SLOVENSKI STANDARD

SIST ISO 15161

maj 2003

Smernice za uporabo ISO 9001:2000 v industriji hrane in pijače (enakovreden ISO 15161:2001)

Guidelines on the application of ISO 9001:2000 for the food and drink industry

Lignes directrices relatives à l'application de l'ISO 9001:2000 aux industries de l'alimentaire et des boissons

Deskriptorji:

ICS 03.120.10; 67.020

Referenčna številka
SIST ISO 15161:2003 (sl)

Nadaljevanje na straneh od 2 do 59

NACIONALNI UVOD

Standard SIST ISO 15161 (sl), Smernice za uporabo ISO 9001:2000 v industriji hrane in pijače, 2003, ima status slovenskega standarda in je enakovreden mednarodnemu standardu ISO 15161 (en),- Guidelines on the application of ISO 9001:2000 for the food and drink industry, 2001-11-01.

NACIONALNI PREDGOVOR

Mednarodni standard ISO 15161:2001 je pripravil tehnični odbor Mednarodne organizacije za standardizacijo ISO/TC 34 Kmetijski pridelki in živilski proizvodi.

Slovenski standard SIST ISO 15161:2003 je prevod mednarodnega standarda ISO 15161:2001. V primeru spora glede besedila slovenskega prevoda v tem standardu je odločilen izvirni mednarodni standard v angleškem jeziku.

Slovensko izdajo standarda je pripravil in odobril dne 2003-04-04 tehnični odbor SIST/TC KŽP Kmetijski pridelki in živilski proizvodi.

ZVEZE S STANDARDI

S prevzemom tega mednarodnega standarda veljajo za omejeni namen referenčnih standardov vsi standardi, navedeni v izvirniku, razen tistih, ki so že sprejeti v nacionalno standardizacijo:

SIST ISO 6658:1997 (en)	Senzorična analiza - Metodologija - Splošno navodilo
SIST ISO 8586-1:1997 (en)	Senzorična analiza - Splošno navodilo za izbiranje, urjenje in nadziranje ocenjevalcev - 1. del: Izbrani ocenjevalci
SIST ISO 8586-2:1997 (en)	Senzorična analiza - Splošno navodilo za izbiranje, urjenje in nadziranje ocenjevalcev - 2. del: Izvedenci
SIST ISO 9000:2002 (sl,en)	Sistemi vodenja kakovosti – Osnove in slovar
SIST ISO 9001:2000 (sl,en)	Sistemi vodenja kakovosti – Zahteve
SIST ISO 10399:1997 (en)	Senzorična analiza - Metodologija - Preskus "duo-trio"

OPOMBE

- Povsod, kjer se v besedilu standarda uporablja izraz “mednarodni standard”, v SIST ISO 15161:2003 to pomeni “slovenski standard”.
- Nacionalni uvod in nacionalni predgovor nista sestavni del standarda.

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Predgovor

ISO (Mednarodna organizacija za standardizacijo) 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 mednarodne vladne in nevladne organizacije, povezane z ISO. V vseh zadevah, ki so povezane s standardizacijo na področju elektrotehnike, ISO tesno sodeluje z Mednarodno elektrotehniško komisijo (IEC).

Mednarodni standardi so pripravljeni v skladu s pravili, podanimi v 3. delu Direktiv ISO/IEC.

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 je lahko nekaj elementov tega mednarodnega standarda predmet patentnih pravic. ISO ne prevzema odgovornosti za identifikacijo katerihkoli ali vseh takih patentnih pravic.

Mednarodni standard ISO 15161 je pripravil tehnični odbor ISO/TC 34 *Kmetijski pridelki in živilski proizvodi.*

Dodatek A tega mednarodnega standarda je podan samo informativno.

Seznam standardov in drugih publikacij, povezanih s tem mednarodnim standardom, je podan v bibliografiji.

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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15161 was prepared by Technical Committee ISO/TC 34, *Food products.*

Annex A of this International Standard is for information only.

A list of standards and other publications related to this International Standard is given in the Bibliography.

Uvod

ISO 9001:2000, Sistemi vodenja kakovosti – Zahteve

0.1 Splošno

Privzem sistema vodenja kakovosti naj bo strateška odločitev organizacije. Na načrtovanje in izvajanje sistema vodenja kakovosti organizacije vplivajo spreminjajoče se potrebe, posebni cilji, ponujeni proizvodi, izvajani procesi ter velikost in struktura organizacije. Ni namen tega mednarodnega standarda, da bi zahteval enotno strukturo sistemov vodenja kakovosti ali poenotenost dokumentacije.

Introduction

ISO 9001:2000, Quality management systems – Requirements

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

Zahteve za sistem vodenja kakovosti, specificirane v tem mednarodnem standardu, so dopolnilo zahtevam za proizvode. Besedilo, označeno z »OPOMBA«, predstavlja napotek pri razumevanju ali razjasnitvi zahtev.

Ta mednarodni standard lahko uporabljajo notranje ali zunanje stranke, vključno s certifikacijskimi organi, za ocenjevanje sposobnosti organizacije glede izpolnjevanja zahtev odjemalcev, regulative ali zahtev, ki si jih postavi organizacija sama.

Pri razvoju tega mednarodnega standarda so bila upoštevana načela vodenja kakovosti, pojasnjena v ISO 9000 in ISO 9004.

0.2 Procesni pristop

Ta mednarodni standard spodbuja privzem procesnega pristopa pri razvijanju, izvajanju in izboljševanju učinkovitosti sistema vodenja kakovosti z namenom, da bi se z izpolnjevanjem zahtev odjemalcev povečalo njihovo zadovoljstvo.

Da bi organizacija delovala učinkovito, mora identificirati in voditi številne povezane aktivnosti. Aktivnost, ki uporablja vire in ki jo vodimo z namenom, da omogoči spremembo vhodov v izhode, lahko obravnavamo kot proces. Izhod enega procesa pogosto tvori vhod v drugi proces.

Uporabo sistema procesov znotraj organizacije, vključno z njihovo identifikacijo in medsebojnimi vplivi, lahko poimenujemo »procesni pristop«.

Prednost procesnega pristopa je v tem, da omogoča nenehni nadzor nad povezavami med posameznimi procesi znotraj sistema procesov, kot tudi nad njihovimi kombinacijami in medsebojnimi vplivi.

Pri uporabi znotraj sistema vodenja kakovosti tak pristop poudari pomen:

a) razumevanja in izpolnjevanja zahtev,

b) potrebe po obravnavanju procesov z vidika dodane vrednosti,

c) pridobivanja rezultatov delovanja in učinkovitosti procesov,

d) nenehnega izboljševanja procesov na osnovi objektivnih merjenj.

Slika 1 prikazuje model sistema vodenja kakovosti, ki je osnovan na procesih. Model ponazarja procesne povezave, kot so predstavljene v točkah od 4 do 8. Slika prikazuje, da imajo odjemalci pomembno vlogo pri določanju vhodnih zahtev. Spremljanje zadovoljstva odjemalca zahteva ocenjevanje njegovega zaznavanja, ali je organizacija izpolnila njegove zahteve. Model, prikazan na sliki 1, pokriva vse zahteve tega mednarodnega standarda, vendar procesov ne prikazuje podrobneje.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9004:2000 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and fulfilling requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

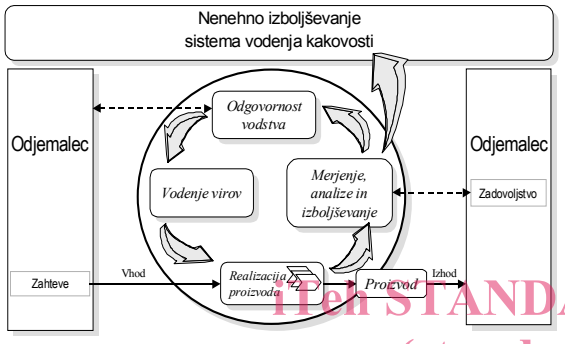
OPOMBA: Poleg zgoraj opisanega se lahko pri vseh procesih uporabi metodologija, poznana kot “Planiraj-Izvedi-Preveri-Ukrepaj” (PDCA). PDCA lahko na kratko opišemo na spodaj navedeni način.

Planiraj: Vzpostavi cilje in procese, potrebne za doseganje rezultatov, v skladu z zahtevami odjemalcev in načeli organizacije.

Izvedi: Izvajaj procese.

Preveri: Nadzoruj in meri procese in proizvod glede načel, ciljev in zahtev za proizvod ter poročaj o rezultatih.

Ukrepaj: Ukrepaj tako, da se delovanje procesa nenehno izboljšuje.



Legenda:

→ Aktivnosti, ki dodajajo vrednost

- - - - → Tok informacij

Slika 1: Model sistema vodenja kakovosti, osnovan na procesih

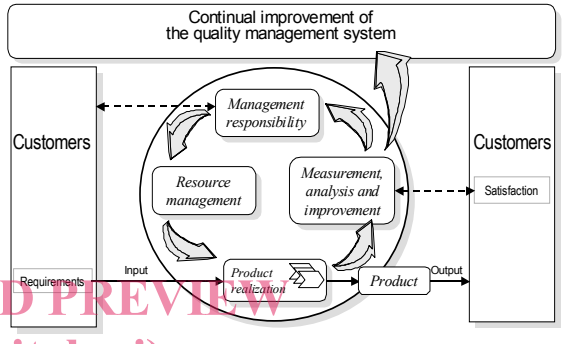
NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.



Key

→ Value-adding activities

- - - - → Information flow

Figure 1 – Model of a process-based quality management system

0.3 Razmerje do ISO 9004

Ta izdaja ISO 9001 in ISO 9004 sta bila razvita kot skladni par standardov za sistem vodenja kakovosti, ki sta bila zasnovana tako, da drug drugega dopolnjujeta, vendar pa se lahko uporabljata tudi samostojno. Ta dva mednarodna standarda imata kljub različnemu namenu podobno strukturo, da bi bilo to v pomoč pri njuni uporabi.

ISO 9001 specificira zahteve za sistem vodenja kakovosti za uporabo znotraj organizacije, certificiranje ali pogodbene namene. Osredotoča se na učinkovitost sistema vodenja kakovosti pri izpolnjevanju zahtev odjemalcev.

ISO 9004:2000 daje navodila na podlagi širšega obsega ciljev sistema vodenja kakovosti kot ISO 9001, zlasti za nenehno izboljševanje celotnega delovanja in uspešnosti organizacije kot tudi njene učinkovitosti. ISO 9004:2000 se priporoča kot vodilo za organizacije, katerih najvišje vodstvo želi v prizadevanju za nenehno izboljševanje delovanja

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the

preseči okvire zahtev ISO 9001. Vendar pa ni namenjen za certificiranje ali uporabo v pogodbenih odnosih.

requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Združljivost z ostalimi sistemi vodenja

0.4 Compatibility with other management systems

Ta mednarodni standard je usklajen z ISO 14001:1996 z namenom, da se poveča združljivost obeh standardov v korist skupnosti uporabnikov.

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

Ta mednarodni standard ne vključuje zahtev, specifičnih za ostale sisteme vodenja, kot na primer specifičnih zahtev za ravnanje z okoljem, varovanje zdravja in varnost pri delu, finančno vodenje ali obvladovanje tveganj. Kljub temu ta mednarodni standard organizaciji omogoča, da uskladi ali združi svoj sistem vodenja kakovosti z zahtevami sorodnih sistemov vodenja. Da bi organizacija vzpostavila sistem vodenja kakovosti, ki izpolnjuje zahteve tega mednarodnega standarda, lahko prilagodi svoj(e) obstoječi(e) sistem(e) vodenja.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Organizacije z vseh področij industrije hrane in pijače, kot so proizvodnja, predelava in pakiranje, potrebujejo napotke za izvedbo zahtev ISO 9001. Namen tega mednarodnega standarda je vzpodbujati uporabo standardov skupine ISO 9000 v industriji hrane in pijače. Uporaba teh standardov hkrati z drugimi skupnimi sistemi, ki se uporabljajo v tej panogi, lahko pomaga organizaciji, da bolje obravnava zadovoljstvo odjemalcev in učinkovitost organizacije z učinkovito uporabo sistema vodenja kakovosti.

There is a need for guidance on implementing the requirements of ISO 9001 for organizations involved in all aspects of the food and drink industry. This includes organizations involved in sourcing, processing and packaging food and drink products. This International Standard aims to encourage the use of the ISO 9000 series of standards within the food and drink industry - the use of these standards alongside other common systems in use in this sector may assist an organization to better address customer satisfaction and organizational effectiveness by the effective implementation of a quality management system.

ISO 9001 od organizacije zahteva tudi prizadevanje za nenehno izboljševanje njenih sistemov vodenja kakovosti kot vidika, ki pogosto manjka v drugih modelih vodenja varnosti hrane, ki se ponavadi uporabljajo v industriji hrane in pijače.

ISO 9001 also requires organizations to seek to continually improve their quality management systems, an aspect often missing from other models of food safety management commonly used in the food and drink industry.

Privzem sistema vodenja kakovosti naj bo strateška odločitev organizacije. Na načrtovanje in izvajanje sistema vodenja kakovosti organizacije vplivajo spreminjajoče se potrebe, posebni cilji, ponujeni proizvodi, izvajani procesi ter velikost in struktura organizacije. Namen tega mednarodnega standarda ni v tem, da bi zahteval enotno strukturo sistemov vodenja kakovosti ali poenotenost dokumentacije. Procesno usmerjeni temelji ISO 9001 olajšajo predstavo o medsebojni povezavi različnih sistemov znotraj poslovanja; težave pogosto nastopajo pri medsebojnih povezavah med notranjimi odjemalci in dobavitelji ali med različnimi sistemi. Vsak model, ki pojasnjuje ta

The adoption of a quality management system needs to be a strategic decision of the organization. The design and the implementation of an organization's quality management system is influenced by varying needs: the particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the purpose of ISO 9001 to imply uniformity in the structure of quality management systems or uniformity of the documentation. The process-oriented base of ISO 9001 makes it easier to envisage how different systems within a business link together; often it is at the interfaces between internal customers and suppliers or between different

kritična področja za organizacijo, ji bo pomagal, da poslovanje gladko teče.

ISO 9001 se osredotoča na potrebe in pričakovanja odjemalcev. Eno najpomembnejših pričakovanj odjemalcev (in pogosto tisto, ki je prej posredno kot pa izraženo neposredno) je, da so prehrambni proizvodi varni. ISO 9001 organizaciji dopušča, da poveže svoj sistem vodenja kakovosti z uporabo sistemov varnosti hrane, kot je HACCP (analiza tveganja in kritične kontrolne točke). Mednarodno priznana načela in korake HACCP je opredelila Komisija "Codex Alimentarius" v svojih priporočenih načelih prakse o splošnih načelih higiene hrane. Seveda se lahko v sistem vodenja kakovosti poveže tudi katerikoli drug sistem varnosti hrane. Kakorkoli že, ob upoštevanju dejstva, da je uporaba HACCP široko razširjena, je bil ta sistem izbran za prikaz, kako je možno doseči to povezovanje.

Uporaba HACCP znotraj sistema vodenja kakovosti se lahko skladno z ISO 9001 odrazi v sistemu varnosti hrane, ki je učinkovitejši kot posamezna uporaba ISO 9001 ali HACCP ter vodi k povečanju zadovoljstva odjemalcev in izboljšanju učinkovitosti organizacije. Na primer, uporaba HACCP pri identifikaciji tveganj in obvladovanju nevarnosti je povezana s planiranjem kakovosti in preventivnimi ukrepi, ki jih zahteva ISO 9001. Ko se identificirajo kritične točke, se pri njihovem nadzorovanju in spremljanju lahko uporabijo načela ISO 9001. Postopki izvajanja HACCP-študije se brez težav dokumentirajo znotraj sistema kakovosti.

V pomoč uporabnikom so v tem mednarodnem standardu podane zahteve ISO 9001 v okvirjenem besedilu, ki mu sledijo ustrezni napotki.

Povezave med temeljnimi načeli HACCP in specifičnimi točkami ISO 9001 so prikazane v dodatku A.

Ta mednarodni standard predstavlja poizkus identifikacije specifičnih tem za premislek pri vzpostavljanju sistema vodenja kakovosti na področju industrije hrane in pijače. Zato se uporabnike tega mednarodnega standarda vzpodbuja k zbiranju izkušenj, pridobljenih z njegovo uporabo, in k informiranju sekretariata ISO/TC 34 o tem, da bi se lahko njihovi pogledi upoštevali pri prvi reviziji.

systems that problems occur. Any model which clarifies these critical areas for an organization will assist in the smooth running of its business.

ISO 9001 focuses on customers' needs and expectations. One of the most important customer expectations (and often one which is implicit rather than stated directly) is to have safe food products. ISO 9001 allows an organization to integrate its quality management system with the implementation of food safety systems such as HACCP (hazard analysis and critical control point). The internationally recognized principles and steps of HACCP are defined by the Codex Alimentarius Commission in its recommended international code of practice on general principles of food hygiene. Any other accepted food safety system can, of course, also be integrated into the quality management system. However, considering the fact that HACCP is widely used comprehensively, this system was chosen to demonstrate how integration may be achieved.

The application of HACCP within a quality management system conforming to ISO 9001 can result in a food safety system that is more effective than the application of either ISO 9001 or HACCP alone, leading to enhanced customer satisfaction and improved organizational effectiveness. As an example, the application of HACCP for the identification of hazards and control of risks is related to quality planning and preventive actions required by ISO 9001. Once the critical points have been identified, the principles of ISO 9001 can be used for control and monitoring. Procedures for conducting an HACCP study can easily be documented within the quality system.

To assist the user, the requirements of ISO 9001 are given in boxed text in this International Standard, followed by relevant guidance.

Linkages between the basic HACCP principles and specific clauses of ISO 9001 are shown in annex A.

This International Standard represents an attempt to identify the specific issues to be considered when establishing a quality management system in the field of the food and drink industry. Therefore, users of this International Standard are encouraged to gather any experience gained in connection with its application and inform the ISO/TC 34 Secretariat accordingly, so that their views can be taken into account in the first revision.

Smernice za uporabo ISO 9001:2000 v industriji hrane in pijače

1 Področje uporabe

Ta mednarodni standard podaja organizacijam napotke za uporabo zahtev ISO 9001 pri razvoju in izvajanju sistema vodenja kakovosti v industriji hrane in pijače.

Ta mednarodni standard podaja informacije o možnih medsebojnih vplivih standardov skupine ISO 9000 in sistema za analizo tveganja in kritičnih kontrolnih točk (HACCP) za zahteve za varnost hrane.

Ta mednarodni standard ni namenjen certificiranju, uporabi v regulativi ali v pogodbah.

2 Zveza s standardom

Spodaj navedeni normativni dokument vsebuje določila, ki s sklicevanjem v tem besedilu določa tudi vsebino tega mednarodnega standarda. Pri datiranem sklicevanju se njegova kasnejša dopolnila in revizije ne navaja, vendar naj stranke v pogodbah, ki temeljijo na temu mednarodnemu standardu, uporabljajo najnovejšo izdajo spodaj navedenega normativnega dokumenta. Pri nedatiranemu sklicevanju se njegova uporaba nanaša na zadnjo izdajo normativnega dokumenta. Člani IEC in ISO vzdržujejo registre splošno veljavnih mednarodnih standardov.

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 naslednji izrazi in definicije.

3.1
Pogodba
Zahteve, dogovorjene med dobaviteljem in odjemalcem, prenesene na kakršenkoli način.

3.2
Korektivni ukrep
Ukrep za odpravo vzroka ugotovljene neskladnosti ali druge morebitne nezaželene situacije, vključno z ukrepi, ki se morajo izvesti, ko rezultati monitoringa na katerikoli kritični kontrolni točki kažejo na neuspešno obvladovanje.

Guidelines on the application of ISO 9001:2000 for the food and drink industry

1 Scope

This International Standard gives guidance to organizations in applying the requirements of ISO 9001 during the development and implementation of a quality management system in the food and drink industry.

This International Standard gives information on the possible interactions of the ISO 9000 series of standards and the hazard analysis and critical control point (HACCP) system for food safety requirements.

This International Standard is not intended for certification, regulatory or contractual use.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

3 Terms and definitions

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

3.1
contract
agreed requirements between a supplier and a customer, transmitted by any means

3.2
corrective action
action to eliminate the cause of a detected nonconformity or other undesirable potential situation, including any action to be taken when the results of monitoring at any critical control point indicate a loss of control

OPOMBA 1: Za posamezno neskladnost lahko obstaja več kot samo en vzrok.

OPOMBA 2: Korektivni ukrep se sprejme, da bi se preprečila ponovitev neskladnosti, medtem ko se preventivni ukrep sprejme, da bi se preprečil pojav neskladnosti.

OPOMBA 3: Obstaja razlika med korekcijo in korektivnim ukrepom. Korekcija je odprava neskladnosti, s korektivnim ukrepom pa odpravimo njen vzrok.

OPOMBA 4: Definicije za »neskladnost«, »korekcijo« in »preventivni ukrep« so podane v ISO 9000.

OPOMBA 5: Ta definicija je kombinacija definicij, podanih v ISO 9000 in v referenčnem dokumentu [20].

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action. Correction is the elimination of the nonconformity, while corrective action eliminates its cause.

NOTE 4 Definitions of "nonconformity", "correction" and "preventive action" can be found in ISO 9000.

NOTE 5 This definition is a combination of the definitions given in ISO 9000 and reference [20].

3.3
Kritična kontrolna točka
KKT
Stopnja, na kateri se lahko izvede nadzor in ki je bistvena za preprečitev ali odstranitev tveganja za varnost hrane ali zmanjšanje tveganja na sprejemljivo raven.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.3
critical control point
CCP
step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

NOTE Taken from reference [20].

3.4
Kritična mejna vrednost
Kriterij, ki ločuje sprejemljivo od nesprejemljivega.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.4
critical limit
criterion which separates acceptability from unacceptability

NOTE Taken from reference [20].

3.5
Diagram poteka
Sistematičen prikaz zaporedja korakov ali operacij, ki se izvajajo pri pridelavi ali proizvodnji določenega prehrambnega artikla.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.5
flow diagram
systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item

NOTE Taken from reference [20].

3.6
Dobra proizvodna praksa
Kombinacija proizvodnih postopkov in postopkov kakovosti, katerih namen je zagotoviti, da se proizvodi dosledno proizvajajo po njihovih specifikacijah in da se izogne onesnaževanju proizvoda iz notranjih ali zunanjih virov.

3.6
good manufacturing practice
combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources

3.7
Tveganje
Biološki, kemični ali fizikalni dejavnik v hrani ali stanje hrane, ki lahko škodljivo vpliva na zdravje.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.7
hazard
biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

NOTE Taken from reference [20].

3.8
Analiza tveganja
Proces zbiranja in vrednotenja informacij o tveganjih in pogojih, ki vodijo k njihovi prisotnosti, za odločanje o njihovi pomembnosti za varnost hrane; zato naj bo vključen v HACCP-načrt.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.9
Primarna proizvodnja
Faza v prehrambni verigi do in vključno z, na primer, žetvijo, zakolom, molžo, ribolovom.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.10
Stopnja
Mesto, postopek, operacija ali faza v prehrambni verigi, vključno s surovinami, od primarne proizvodnje do končne porabe.

OPOMBA: Vzeto iz referenčnega dokumenta [20].

3.11
Validacija
Potrditev, na podlagi stvarnega dokaza, da so bile zahteve za specifičen predviden namen ali uporabo izpolnjene, vključno z dokazi, da so elementi HACCP-načrta učinkoviti.

OPOMBA 1: Izraz »validiran« se uporablja za označitev ustreznega statusa.

OPOMBA 2: Pogoji uporabe za validacijo so lahko realni ali simulirani.

OPOMBA 3: Definiciji izrazov »stvarni dokaz« in »zahteve« sta podani v ISO 9000.

OPOMBA 4: Ta definicija je kombinacija definicij, podanih v ISO 9000 in v referenčnem dokumentu [20].

3.12
Overjanje
Potrditev, na podlagi stvarnega dokaza, da so bile specificirane zahteve izpolnjene, vključno z uporabo metod, postopkov, preskusov in drugih vrednotenj ter monitoringom, da se potrdi skladnost s HACCP načrtom.

OPOMBA 1: Izraz »overjen« se uporablja za oznako ustreznega statusa.

OPOMBA 2: Potrjevanje lahko obsega aktivnosti, kot so:

- izvedba alternativnih izračunov,
- primerjava specifikacije nove zasnove s specifikacijo podobne že preskušene zasnove,

3.8
hazard analysis
process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

NOTE Taken from reference [20].

3.9
primary production
those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing

NOTE Taken from reference [20].

3.10
step
point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption

NOTE Taken from reference [20].

3.11
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled, including evidence that the elements of the HACCP plan are effective

NOTE 1 The term "validated" is used to designate the corresponding status.

NOTE 2 The conditions of use for validation can be real or simulated.

NOTE 3 Definitions of the terms "objective evidence" and "requirements" can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

3.12
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled, including the application of methods, procedures, tests and other evaluations, and monitoring to determine compliance with the HACCP plan

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

- performing alternative calculations,
- comparing a new design specification with a similar proven design specification,

- izvedba prekusov in prikazov, ki niso omenjeni v definiciji in
- pregledovanje dokumentov pred izdajo.

OPOMBA 3: Definiciji izrazov »specifikacija« in »preskus« sta podani v ISO 9000.

OPOMBA 4: Ta definicija je kombinacija definicij, podanih v ISO 9000 in v referenčnem dokumentu [20].

- undertaking tests and demonstrations other than mentioned in the definition, and
- reviewing documents prior to issue.

NOTE 3 Definitions of the terms "specification" and "tests" can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

4 Sistem vodenja kakovosti

4.1 Splošne zahteve

ISO 9001:2000, Sistemi vodenja kakovosti – Zahteve

4.1 Splošne zahteve

Organizacija mora vzpostaviti, dokumentirati, izvajati in vzdrževati sistem vodenja kakovosti ter nenehno izboljševati njegovo učinkovitost v skladu z zahtevami tega mednarodnega standarda.

Pri izvajanju sistema vodenja kakovosti mora organizacija:

a) identificirati procese, potrebne za sistem vodenja kakovosti, in njihovo uporabo v celotni organizaciji (glej 1.2),

b) določiti zaporedje in medsebojne vplive teh procesov,

c) določiti kriterije in metode, potrebne za zagotovitev tako učinkovitega delovanja kot tudi učinkovitega obvladovanja teh procesov,

d) zagotoviti, da so na voljo viri in informacije, potrebne za podporo delovanja in nadzorovanja teh procesov,

e) nadzorovati, meriti in analizirati te procese in

f) izvajati ukrepe, potrebne za doseganje planiranih rezultatov in za nenehno izboljševanje teh procesov.

Organizacija mora voditi te procese skladno z zahtevami tega mednarodnega standarda.

V primeru, da se organizacija odloči predati zunanjim izvajalcem v izvajanje katerikoli proces, ki vpliva na skladnost proizvoda z zahtevami, mora organizacija zagotoviti obvladovanje teh procesov. Obvladovanje teh procesov mora biti vključeno v sistem vodenja kakovosti.

OPOMBA: Procesi, potrebni za sistem vodenja kakovosti, na katere se sklicuje zgornje besedilo, naj vključujejo procese za vodstvene aktivnosti, priskrbo virov, realizacijo proizvoda in merjenje.

4 Quality management system

4.1 General requirements

ISO 9001:2000, Quality management systems - Requirements

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities. provision of resources. product realization and measurement.

Močno poudarjen procesni vidik te točke naj bi bil znan organizacijam, ki delujejo v sektorju hrane in pijače. Uporaba diagramov poteka procesa in drugih orodij za izdelavo načrtov proizvodnega procesa je splošna praksa - vsekakor prva stopnja HACCP študije zahteva tako definicijo procesa. Struktura sistema vodenja kakovosti naj bo primerna organizaciji, pri čemer naj izpolnjuje njene potrebe toliko, kolikor organizacija dela za svoje odjemalce. Sistem vodenja kakovosti naj zagotovi, da so vse tiste aktivnosti v organizaciji, ki bi lahko vplivale na kakovost in varnost proizvoda, dosledno določene (kar običajno pomeni dokumentirane) in da se učinkovito izvajajo. Koristno je vključiti ustrezne kodekse prakse in zahteve zakonodaje, kot so kontrola mase, analiza tveganja, higiena, dobra proizvodna praksa (DPP) in dobra laboratorijska praksa (DLP).

The strong process aspect of this clause should be familiar to organizations operating within the food and drink sector. It is common practice to use process flow charts and other tools to "map" the process of manufacture - indeed the first stage of a HACCP study requires such a definition of the process. The structure of the quality management system should be right for the organization, meeting its needs as much as the organization does for its customers. The quality system should ensure that all those activities within the organization that could impact on the quality and safety of the product are consistently defined (which usually means documented) and effectively implemented. Useful inclusions are relevant codes of practice and legislative requirements, such as weight control, hazard analysis, hygiene, good manufacturing practice (GMP) and good laboratory practice (GLP).

4.2 Zahteve glede dokumentacije

4.2 Documentation requirements

4.2.1 Splošno

4.2.1 General

ISO 9001:2000, Sistemi vodenja kakovosti – Zahteve

4.2.1 Splošno

Dokumentacija sistema vodenja kakovosti mora vključevati:

a) dokumentirane izjave o politiki kakovosti in ciljih kakovosti,

b) poslovnik kakovosti,

c) dokumentirane postopke, ki jih zahteva ta mednarodni standard,

d) dokumente, ki jih organizacija potrebuje, da bi zagotovila učinkovito planiranje, delovanje in obvladovanje njenih procesov,

e) zapise, ki jih zahteva ta mednarodni standard (glej 4.2.4).

OPOMBA 1: Kjer se v tem mednarodnem standardu pojavlja izraz »dokumentiran postopek«, to pomeni, da je postopek vzpostavljen, dokumentiran, da se izvaja in vzdržuje.

OPOMBA 2: Obseg dokumentacije sistema vodenja kakovosti se lahko razlikuje od ene do druge organizacije zaradi:

a) velikosti organizacije in vrste aktivnosti,

b) kompleksnosti procesov in njihovih medsebojnih vplivov in

c) kompetentnosti osebja.

OPOMBA 3: Dokumentacija je lahko v kakršnikoli obliki ali v kateremkoli mediju.

ISO 9001:2000, Quality management systems - Requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

Dokumenti, ki jih potrebuje organizacija, da bi zagotovila učinkovito planiranje, delovanje in obvladovanje njenih procesov, lahko vključuje naslednje teme ustrezne zakonodaje, ki se nanaša na proizvodnjo hrane in pijače. Ta zakonodaja lahko pokriva naslednja področja:

– varnost,
– standardi za sestavine,
– metrologija,
– dodatki,
– identifikacija in sledljivost partije,
– informacije o označevanju in pakiranju.

Obstajajo lahko še drugi primeri; vključeni so lahko tudi dokumenti odjemalcev.

4.2.2 Poslovnik kakovosti

ISO 9001:2000, Sistemi vodenja kakovosti – Zahteve

4.2.2 Poslovnik kakovosti

Organizacija mora izdelati in vzdrževati poslovnik kakovosti, ki vključuje:

a) predmet sistema vodenja kakovosti, vključno z razlogi in s podrobnostmi glede morebitnih opustitev (glej 1.2),

b) dokumentirane postopke, vzpostavljene za sistem vodenja kakovosti, ali sklicevanje nanje,

c) opis medsebojnega vpliva procesov sistema vodenja kakovosti.

Zahteva izdelati poslovnik kakovosti ne pomeni nujno samostojnega dokumenta najvišjega nivoja. Poslovnik kakovosti naj jasno opiše strukturo sistema vodenja kakovosti in v idealnem primeru deluje kot njegov »zemljevid«. Vsa združevanja in povezave z drugimi sistemi ali dokumenti, po katerih bi lahko zahtevali, da organizacija deluje, naj bodo podrobno navedeni v poslovniku kakovosti. Posebno pomembna je zveza s HACCP dokumentacijo (kot je HACCP načrt) in povezava med HACCP študijo in poslovnikom kakovosti naj bo zelo jasna. Poslovnik kakovosti je dokument, ki najbolj jasno kaže, kako je HACCP študija integrirana v sistem vodenja kakovosti in kako so rezultati HACCP študije vključeni v običajno delovanje organizacije.

Documents needed by the organization to ensure the effective planning, operation and control of its processes may include the current issue of relevant legislation pertaining to food and drink manufacture. This legislation could cover the following areas:

– safety;
– compositional standards;
– metrology;
– additives;
– lot identification and traceability;
– labelling and packaging information.

There could be other examples, and customer documents may also be included.

4.2.2 Quality manual

ISO 9001:2000, Quality management systems - Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The requirement to produce a quality manual need not mean a top-level document which stands alone. A quality manual should clearly describe the structure of the quality management system and, ideally, act as a "road-map" through it. All associations and links to other systems or documents, which the organization may be required to operate to, should be detailed within the quality manual. The association with HACCP documentation (such as the HACCP plan) is particularly important and the linkage between the HACCP study and the quality manual should be very clear. It is this document which most clearly shows how the HACCP study is integrated with the quality management system and how the outcomes of the HACCP study are incorporated in the way the organization usually operates.

4.2.3 Obvladovanje dokumentov

ISO 9001:2000, Sistemi vodenja kakovosti – Zahteve

4.2.3 Obvladovanje dokumentov

Dokumente, ki jih zahteva sistem vodenja kakovosti, je treba obvladovati. Zapisi so posebna vrsta dokumentov in jih je treba obvladovati v skladu z zahtevami, podanimi v 4.2.4.

Vzpostaviti je treba dokumentiran postopek, ki opredeljuje potreben način obvladovanja za:

a) odobritev primernosti dokumentov pred njihovo izdajo,

b) pregled in posodobitev ter ponovno odobritev dokumentov, ko je to potrebno,

c) zagotovitev, da so identificirane spremembe in trenutni status popravkov dokumentov,

d) zagotovitev, da so ustrezne izdaje primernih dokumentov na voljo na mestih uporabe,

e) zagotovitev, da dokumenti ostanejo čitljivi in prepoznavni brez težav,

f) zagotovitev, da so dokumenti zunanjega izvora identificirani, njihovo razdeljevanje pa obvladovano,

g) preprečitev nenamerne uporabe zastarelih dokumentov in uporabo primerne identifikacije zanje, če se obdržijo za kakršenkoli namen.

Ostala dokumentacija (v papirni ali elektronski obliki), ki se uporablja v industriji hrane in pijače, je lahko del sistema vodenja kakovosti in lahko vključuje naslednje:

a) specifikacije (npr. za surovine, predelavo, recepture in proizvode);

b) risbe (npr. ilustracija za embalažo);

c) veljavno zakonodajo in kodeks prakse;

d) ostale dokumente zunanjega izvora (npr. navodila za delo z opremo);

e) HACCP načrt in HACCP dokumentacijo.

Ta dokumentacija naj se obvladuje, čeprav se lahko mehanizmi obvladovanja razlikujejo od tistih, ki se uporabljajo za obvladovanje proceduralnih dokumentov. Do napak pogosto prihaja ob ponovnih izdajah receptur in/ali specifikacij, ko zaradi slabe komunikacije del organizacije uporablja staro izdajo.

Odobritev dokumentov pred izdajo (in nadaljnji pregledi sprememb, ki jih opravijo iste strani) zagotavlja, da vsebina ni v nasprotju z ostalimi dokumenti v sistemu, da ustreza ciljem organizacije in da se z njo strinjajo prave osebe. Pazljiv pregled dokumentov pred izdajo je

4.2.3 Control of documents

ISO 9001:2000, Quality management systems - Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Other documentation (in paper or electronic formats) utilized in the food and drink industry, which may be part of the quality management system, could include the following:

a) specifications (e.g. for raw materials, processing, recipes and products);

b) drawings (e.g. artwork for packaging);

c) current legislation and codes of practice;

d) other externally generated documents (e.g. equipment manuals);

e) HACCP plan and HACCP documentation.

These should also be under document control, although the mechanism for control may differ from that used to control procedural documents. Errors often occur where recipes and/or specifications have been re-issued but communication has been poor and part of the organization is operating to a different issue.

The approval of documents before issue (and subsequent same-party review of changes) ensures that the content of documents will not clash with any other document in the system, fits into the organization's objectives and is agreed by the correct people. Careful review of