INTERNATIONAL WORKSHOP **AGREEMENT**

IWA 37-3

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Safety, security and sustainability of cannabis facilities and operations —

Part 3:

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Co	ntent		Page
Fore	word		v
Intr	oductio	on	vi
1	Scor	De	1
2		mative references	
3	Terr	ns and definitions	2
4		eral	
	4.1	Understanding the organization and its context	
	4.2	Understanding the needs and expectations of interested parties	
	4.3	Establishing the CQP 4.3.1 General	
		4.3.2 Control of externally provided processes, products or services	
	4.4	Licences	
	4.5	Policy	
	110	4.5.1 Establishing the CQP policy	
		4.5.2 Communicating the CQP policy	
	4.6	Organizational roles, responsibilities and authorities	
		4.6.1 General	
		4.6.2 Quality and safety team leader	
		4.6.3 Product security	
	4.7	Planning of changes	
5	Supp	port	13
	5.1	Resources	
		5.1.1 General	13
		5.1.2 People	
		5.1.3 Infrastructure	
	5 0	5.1.4 Work environment	14
	5.2	Documented information	
		5.2.1 General 5.2.2 Creating and updating 5.2.2	
		5.2.3 Control of documented information	
		5.2.4 Data integrity and backup	
_	ъ.		
6		igning and implementing GPP within the operation	15
	6.1 6.2	Development of processes Establishing criteria for processes	
	0.2	6.2.1 Characteristics of raw materials, ingredients and product contact materials	
		6.2.2 Characteristics of end products (finished products)	
		6.2.3 Intended use	
		6.2.4 Flow diagrams and description of processes	
	6.3	Risk assessment/Hazard analysis	18
		6.3.1 General	18
		6.3.2 Hazard identification and determination of acceptable levels	18
		6.3.3 Hazard assessment	
		6.3.4 Selection and categorization of control measures	
	6.4	Implementing process controls	20
		6.4.1 Good production practices (GPP)	
		6.4.2 Control measures for significant hazards	
		6.4.4 Control of monitoring and measuring methods	
	6.5	Process control documentation	
	0.5	6.5.1 Master manufacturing records (MMRs)	
		6.5.2 Batch manufacturing records	
	6.6	Verification related to GPP and the hazard control plan	

IWA 37-3:2022(E)

	6.6.1 Verification		Z4
. =	J .	cation activities	
6.7	Laboratory system/Product testin	g	25
		oids	
6.8	,	nconformities	
0.0		ilcontot mittes.	
		afe products	
6.9	9 1	F	
6.10			
6.11			
	6.11.2 Packaging: Sustainability, s	afety and quality	31
		wrappers	
		ct identifiers	
	6.11.5 Packaging labelling: Advert	tising	33
nex A (no	rmative) GPP for cannabis and can	nabis product quality and safety	34
nex B (in	formative) Guidance on applying G	PP to cannabis edibles	54
oliograph	V		66

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.

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 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.

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of workshop pa Supporting material to accompany the IWA 37 series is available at the following website:

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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;
- cannabis derivatives;
- cannabis topicals;

IWA 37-3:2022(E)

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.

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/