

IWA 37-3:2022

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Safety, security and sustainability of cannabis facilities and operations — Part 3:
Good production practices (GPP)

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PRF IWA 37-3

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[Contents ¶](#)

[Contents ¶](#)

Introduction iii¶

Foreword ix¶

1 Scope 1¶

2 Normative references 3¶

3 Terms and definitions 3¶

4 Quality System- General 10¶

4.1 Understanding the organization and its context 10¶

4.2 Understanding the needs and expectations of interested parties 11¶

4.3 Establishing the CQP 11¶

4.3.1 Control of externally provided processes, products or services 11¶

4.4 Licences 12¶

4.5 Policy 12¶

4.5.1 Establishing the CQP policy 12¶

4.5.2 Communicating the CQP policy 12¶

4.6 Organizational roles, responsibilities and authorities 12¶

4.6.1 Quality & Safety Team Leader 12¶

4.6.2 Product Security 13¶

4.7 Planning of changes 14¶

5 Support 14¶

5.1 Resources 14¶

5.1.2 People 14¶

5.1.3 Infrastructure 14¶

5.1.4 Work environment 15¶

5.2 Documented information 15¶

5.2.1 General 15¶

5.2.2 Creating and updating 15¶

5.2.3 Control of documented information 15¶

5.2.4 Data Integrity and Backup 16¶

6 Designing and Implementing GPPs within the Operation 16¶

6.1 Development of Processes 16¶

6.2 Establishing Criteria for processes 16¶

6.2.1 Characteristics of raw materials, ingredients and product contact materials 16¶

6.2.2 Characteristics of end products (finished products) 17¶

6.2.3 Intended use 17¶

6.2.4 Flow diagrams and description of processes 18¶

6.3 Risk assessment/Hazard analysis 19¶

6.3.1 General 19¶

6.3.2 Hazard identification and determination of acceptable levels 19¶

6.3.3 Hazard assessment 20¶

6.3.4 Selection and categorization of control measure(s) 21¶

6.4 Implementing process controls 22¶

6.4.1 Good production practices (GPPs) 22¶

6.4.2 Control measures for significant hazards 22¶

6.4.3 Validation of control measures for significant hazards 23¶

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PRF IWA 37-3

<https://standards.iteh.ai/catalog/standards/sist/1022b6e6-5293-7c993da306c0/prf-iwa-37-3>

Contents

Introduction	vi
1 Scope	1
2 Normative references	2
3 Terms and definitions	3
4 General	11
4.1 Understanding the organization and its context.....	11
4.2 Understanding the needs and expectations of interested parties.....	11
4.3 Establishing the COP.....	12
4.3.1 General.....	12
4.3.2 Control of externally provided processes, products or services.....	12
4.4 Licences.....	12
4.5 Policy.....	13
4.5.1 Establishing the COP policy.....	13
4.5.2 Communicating the COP policy.....	13
4.6 Organizational roles, responsibilities and authorities.....	13
4.6.1 General.....	13
4.6.2 Quality and safety team leader.....	13
4.6.3 Product security.....	14
4.7 Planning of changes.....	14
5 Support	15
5.1 Resources.....	15
5.1.1 General.....	15
5.1.2 People.....	15
5.1.3 Infrastructure.....	15
5.1.4 Work environment.....	15
5.2 Documented information.....	16
5.2.1 General.....	16
5.2.2 Creating and updating.....	16
5.2.3 Control of documented information.....	16
5.2.4 Data integrity and backup.....	17
6 Designing and implementing GPP within the operation	17
6.1 Development of processes.....	17
6.2 Establishing criteria for processes.....	17
6.2.1 Characteristics of raw materials, ingredients and product contact materials.....	17
6.2.2 Characteristics of end products (finished products).....	18
6.2.3 Intended use.....	18
6.2.4 Flow diagrams and description of processes.....	18
6.3 Risk assessment/Hazard analysis.....	19
6.3.1 General.....	19
6.3.2 Hazard identification and determination of acceptable levels.....	19
6.3.3 Hazard assessment.....	21
6.3.4 Selection and categorization of control measures.....	21
6.4 Implementing process controls.....	22
6.4.1 Good production practices (GPP).....	22
6.4.2 Control measures for significant hazards.....	22
6.4.3 Validation of control measures for significant hazards.....	23
6.4.4 Control of monitoring and measuring methods.....	23
6.5 Process control documentation.....	24

6.5.1 Master manufacturing records (MMRs)	24
6.5.2 Batch manufacturing records	25
6.6 Verification related to GPP and the hazard control plan	26
6.6.1 Verification	26
6.6.2 Verification results	26
6.6.3 Analysis of results of verification activities	27
6.7 Laboratory system/Product testing	27
6.7.1 Testing for phytocannabinoids	27
6.7.2 Testing for contaminants	27
6.7.3 Testing for pesticides	28
6.7.4 Sample retention	28
6.7.5 Durable life/Durable life date	28
6.8 Control of product and process nonconformities	29
6.8.1 General	29
6.8.2 Corrections	29
6.8.3 Corrective actions	30
6.8.4 Handling of potentially unsafe products	30
6.9 Complaint management	32
6.10 Identification and traceability	32
6.11 Packaging system	33
6.11.1 General	33
6.11.2 Packaging: Sustainability, safety and quality	33
6.11.3 Packaging: Containers and wrappers	34
6.11.4 Packaging labelling: Product identifiers	34
6.11.5 Packaging labelling: Advertising	35
Annex A (normative) GPP for cannabis and cannabis product quality and safety	37
Annex B (informative) Guidance on applying GPP to cannabis edibles	58
Bibliography	70

<https://standards.iteh.ai/catalog/standards/sist/1022b6e6-5293-4c61-a5ca-7c993da306c0/prf-iwa-37-3>

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

International Workshop Agreement IWA 37 was approved at a series of workshops hosted by the Standards Council of Canada (SCC), in association with Underwriters Laboratories of Canada (ULC), held virtually between December 2020 and June 2021.

A list of all parts in the IWA 37 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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In order to respond to urgent market requirements, ISO has also introduced the possibility of preparing documents through a workshop mechanism, external to its normal committee processes. These documents are published by ISO as International Workshop Agreements. Proposals to hold such workshops may come from any source and are subject to approval by the ISO Technical Management Board which also designates an ISO member body to assist the proposer in the organization of the workshop. International Workshop Agreements are approved by consensus amongst the individual participants in such workshops. Although it is permissible that competing International Workshop Agreements exist on the same subject, an International Workshop Agreement shall not conflict with an existing ISO or IEC standard.¶

¶ An International Workshop Agreement is reviewed after three years, under the responsibility of the member body designated by the Technical Management Board, in order to decide whether it will be confirmed for a further three years, transferred to an ISO technical body for revision, or withdrawn. If the International Workshop Agreement is confirmed, it is reviewed again after a further three years, at which time it must be either revised by the relevant ISO technical body or withdrawn.¶

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This document, ISO IWA 37-3 is one of the set of documents prepared by the ISO International Workshop Agreements on the Safety, security and sustainability of cannabis facilities and operations (ISO IWA 37) and was developed by Working Group 3, ISO IWA 37/WG3. The Workshop was conducted virtually from December 2020 through June 2021.¶

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Supporting material to accompany this

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Introduction

While cannabis has been fully legalized in Canada and in many states in the USA, it is a new and emerging industry that is moving at a very fast pace in many other parts of the world. While legalization is being deliberated by governments and legislative bodies, companies are creating their own infrastructure in anticipation of legal approval. Meanwhile, government regulators and the societies they serve are grappling with the lack of consistent rules and guidance to deliver safety, security and sustainability of cannabis facilities and operations, while growers and producers use their own judgment on how to establish and operate facilities.

It has become very clear that the global cannabis market is opening up very rapidly. The cannabis product and the industry will become more and more ubiquitous as the global barriers start to lower and come down. If the current trend continues, it is predicted that well over one third of the globe will accommodate cannabis by 2024.

What is unique about this new and emerging industry is that it is coming from an illicit status into decriminalization and evolving into a legitimate burgeoning business. Due to its pioneering status, very little exists in terms of research, studies, historical experience and best practices. Standardization is likewise very slow on the uptake, and the cannabis industry remains severely underserved.

There are therefore distinct challenges for the safety, security and sustainability of cannabis facilities and operations, which the IWA 37 series seeks to address as follows:

- Part 1: Requirements for the safety of cannabis buildings, equipment and oil extraction operations;
- Part 2: Requirements for the secure handling of cannabis and cannabis products;
- Part 3 (this document): Good production practices (GPP).

The good production practices (GPP) specified in this document are intended to ensure product quality by mitigating threats of mislabelling or adulterating cannabis products. These practices are compatible with the requirements for safety, product security, and facility safety specified in IWA 37-1 and IWA 37-2.

To align with international best practices, this document builds upon the internationally recognized framework and principles used in good manufacturing practices (GMP) and GPP, which comprise a system of processes, procedures, and documentation that help to ensure products are consistently produced and controlled in accordance with quality standards. These practices are typically required to conform to guidelines and regulations recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug products and active pharmaceutical products. The application of these guidelines require that manufacturers, processors and packagers of drugs, medical devices and food take proactive steps to ensure that their products are safe, pure and effective.

The production of cannabis products presents unique and challenging hazards and requires additional control measures and prerequisite programmes, from the perspectives of safety, product quality and safety, product security and facility safety, as well as from the perspective of compliance with statutory or regulatory requirements, which in most jurisdictions are in addition to those governing conventional product manufacturing.

The production and sale of cannabis products encompasses the full supply chain from the cultivation and harvesting of the cannabis plant, through the processing of the plants and the extraction of concentrated oils, to the manufacturing of cannabis products using conventional methods, and it includes the storage, handling, distribution and retailing of these products.

Given the unique aspects associated with cannabis edibles, this sub-set of cannabis products is considered separately. It is felt that the most effective approach for the development of future ISO standards for cannabis edibles is to build upon the strong foundation for food safety management systems set out in ISO 22000 and in ISO/TS 22002-1, together with the technical guidance contained in

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All of these provide...here are therefore distinct challenges for the safety, security and sustainability of cannabis buildings, premises, ...acilities and operations.

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Following approval by the Technical Management Board of ISO, the Standards Council of Canada (SCC) and UL in Canada, have organized a workshop to develop an International Workshop Agreement (IWA 37) on the Safety, Security and Sustainability of Cannabis Facilities and Operations. ¶
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Workshop document #1 - Technical guide

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Workshop document #... Part 2 - Technical guide... Requirements for the secure handling of cannabis and cannabis products; and

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Workshop document #... Part 3 - Technical guide for good production practices for cannabis products, with Annex B specifically dedicated to the unique aspects related to cannabis edibles. ¶
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This International Workshop Agreement, prepared by ISO IWA 37-3,

Deleted: Guide ...GPP) for cannabis was developed by ISO IWA 37/WG3.

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A "cannabis product" is a packaged good which includes cannabis or cannabis derivative available in multiple formats for commercial and or retail distribution. A

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Deleted: may also include a 'cannabis edible' or "food" which is infused with a cannabis derivative, most often an extracted oil, of the cannabis plant. ¶
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the main body of this document, rather than to develop a new set of GPP exclusively for cannabis edibles.

Annex B outlines this approach in more detail.

Supporting material to accompany the IWA 37 series is available at the following website: IWA 37 – Safety, security and sustainability of cannabis facilities and operations.

A list of workshop participants is available from the Standards Council of Canada (SCC).

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This document provides both new requirements and guidance for

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Deleted: this new category of products. Such technical guidance must be considered in the development and production of cannabis products and is driven by quality systems designed to assure the highest standards of quality

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Safety, security and sustainability of cannabis facilities and operations — Part 3: Good production practices (GPP)

1 Scope

This document specifies requirements and recommendations for organizations directly or indirectly involved in the cannabis supply chain, to enable them to:

- plan, implement, operate, maintain and update a good production practice programme for providing products that are safe, according to their intended use;
- demonstrate compliance with applicable statutory and regulatory requirements;
- evaluate and assess mutually agreed customer requirements and demonstrate conformity to them;
- effectively communicate with interested parties and demonstrate conformity to relevant interested parties;
- demonstrate conformity to stated policies in a cannabis quality programme (CQP) for product safety, product quality, product security and facility safety;
- support the evaluation of quality programmes by external organizations or to permit self-assessment or self-declaration of adherence to some or all of the guidance contained in this document.

All requirements in this document are generic and intended to be applicable to all organizations in the cannabis supply chain, regardless of size and/or complexity. Organizations that are directly or indirectly involved include, but are not limited to, growers/cultivators, harvesters, primary processors, producers of cannabis, manufacturers of cannabis derivatives, cannabis edibles and/or cannabis products, testing providers, retailers and organizations providing transportation, storage and distribution services, suppliers of equipment, packaging materials and other contact materials.

This document intended to enable any organization, including small and/or less developed organizations, to implement externally developed elements in its CQP.

NOTE 1 Organizations in the cannabis supply chain are diverse in nature and not all the requirements specified in this document apply to each establishment or process. Justifications for exclusions or the use of alternative measures can be documented by a risk assessment/hazard analysis or other appropriate means.

This document provides guidance related to the following categories of cannabis, cannabis derivatives and cannabis products:

- cannabis plant seeds;
- cannabis plants;
- fresh cannabis;
- dried cannabis;

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— cannabis derivatives;

— cannabis topicals;

— inhalable cannabis.

NOTE 2 Annex B provides additional guidance on applying GPP to cannabis edibles with respect to requirements and recommendations in existing food safety standards.

Where buildings or premises combine cultivation and processing of cannabis plants, including ancillary activities, along with other operational activities, the requirements and recommendations in this document apply only to that portion of the facility.

NOTE 3 Where joint use activities are present in a common building, specific statutory and regulatory requirements can apply for each category.

This document does not address the following:

— requirements related to research and development activities for finished products;

— general fire prevention or building construction features that are normally a function of local building and fire codes where applicable;

— premises used exclusively for operational activities, such as office space, call centres and retail outlets, used for the distribution, marketing, or sale of cannabis;

NOTE 4 Shipping and receiving of products from the production facility for further distribution are not considered as a retail outlet.

— the safe consumption or use of the cannabis or cannabis products produced by organizations applying these good production practices;

— occupational health and safety requirements governing cannabis workers and personnel except as identified in A.8.4 and A.8.6;

— the protection of the environment;

— security of the supply chain monitoring system, including cybersecurity and notifications;

NOTE 5 Security and monitoring of the supply chain are dealt with specifically in IWA 37-2.

— outdoor cultivation of cannabis and industrial hemp;

— growing of cannabis intended for personal use;

— the use of cannabinoids as ingredients that are derived from plants other than cannabis, or derived from other organisms, or created synthetically.

2 Normative references

There are no normative references in this document.

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Note: (Informative), Clause A.1.1. ¶

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A.1.1 In many cases a building or facility may be utilized for both the cultivation of cannabis plants and processing of cannabis products, along with a retail store front, call centre, or office administration space.¶

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Users of this document should be aware that where such

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Deleted: may also apply (for example Good Manufacturing Practice (GMP) for the production of Medicines may also apply for Cannabis used as a Medicine).

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Deleted: requirements related to the licensing, accreditation nor certification of organizations offering services related to third party auditing or certification of an organization who meet or exceed this Technical Guide; ¶

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3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

3.1 acceptable level

level of a *safety hazard* (3.38) not to be exceeded in the *end product* (3.18) provided by the *organization* (3.27)

[SOURCE: ISO 22000:2018, 3.1]

3.2 audit

systematic, independent and documented *process* (3.32) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.27) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011.

Note 4 to entry: Relevant disciplines are, for example, food safety management, quality management or environmental management.

[SOURCE: ISO 22000:2018, 3.3]

3.3 cannabis

genus of flowering plants made up of many different phytocannabinoids and chemical compounds

Note 1 to entry: Research into cannabis by governing bodies and organizations is ongoing around the world, and drug classifications are constantly under review. Regulation of cannabis legalization frameworks can vary between jurisdictions, based on the levels of tetrahydrocannabinol (THC) available in the plant.

3.4 cannabis derivative

secondary product (3.33) that can be extracted or obtained from a *cannabis* (3.3) biomass

Note 1 to entry: Classification of synthetically derived cannabinoids can vary between jurisdictions.

3.5 cannabis edible

food (3.19) which includes *cannabis* (3.3) or *cannabis derivative* (3.4) as an ingredient

Note 1 to entry: Dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds are not in themselves considered food.

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ISO 22002-1:2009 Prerequisite programmes on food safety – Part 1 Food Manufacturing

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Deleted: Note: Cannabis is currently in research, review, and drug reclassification globally by different

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3.6
cannabis product

packaged goods containing *cannabis* (3.3) or *cannabis derivative* (3.4), available in multiple formats for commercial and/or retail distribution

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3.7
cannabis waste

solid, liquid or gaseous material that is a *cannabis product* (3.6), contains *cannabis* (3.3) or has come into contact with *cannabis*, destined for disposal and not intended for sale or for use in any way other than for agronomic purposes such as compost

Note 1 to entry: Definitions of cannabis waste can vary between jurisdictions. For example, in a jurisdiction that sets a specific tetrahydrocannabinol (THC) threshold to define cannabis waste at a specific concentration of THC (e.g. 10 µg/g), waste that has a concentration below that threshold is not considered to be cannabis waste.

3.8
competence

ability to apply knowledge and skills to achieve intended results

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Moved (insertion) [6]

[SOURCE: ISO 22000:2018, 3.4]

3.9
conformity

fulfilment of a *requirement* (3.35)

[SOURCE: ISO 22000:2018, 3.5]

3.10
contamination

introduction or occurrence of a contaminant including a *safety hazard* (3.38) in a *product* (3.33) or processing environment

[SOURCE: ISO 22000:2018, 3.6]

3.11
continual improvement

recurring activity to enhance *performance* (3.29)

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[SOURCE: ISO 22000:2018, 3.7]

3.12
control measure

action or activity that is essential to prevent a *safety hazard* (3.38) and/or *significant safety hazard* (3.39) or reduce it to an *acceptable level* (3.1)

Note 1 to entry: Control measure(s) is (are) identified by risk assessment/hazard analysis.

[SOURCE: ISO 22000:2018, 3.8, modified — The words “a significant food safety hazard” have been replaced with “a safety hazard and/or significant safety hazard” in the definition; the original Note 1 to entry has been deleted and the words “risk assessment” have been added to the remaining Note to entry.]

3.13

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corrective action

action to eliminate the cause of a *nonconformity* (3.25) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action includes cause analysis.

[SOURCE: ISO 22000:2018, 3.10]

3.14

documented information

information required to be controlled and maintained by an *organization* (3.27) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media, and from any source.

Note 2 to entry: Documented information can refer to:

- the *management system* (3.22), including related *processes* (3.32);
- information created in order for the organization to operate (documentation);
- evidence of results achieved (records).

[SOURCE: ISO 22000:2018, 3.13]

3.15

durable life

period, commencing on the day on which a *cannabis product* (3.6) is packaged as an *end product* (3.18), during which the product, when it is stored under conditions appropriate to that product, will retain, without any appreciable deterioration, normal palatability and any other qualities claimed for it

3.16

durable life date

date on which the *durable life* (3.15) of a *cannabis product* (3.6) ends

3.17

effectiveness

extent to which planned activities are realized and planned results achieved

[SOURCE: ISO 22000:2018, 3.14]

3.18

end product

product (3.33) that will undergo no further processing or transformation by the *organization* (3.27)

Note 1 to entry: 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, an input, or an ingredient in the context of the second organization.

[SOURCE: ISO 22000:2018, 3.15, modified — The words “an input” have been added in the Note to entry.]

3.19

food

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Note the definition of “food” as defined in ISO 22000:2018 Clause 3.18:

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IWA 37-3:2022

substance (ingredient), whether processed, semi-processed or raw, which is intended for consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances (ingredients) used only as drugs.

[SOURCE: ISO 22000:2018, 3.18, modified — The original Note to entry has been deleted.]

3.20

interested party

person or organization (3.27) that can affect, be affected by, or perceive itself to be affected by a decision or activity

[SOURCE: ISO 22000:2018, 3.23, modified — The admitted term "stakeholder" has been deleted.]

3.21

lot

defined quantity of a product (3.33) produced and/or processed and/or packaged essentially under the same conditions

Note 1 to entry: The lot is determined by parameters established beforehand by the organization (3.27) and may be described by other terms, e.g. batch.

Note 2 to entry: The lot may be reduced to a single unit of product.

[SOURCE: ISO 22000:2018, 3.24]

3.22

management system

set of interrelated or interacting elements of an organization (3.27) to establish policies (3.30) and objectives (3.26) and processes (3.32) to achieve those objectives.

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

Note 4 to entry: Relevant disciplines are, for example, a quality management system or an environmental management system.

[SOURCE: ISO 22000:2018, 3.25]

3.23

measurement

process (3.32) to determine a value

[SOURCE: ISO 22000:2018, 3.26]

3.24

monitoring

determining the status of a system, a process (3.32) or an activity

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Moved up [5]: competence

Moved up [6]: ability to apply knowledge and skills to achieve intended results

Moved up [7]: continual improvement

Deleted: recurring activity to enhance performance (3.26)
[SOURCE: ISO Directives Part 1, Annex SL, Appendix 2, (2021)]

Moved up [8]: durable life date

Deleted:

Moved up [9]: extent to which planned activities are

Moved up [10]: end product

Deleted:

Deleted: [SOURCE: ISO Directives Part 1, Annex SL, ...]

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Deleted: product (3.30) that will undergo no further

Deleted: ...SOURCE: ISO 22000:2018]

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Deleted: (preferred term)

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Deleted: 24...7) to establish policies (3.27...0) and

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Deleted: ...rocess (3.29

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