeno politiko zagotavljanja varnih živil;
- f) prikazati tako usklajenost pomembnim zainteresiranim strankam in
- g) pridobiti certifikacijo ali registracijo svojega sistema vodenja varnosti živil pri zunanji organizaciji ali izvesti samoocenjevanje ali samodeklariranje skladnosti s tem mednarodnim standardom.

Vse zahteve tega mednarodnega standarda so splošne in so namenjene vsem organizacijam v prehranski verigi ne glede na velikost in

Food safety management systems – Requirements for any organization in the food chain

1 Scope

This International Standard specifies requirements for a food safety management system where an organization in the food chain needs to demonstrate its ability to control food safety hazards in order to ensure that food is safe at the time of human consumption.

It is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain and want to implement systems that consistently provide safe products. The means of meeting any requirements of this International Standard can be accomplished through the use of internal and/or external resources.

This International Standard specifies requirements to enable an organization

- a) to plan, implement, operate, maintain and update a food safety management system aimed at providing products that, according to their intended use, are safe for the consumer,
- b) to demonstrate compliance with applicable statutory and regulatory food safety requirements,
- c) to evaluate and assess customer requirements and demonstrate conformity with those mutually agreed customer requirements that relate to food safety, in order to enhance customer satisfaction,
- d) to effectively communicate food safety issues to their suppliers, customers and relevant interested parties in the food chain,
- e) to ensure that the organization conforms to its stated food safety policy,
- f) to demonstrate such conformity to relevant interested parties, and
- g) to seek certification or registration of its food safety management system by an external organization, or make a self-assessment or self-declaration of conformity to this International Standard.

All requirements of this International Standard are generic and are intended to be applicable to all organizations in the food chain regardless of

kompleksnost. To vključuje vse organizacije, ki so neposredno ali posredno vključene v enega ali več členov prehranske verige. Med organizacijami, ki so neposredno vključene, so proizvajalci krme, kmetije, proizvajalci sestavin, proizvajalci živil, trgovci, izvajalci strežbe hrane, oskrbe z živili, izvajalci čiščenja in sanitacije, prevoza, skladiščenja in distribucije. Med drugimi organizacijami, ki so posredno vključene, so dobavitelji opreme, čistilnih in sanitacijskih sredstev, embalaže in drugih materialov, ki vstopajo v stik z živili.

Ta mednarodni standard omogoča majhnim in/ali manj razvitim organizacijam (npr. malim kmetijam, distributerjem, trgovcem ali strežbi), da izvajajo kombinacijo kontrolnih ukrepov, ki je bila razvita z zunanjo pomočjo.

OPOMBA: Napotki za uporabo tega mednarodnega standarda so podani v ISO/TS 22004.

size and complexity. This includes organizations directly or indirectly involved in one or more steps of the food chain. Organizations that are directly involved include, but are not limited to, feed producers, harvesters, farmers, producers of ingredients, food manufacturers, retailers, food services, catering services, organizations providing cleaning and sanitation services, transportation, storage and distribution services. Other organizations that are indirectly involved include, but are not limited to, suppliers of equipment, cleaning and sanitizing agents, packaging material, and other food contact materials.

This International Standard allows an organization, such as a small and/or less developed organization (e.g. a small farm, a small packer-distributor, a small retail or food service outlet), to implement an externally developed combination of control measures.

NOTE Guidance on the application of this International Standard is given in ISO/TS 22004.

2 Zveza z drugimi standardi

V nadaljevanju navedeni dokumenti so za uporabo tega dokumenta nujni. Pri datiranem sklicevanju se uporablja samo navedena izdaja; pri nedatiranem sklicevanju se uporablja zadnja izdaja dokumenta (vključno z morebitnimi spremembami).

ISO 9000:2000, Sistemi vodenja kakovosti – Osnove in slovar

3 Izrazi in definicije

V tem mednarodnem standardu se uporabljajo izrazi in definicije, ki so podani v standardu ISO 9000, in tisti, ki so navedeni v nadaljevanju.

Za lažjo uporabo tega mednarodnega standarda so nekaterim definicijam iz ISO 9000 dodane opombe, ki so uporabne le v posameznem primeru.

OPOMBA: Izrazi niso definirani, če so obdržali običajno definicijo iz slovarja. Poudarjeni tisk definicije pomeni navzkrižno referenco za drug izraz, uporabljen v tem členu, številka reference za izraz pa je navedena v oklepaju.

3.1 varnost živil

(pojem) zagotovilo, da živilo, ki je pripravljeno in/ali zaužito glede na nameravano uporabo, ne

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, Quality management systems - Fundamentals and vocabulary

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

For the convenience of the users of this International Standard, some of the definitions in ISO 9000 are quoted with added notes that are applicable only to this special application.

NOTE Terms are not defined where they retain their normal dictionary definition. Where bold type is used in a definition, this indicates a cross-reference to another term defined in this clause, and the number reference for the term is given in parentheses.

3.1 food safety

concept that food will not cause harm to the consumer when it is prepared and/or eaten

ogroža zdravja potrošnika

OPOMBA 1: Povzeto iz reference (11).

OPOMBA 2: Varnost živil se navezuje na pojav dejavnikov tveganja (3.3) in ne vključuje drugih povezanih zdravstvenih vidikov, na primer podhranjenosti.

3.2 prehranska veriga

zaporedje stopenj in postopkov proizvodnje, predelave, distribucije, skladiščenja in rokovanja z živili in njihovimi sestavinami od primarne proizvodnje do porabe

OPOMBA 1: To vključuje proizvodnjo krme za živali, namenjene za proizvodnjo živil.

OPOMBA 2: Prehranska veriga vključuje proizvodnjo materialov, ki prihajajo v stik z živili ali s surovinami.

3.3 dejavnik tveganja

biološki, kemični ali fizikalni dejavnik v živilu ali stanje živila, ki lahko ogroža zdravje

OPOMBA 1: Povzeto iz reference (11).

OPOMBA 2: Izraz "tveganje" se ne sme zamenjati z izrazom "tveganost", ki v kontekstu varnosti živil pomeni funkcijo verjetnosti pojava, ki ogroža zdravje ljudi (npr. pojav bolezni/obolenja), in resnosti tega vpliva (smrt, zdravljenje, odsotnost z dela ...) ob izpostavljenosti / ~~st. določenemu tveganju~~ (npr. smrtnost, hospitalizacija, odsotnost z dela ...) ob izpostavljenosti. Tveganost (ang. risk) je v ISO/IEC Guide 51 opredeljena kot kombinacija verjetnosti pojava nevarnosti in resnosti te nevarnosti.

OPOMBA 3: Dejavniki tveganja vključujejo alergene.

OPOMBA 4: Pri krmi in sestavinah krme so pomembni dejavniki tveganja tisti, ki so lahko prisotni v krmi in/ali na njej in so lahko nato naknadno vneseni v živila pri hranjenju živali s krmo in tako lahko ogrožajo zdravje ljudi. Razen tistih postopkov, ki so neposredno povezani z ravnanjem s krmo ali z živili (proizvajalci embalažnih materialov, čistil ...), so pomembni dejavniki tveganja tudi tisti, ki so lahko posredno ali neposredno preneseni v živila pri nameravani uporabi dobavljenih proizvodov in/ali servisiranju in tako lahko ogrozijo zdravje ljudi.

3.4 politika varnosti živil

splošni cilji in usmeritve organizacije, vezani na varnost živil, ki jih formalno izrazi najvišje vodstvo

3.5 končni proizvod

proizvod, ki ne gre več v nadaljnjo predelavo in spremembo v organizaciji

according to its intended use

NOTE 1 Adapted from Reference [11].

NOTE 2 Food safety is related to the occurrence of food safety hazards (3.3) and does not include other human health aspects related to, for example, malnutrition.

3.2 food chain

sequence of the stages and operations involved in the production, processing, distribution, storage and handling of a food and its ingredients, from primary production to consumption

NOTE 1 This includes the production of feed for food-producing animals and for animals intended for food production.

NOTE 2 The food chain also includes the production of materials intended to come into contact with food or raw materials.

3.3 food safety hazard

biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect

NOTE 1 Adapted from Reference [11].

NOTE 2 The term "hazard" is not to be confused with the term "risk" which, in the context of food safety, means a function of the probability of an adverse health effect (e.g. becoming diseased) and the severity of that effect (death, hospitalization, absence from work, etc.) when exposed to a specified hazard. Risk is defined in ISO/IEC Guide 51 as the combination of the probability of occurrence of harm and the severity of that harm.

NOTE 3 Food safety hazards include allergens.

NOTE 4 In the context of feed and feed ingredients, relevant food safety hazards are those that may be present in and/or on feed and feed ingredients and that may subsequently be transferred to food through animal consumption of feed and may thus have the potential to cause an adverse human health effect. In the context of operations other than those directly handling feed and food (e.g. producers of packaging materials, cleaning agents, etc.), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food because of the intended use of the provided products and/or services and thus can have the potential to cause an adverse human health effect.

3.4 food safety policy

overall intentions and direction of an organization related to food safety (3.1) as formally expressed by top management

3.5 end product

product that will undergo no further processing or transformation by the organization

OPOMBA: Proizvod, ki gre skozi nadaljnjo predelavo ali preoblikovanje v drugi organizaciji, je končni proizvod v prvi organizaciji in surovina ali sestavina v drugi organizaciji.

NOTE A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.

3.6 diagram poteka

shematičen in sistematičen prikaz zaporedja in medsebojnega vpliva stopenj

3.6 flow diagram

schematic and systematic presentation of the sequence and interactions of steps

3.7 kontrolni ukrep

(varnost živil) postopek ali aktivnost, ki se lahko izvede za preprečitev ali izločitev dejavnika tveganja ali njegovo zmanjšanje na sprejemljivo raven

3.7 control measure

(food safety) action or activity that can be used to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level

OPOMBA: Povzeto iz reference (11).

NOTE Adapted from Reference [11].

3.8 prerekvizitni programi (PRP)

(varnost živil) osnovni pogoji in aktivnosti, ki so potrebni za vzdrževanje higienskega okolja v celotni prehranski verigi (3.2), primerne za proizvodnjo, ravnanje in zagotavljanje varnih končnih proizvodov (3.5) in varne hrane za prehrano ljudi

3.8 PRP prerequisite programme

(food safety) basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain (3.2) suitable for the production, handling and provision of safe end products (3.5) and safe food for human consumption

OPOMBA: Potrebni prerekvizitni programi so odvisni od področja prehranske verige, v kateri organizacija deluje, in od vrste organizacije (glej dodatek C). Primeri enakovrednih izrazov so: dobra kmetijska praksa (DKP), dobra veterinarska praksa (DVP), dobra proizvodna praksa (DPP), dobra higienska praksa (DHP), dobra trgovinska praksa (DTP).

NOTE The PRPs needed depend on the segment of the food chain in which the organization operates and the type of organization (see Annex C). Examples of equivalent terms are: Good Agricultural Practice (GAP), Good Veterinarian Practice (GVP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP), Good Production Practice (GPP), Good Distribution Practice (GDP) and Good Trading Practice (GTP).

3.9 delujoči PRP, delujoči prerekvizitni programi

PRP (3.8), določeni z analizo tveganja kot bistveni za nadzorovanje verjetnosti vnosa dejavnikov tveganja in s tem onesnaževanja ali razširjanja dejavnikov tveganja (3.3) v proizvodu(-ih) ali v okolju predelave

3.9 operational PRP operational prerequisite programme

PRP (3.8) identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards (3.3) to and/or the contamination or proliferation of food safety hazards in the product(s) or in the processing environment

3.10 KKT, kritična kontrolna točka

(varnost živil) stopnja, na kateri je lahko uporabljen nadzor, ki je bistven za preprečitev ali izločitev dejavnika tveganja (3.3) ali za zmanjšanje le-tega na sprejemljivo raven

3.10 CCP critical control point

<food safety> step at which control can be applied and is essential to prevent or eliminate a food safety hazard (3.3) or reduce it to an acceptable level

OPOMBA: Povzeto iz reference (11).

NOTE Adapted from Reference [11].

3.11 kritična meja

kriterij, ki ločuje sprejemljivo od nesprejemljivega

3.11 critical limit

criterion which separates acceptability from unacceptability

<p>OPOMBA 1: Prirejeno iz reference (11).</p>	<p>NOTE 1 Adapted from Reference [11].</p>
<p>OPOMBA 2: Kritične meje so vpeljane, da opredelijo, ali KKT (3.10) ostajajo nadzorovane. Če je kritična meja presežena ali prekršena, so proizvodi obravnavani, kot da potencialno niso varni.</p>	<p>NOTE 2 Critical limits are established to determine whether a CCP (3.10) remains in control. If a critical limit is exceeded or violated, the products affected are deemed to be potentially unsafe.</p>
<p>3.12 monitoring izvajanje načrtovanih zaporedij opazovanj ali merjenj, da se oceni, ali kontrolni ukrepi (3.7) delujejo tako, kot je načrtovano</p>	<p>3.12 monitoring conducting a planned sequence of observations or measurements to assess whether control measures (3.7) are operating as intended</p>
<p>3.13 korekcija ukrep za odpravo ugotovljene neskladnosti</p> <p>[ISO 9000:2000, definicija 3.6.6]</p> <p>OPOMBA 1: V tem mednarodnem standardu se korekcija navezuje na ravnanje s proizvodi, ki potencialno niso varni, in zato lahko pride do povezave s korektivnim ukrepom (3.14).</p> <p>OPOMBA 2: Korekcija je lahko npr. ponovna predelava, nadaljnja predelava in/ali izločitev škodljivih posledic neskladnosti (kot je razporeditev/odreditve za drugo uporabo ali posebno označevanje).</p>	<p>3.13 correction action to eliminate a detected nonconformity</p> <p>[ISO 9000:2000, definition 3.6.6]</p> <p>NOTE 1 For the purposes of this International Standard, a correction relates to the handling of potentially unsafe products, and can therefore be made in conjunction with a corrective action (3.14).</p> <p>NOTE 2 A correction may be, for example, reprocessing, further processing, and/or elimination of the adverse consequences of the nonconformity (such as disposal for other use or specific labelling).</p>
<p>3.14 korektivni ukrep ukrep za odpravo vzrokov ugotovljene neskladnosti ali drugega neželenega stanja</p> <p>[ISO 9000:2000, definicija 3.6.5]</p> <p>OPOMBA 1: Vzrokov za ugotovljeno neskladnost je lahko več.</p> <p>OPOMBA 2: Korektivni ukrep vključuje analizo vzroka in se izvede zato, da se prepreči ponavljanje.</p>	<p>3.14 corrective action action to eliminate the cause of a detected nonconformity or other undesirable situation</p> <p>[ISO 9000:2000, definition 3.6.5]</p> <p>NOTE 1 There can be more than one cause for a nonconformity.</p> <p>NOTE 2 Corrective action includes cause analysis and is taken to prevent recurrence.</p>
<p>3.15 validacija (varnost živil) pridobitev dokazov, da so kontrolni ukrepi (3.7), ki izhajajo iz načrta HACCP in delujočih PRP (3.9), uspešni</p> <p>OPOMBA: Ta definicija je povzeta iz reference (11) in je bolj uporabna za področje varnosti živil (3.1) kot definicija, podana v ISO 9000.</p>	<p>3.15 validation <food safety> obtaining evidence that the control measures (3.7) managed by the HACCP and by the operational PRPs (3.9) are capable of being effective</p> <p>NOTE This definition is based on Reference [11] and is more suitable for the field of food safety (3.1) than the definition given in ISO 9000.</p>
<p>3.16 overjanje potrditev na podlagi stvarnega dokaza, da so specificirane zahteve izpolnjene</p> <p>[ISO 9000:2000, definicija 3.8.4]</p>	<p>3.16 verification confirmation, through the provision of objective evidence, that specified requirements have been fulfilled</p> <p>[ISO 9000:2000, definition 3.8.4]</p>
<p>3.17 posodabljanje takojšnja in/ali načrtovana aktivnost za zagotovitev uporabe najnovejših informacij</p>	<p>3.17 updating immediate and/or planned activity to ensure application of the most recent information</p>

4 Sistem vodenja varnosti živil

4.1 Splošne zahteve

Organizacija mora vzpostaviti, dokumentirati, izvajati in vzdrževati uspešen sistem vodenja varnosti živil ter ga posodabljati, kadar je potrebno, v skladu z zahtevami tega mednarodnega standarda.

Organizacija mora opredeliti obseg sistema vodenja varnosti živil. Obseg mora določiti proizvod ali skupino proizvodov, proces ter lokacijo predelave in proizvodnje, na katere se nanaša sistem vodenja varnosti živil.

Organizacija mora:

- a) zagotoviti, da so dejavniki tveganja, ki jih je mogoče razumno pričakovati v zvezi s proizvodi znotraj obsega sistema, prepoznavni, vrednoteni in nadzorovani v tolikšni meri, da proizvodi organizacije neposredno ali posredno ne škodujejo zdravju potrošnika,
- b) posredovati pravilne informacije glede varnosti njenih proizvodov vsem v prehranski verigi,
- c) posredovati informacijo glede razvoja, izvajanja in posodabljanja sistema vodenja varnosti živil v organizaciji v takšnem obsegu, da zagotovi varnost živil skladno z zahtevami tega mednarodnega standarda, in
- d) periodično vrednotiti in posodabljati, kadar je potrebno, sistem vodenja varnosti živil, da zagotovi, da sistem odraža aktivnosti organizacije in vključuje najnovejše informacije o dejavnih tveganja, ki jih je treba nadzorovati.

Če organizacija za katerikoli proces izbere zunanega izvajalca in to lahko vpliva na skladnost končnega proizvoda, mora zagotoviti nadzor nad tem procesom. Nadzor takšnega zunanjega izvajalca mora biti prepoznan in dokumentiran v sklopu sistema vodenja varnosti živil.

4.2 Zahteve glede dokumentacije

4.2.1 Splošno

4 Food safety management system

4.1 General requirements

The organization shall establish, document, implement and maintain an effective food safety management system and update it when necessary in accordance with the requirements of this International Standard.

The organization shall define the scope of the food safety management system. The scope shall specify the products or product categories, processes and production sites that are addressed by the food safety management system.

The organization shall

- a) ensure that food safety hazards that may be reasonably expected to occur in relation to products within the scope of the system are identified, evaluated and controlled in such a manner that the products of the organization do not, directly or indirectly, harm the consumer,
- b) communicate appropriate information throughout the food chain regarding safety issues related to its products,
- c) communicate information concerning development, implementation and updating of the food safety management system throughout the organization, to the extent necessary to ensure the food safety required by this International Standard, and
- d) evaluate periodically, and update when necessary, the food safety management system to ensure that the system reflects the organization's activities and incorporates the most recent information on the food safety hazards subject to control.

Where an organization chooses to outsource any process that may affect end product conformity, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety management system.

4.2 Documentation requirements

4.2.1 General