



Date: 2014-10-20

ISO/TC 34/SC17 'Management systems for food safety' FAQ

FAQ	Reply
ISO 22000 and HACCP	
What does ISO22000 add to CODEX HACCP?	<p>ISO 22000 strengthens the HACCP system in several ways. It is a management system standard and as such, has requirements for policy, planning, implementation and operation, performance assessment, management review and improvement.</p> <p>ISO 22000 reorganizes the traditional concept of dividing control measures into GHP and critical control points (CCPs) by grouping control measures into three groups:</p> <ul style="list-style-type: none">• prerequisite programmes (PRPs) that manage the basic conditions and activities; the PRPs are not selected for the purpose of controlling specific identified hazards but for the purpose of maintaining a hygienic production, processing and/or handling environment;• operational prerequisite programmes (operational PRPs) that control those control measures that the hazard analysis identifies as necessary to control (significant hazards), and which are not controlled by CCPs;• a HACCP plan to manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are applied at critical control points (CCPs). <p>These three categories are linked together through the hazard analysis. ISO 22000 shows how to combine the HACCP plan with PRPs and OPRPs into a single integrated food control system.</p> <p>ISO 22000 promotes the adoption of a food chain approach, whereas CODEX HACCP focuses on the internal system. In this regard, ISO 22000 requires that the effects of the food chain prior to and subsequent to its operations are considered when developing and implementing the food safety management system.</p>



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	<p>The ISO 22000 hazard analysis is more explicit and focuses on identifying hazards wherever they occur, assess them in regard of their need of control, and selecting control measures that control them. Codex HACCP is typically applied with a focus on assessing existing process step in order to assess whether they are CCPs.</p> <ul style="list-style-type: none">• Please clarify procedures involved in relation to Codex HACCP and ISO 22000:2005, particularly on Determining CCPs and Categorization of Control Measures? <p>1. This topic has been identified and discussed during the meetings of WG3 when we wrote 'How to use ISO 22000' and more recently during the meeting of WG7 revision of ISO TS 22004. The experts have made a consensual decision about it, the explanation can be found in 'How to Use' and in ISO 22004:2014.</p> <p>2. The decision tree is not a requirement of ISO 22000, and the experts do not recognize the need to have a decision tree for categorizing PRP, OPRP, and CCP. It is just one tool that may be used to categorize PRPs, OPRPs, and CCPs.</p> <p>The expert panel of ISO/TC 34/SC 17 can provide only generic guidance, our advice to your particular question, will be to purchase a copy of 'How to Use ISO 22000' or ISO 22004:2014 from ISO</p>
What is ISO/TS 22002 series?	<p>ISO 22002 Technical Specifications (TSs) are guidance documents, not intended for certification, but intended for assisting an organization in establishing, implementing and maintaining prerequisite programmes (PRP) in accordance with ISO 22000. PRPs are the basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.</p> <p>Although the use of the TSs is not mandatory for complying with the requirements in ISO 22000, deviations there from (exclusions or alternative measures) need to be justified and documented, when TSs are used as reference for the PRPs implemented.</p> <p>TSs of the ISO 22002 series are primarily developed for (a) specified food chain category(ies) such as farming, manufacturing, and transportation or as sector specific TSs subordinated the TS of the relevant food chain category (e.g. TS for aquaculture subordinated a TS for farming).</p>
What is ISO 22000?	



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What is ISO 22000?	ISO 22000 (Food safety management systems -- Requirements for any organization in the food chain) describes the requirements for a food safety management system. The standard is utilized with ISO 22002-1 (Prerequisite programmes on food safety - Part 1: Food manufacturing) to form the technical basis for a Global Food Safety Initiative (GFSI) recognized audit scheme known as FSSC 22000.
Who developed the ISO 22000 Standard?	ISO 22000 was developed by a working group (WG) under ISO Technical Committee 34 (Food Products). This working group evolved into ISO sub-committee (SC 17). This subcommittee is responsible for the management of the ISO 22000 family of standards.
How transparent is the ISO standard development process? Can I get involved?	ISO develops their standards in a transparent process. Development Work is conducted at two levels: the national level and the international level. At the national level, standards development is done by mirror groups or Technical Advisory Group. The mirror group is responsible for selecting the delegates to the international meetings. If you would like to get involved in developing standards in the ISO 22000 series, please contact your national standards body for more information.
Integrated systems	
How different is ISO 22000 from ISO 9001?	ISO 22000 was specifically developed to be easily integrated with ISO 9001 systems. The management system elements of the standard are largely word-for-word that of the ISO 9001 equivalent, with some small amendments relating specifically to food safety. 'Product Realisation' within ISO 9001 has been replaced in ISO 22000 by the CODEX HACCP principles – not in its original form, but in a form that facilitates consistent implementation and audit through the definition of documentation and records required to be produced by the food business.
Can ISO 22000 be integrated with other management systems?	An organization can choose to integrate any combination of management systems, such as ISO 9001, ISO 14001, and OHSAS 18001. ISO has developed a proposal for the structure and text of <i>management system standards</i> to ensure that management system standards development takes into consideration the necessity for management systems to be easily integrated.
High Level Structure (HLS)	
Scope of ISO 22000	



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<p>What types of businesses are covered by the scope of ISO 22000?</p>	<p>The Scope of ISO 22000 indicates <i>'It (the standard) is applicable to all organizations, regardless of size, which are involved in any aspect of the food chain'</i>.</p> <ul style="list-style-type: none"> • Categories in relation to human drugs? <p>The scope of ISO 22000 is limited to food and feed (for food production). Further, it has been decided that the Standard also covers pet foods (TC34/SC17 resolution No. 69, Dublin 2011).</p> <p>The category L is intended to cover (bio)chemicals that are directly or indirectly used in food production and/or distribution. In this way, the scope of ISO 22000 covers manufacturing (category L) and administration (category I) of veterinary drugs as they are administered to food producing animals and thus may end up in food as contaminants. The FSMS shall ensure that acceptable levels of such drugs in the final food are not exceeded. In doing so, targets along the food chain shall be respected (MRLs).</p> <p>The regulatory set up for human drugs is quite different from that of food, and focus is more on the effect/side-effects relationship than on food safety. The techniques & methodologies required by ISO 22000 are not appropriate for assessing and designing effect/side-effects relationship in relation to human disease.</p> <p>Further, in many cases, the active substances in human drugs required to obtain an effect on a disease would be considered as food safety hazards when consumed by health individuals. To be effective drugs, they often contain, by purpose, hazard levels above what is acceptable from a food safety stand point.</p> <p>This does, however, not preclude the integration of the ISO 22000 approach in a QA system for the manufacture of human drugs.</p> <ul style="list-style-type: none"> • FSSC 22000 wants to extend her scope by taken up the sector specific PRPs PAS 222 for food safety in the manufacture of food and feed for animals. Can you confirm if feed safety for animal health is included in ISO 22000? <p>Within the introduction to ISO 22000 the text includes the following clarification regarding scope, which refers to feed producers:</p> <p>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</p>



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	<p>equipment, packaging material, cleaning agents, additives and ingredients). Service providers are also included.</p> <p>Under the 'scope' clause of the standard it goes further to say:</p> <p>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.</p> <p>Therefore while the 'definition' of an organisation includes feed producers, the standard itself clearly indicates that the scope is for management systems controlling food safety hazards, not animal health hazards. You are therefore correct in your appraisal that the standard is concentrating on the food safety hazards that need to be controlled in the feed to prevent their introduction into the food chain.</p> <ul style="list-style-type: none">• The scope of an organisation's operation is 'the management of the collection and transfer of sewage to a sewage treatment plants'. It appears that the company just collects raw sewage. The organisation has indicated that they believe they are a service organization (category H). Can you please confirm this is acceptable? <p>This site is covered by ISO 14001 ISO 22000 is not an appropriate standard.</p>
ISO/TS 22003:2007 (Has been revised to ISO/TS 22003:2013)	<p>ISO/TS 22003 provides a list of categories that these organisations can be placed in, along with examples of the types of organisations that are included in these categories. Some specific questions that have been raised to date have included:</p> <ul style="list-style-type: none">• Can producers of drugs be certified to ISO 22000? <p>Many drugs or pharmaceuticals are regulated and are required to meet specific GMP requirements by regulation. The term 'drug' used in ISO/TS 22000 is not defined; nor are the sectors included in the table in Annex A of this document exhaustive. However, there is nothing preventing a producer of drugs from seeking ISO 22000 certification if required by a customer. Companies producing other similar products such as herbal medicines and veterinary drugs which are ingested either directly or indirectly may also seek certification.</p> <ul style="list-style-type: none">• Please clarify how to interpret the wording of clause 9.1.1 "The certification body shall not exclude part of the processes, (...)"



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	<p>in the context where a manufacturer has separate and technically separate production lines at one geographic location and wish to certify only one production line against ISO 22000 – is this segregation possible or in conflict with ISO/TS 22003?</p> <p>The intent of 9.1.1 is to ensure that an organization or the site that is being certified has a consistent food safety management system. Thus, any production line or process in the organization that has a bearing on the food safety of the product should be included in the scope of certification and be under control and meet the requirements of ISO 22000. So the certification should focus on the entire scope.</p> <p>In the question that is presented, the organization has two factories in the same location. The individual making the inquiry asked whether one site could be certified given that the sites do not produce identical products and use different manufacturing processes.</p> <p>There are two questions that need to be initially addressed:</p> <ol style="list-style-type: none">1. Is the organization planning to get a single certification at the organizational level that would cover at least one of the sites?2. Is there any significant cross over or interaction between the two sites? <p>If the organization is planning a single food safety management system at the corporate level, then all sites that fall under the certification would need to be certified.</p> <p>If there is no significant cross over between the two factories, then it would be possible to have only one factory certified.</p> <p>In the present case, based on the information provided, there does not appear to be a cross over between either products or processes.</p> <ul style="list-style-type: none">• How to interpret ISO/TS 22003 when it comes to classifying an activity in the category table? It relates to the production of casein plates for use on cheese (at the crust). These casein plates (edible although they are not intended to be digested) derived from milk constituents; they are printed such as labels, and then becomes a component of the whole cheese. We do not know whether to classify them as: Perishable food of animal origin (C1), Packaging for food (I) or Biochemicals (K)? <p>Casein labels' are produced from casein and other food-grade materials, printed and stored at ambient temperature. They are used as a label, however, because they are affixed to the cheese surface</p>



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	<p>during pressing and/or turning of the cheese. Thus, they become part of the surface of the cheese. Therefore, they may be consumed.</p> <p>The material intergrates into the food and becomes part of the food</p> <p>Also, when cheese is sold the label becomes part of the net-weight.</p> <p>Thus, these labels could be considered as cheese or food.</p> <ul style="list-style-type: none"> • The possibility of certification under ISO 22000 for a company manufacturing disposable paper napkin for home use and food contact? <p>YES it is possible. Because of possible migration issues, the appropriate PRP standard is ISO TS 22002-4 Food packaging manufacturing</p>
Additional guidance	
<p>Where can I find additional guidance on ISO 22000?</p>	<p>ISO/TS 22004:2014 (Food safety management systems – Guidance on the application of ISO 22000:2005) is a guide on application of ISO 22000:2005. ISO/TS 22002-1:2009 is a guidance of PRPs on food safety for food manufacturing. And ISO 22005:2007 is a guidance of traceability in feed and food chain.</p>
SMEs	
<p>Can ISO 22000 be used by small businesses without ‘administration overload’?</p>	<p>ISO 22000 was designed to be used by any business within the food chain. This includes both large and small businesses. ISO sees the need to provide resources to small businesses. These resources are designed to help in the implementation process. One resource is “ISO 22000 Food safety management systems - An easy-to-use checklist for small business. Are you ready?” This book can be purchased from ISO. A second resource is “How to use ISO 22000.”. Information for both documents can be obtained at the ISO website. One key issue in developing an effective management system is that documentation should be seen as a tool to help a company manage food safety. ISO 22000 should NOT be seen as a documentation system.</p>
Scope of the FSMS	
<p>Does a business need to consider other issues apart from Food Safety?</p>	<p>Food defence is a matter of concern to the world. Clause 5.7 of ISO 22000:2005 requires emergency preparedness and response. Clause 5.3 of ISO/TS 22004:2014 provides their guidance. And clause 18 of ISO/TS 22002-1, titled “Food defence, biovigilance, and bioterrorism” is also one of the guidance of PRP for manufacturing.</p>

