ARUC

DIRECTIVE ON TECHNICAL STANDARDS AND APPROVED OPERATING PRACTICES

On acceptable practices in the operation of Cannabis Harm Reduction Associations

VERSION: 4.0

UPDATED: 21 JANUARY 2026

IIn exercise of the power conferred by article 38 of SL 628.01, the Authority for the Responsible Use of Cannabis ("the Authority") is hereby issuing the following directive on acceptable practices in the operation of Cannabis Harm Reduction Associations in line with the Authority's aim to ensure that cannabis delivered to the associations' members is safe and of good quality.

Version 3 of the same directive is being repealed and replaced by this version.

The Authority reserves the right to amend this instrument at any time. The Authority shall not be held liable for any costs incurred in ensuring compliance to this instrument, including costs incurred in adjusting operations in line with subsequent amendments.

21 January 2026

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DEFINITIONS

""Association" shall mean a prospective or approved Cannabis Harm Reduction Association as defined in Subsidiary Legislation 628.01.

"Authority" shall mean the Authority for the Responsible Use of Cannabis as defined in Chapter 628 of the Laws of Malta.

"CCTV" (Closed Circuit Television) shall mean a surveillance system comprising of cameras and associated equipment used for monitoring and recording of activities within a defined zone for security purposes.

"ERA" shall mean the Environment and Resources Authority as defined in Chapter 549 of the Laws of Malta.

"Permit" shall have the same meaning as defined in Article 35 of Subsidiary Legislation 628.01.

STANDARD 1 – OPERATIONAL ENVIRONMENT

I.1 Purpose

I.1.1 This standard stipulates the operational environmental requirements in all premises managed by the associations including their external perimeters.

I.2 Responsibilities

I.1.2 The Key Officer and individuals in other designated key positions (where applicable) must ensure that facilities are maintained in good condition to guarantee that the cannabis produced and distributed by the Association is of a good quality.

I.3 Operational Environment

I.3.1 Cleaning and Hygiene

I.3.1.1 All areas within properties managed by the association and their external perimeter shall be kept clean and well maintained. This also applies for tools, equipment, and accessories. Preventive maintenance must be done on a regular basis.

I.3.1.2 All personnel must maintain proper personal hygiene. Persons suffering from infectious diseases must not access areas where they could come into contact with cannabis.

I.3.1.3 Individuals must wear personal protective equipment before accessing processing rooms and when handling the product.

I.3.1.4 Associations shall have in place detailed policies and procedures which cater for all aspects of hygiene and sanitation management.

I.3.2 Pest Control

I.3.2.1 Adequate pest and vermin control monitors shall be installed inside the facility and along the external perimeters.

I.3.2.2 Pest monitoring devices are to be inspected on a regular basis and pest control activity is to be recorded.

I.3.2.3 Pesticides shall be suitable for the intended use and compliant with the standards used in the food industry.

I.3.2.4 The location of pest control monitors and instruments is to be recorded on a layout plan.

I.3.2.5 A log shall be kept to record the types and quantities of pesticides used and activities related to the pest control monitors and instruments.

I.3.3 Environmental Conditions

I.3.3.1 The entire process from seed to sale is to be done within a built and roofed structure or a fully enclosed glasshouse. Greenhouses must be made from durable, sturdy materials.

I.3.3.2 Temperature and humidity should be controlled and monitored to ensure adequate environmental conditions. No activity may be carried out between the 15th May and 15th October if the temperature may not be effectively controlled (such as in greenhouses). The Authority may, at its discretion, reduce the period when no activity may be carried out if partial control of the operating environment is achieved.

I.3.3.3 Temperature and humidity readings should be monitored and logged daily.

I.3.3.4 Areas where substantial activity will take place must be well lit.

I.3.3.5 An adequate filtration system to prevent the ingress and release of particles, microbial organisms and odours must be in place.

I.3.3.6 Air intake and extraction should be through the filtration system. If this is not feasible due to the need to ensure a continuous circulation of air in high volumes (such as in greenhouses), air intake openings and vents should be covered by insect screens and additional environmental testing is to be carried out as stipulated by the Authority.

I.3.3.7 Doors which lead from the processing rooms to external areas must be segregated from through an ante-room.

I.3.3.8 Policies and procedures shall be in place for the setting up, maintenance and cleaning of equipment required to adhere to these Standards.

I.3.4 Water

I.3.4.1 Water used for irrigation should be free from pathogens and pesticides. Mandatory testing as directed by the Authority is to be carried out if ground water or rainwater is to be used for irrigation. Total dissolved solids (TDS) shall not exceed 250 parts per million (ppm).

I.3.4.2 Irrigation systems, reservoirs and containers used to hold water are to be in good condition and maintained on a regular basis.

I.3.4.3 Reservoirs and containers used to hold water are to be equipped with water pumps, circulators, or similar equipment to prevent stagnation.

STANDARD 2 – DISTRIBUTION

II.1 Purpose

II.1.1 This standard stipulates how the movement of cannabis from the approved cultivation to distribution sites and the subsequent distribution to the members shall take place.

II.2 Responsibilities

II.2.1 The Key Officer and individuals in other designated key positions (where applicable) shall be responsible for the transfer, handling, movement, and distribution of material. They must also ensure that cannabis is safely secured to prevent theft or mishandling by third parties.

II.3 Distribution

II.3.1 Movement of Material

II.3.1.1 The cultivation and distribution sites must be retained physically segregated, even if the sites are physically interconnected.

II.3.1.2 Transfer of cannabis between the cultivation and distribution sites should be done using secured container.

II.3.1.3 Movement of cannabis between sites should be recorded and verified by a second person, who must be the Key Officer or an individual in a designated key position.

II.3.1.4 The net weight of cannabis must be recorded before each movement. Equipment must be calibrated on a yearly basis. Calibration should be recorded.

II.3.1.5 Movement of cannabis may only be carried out by an employee or by service provider approved by the Authority.

II.3.1.6 Association which use service providers must ensure that the service provider is authorized by the Authority to carry out transportation prior to the commencement of operations. A service agreement which details each party's responsibilities is to be signed and forwarded to the Authority prior to commencement of operations.

II 3.1.7 Transportation of cannabis may only be carried out:

a) by the individual approved by the Authority

b) using the vehicle approved by the Authority;

c) between the association's cultivation and distribution sites or to transport samples to the approved laboratory.

d) between 7.00am and 7.00pm;

e) using the most feasible route without undue detours and without any stopping en route;

f) In a temperature-controlled container which must be kept inside a secure container.

II.3.1.8 The Association is to obtain logs of the GPS tracking of the vehicle used for transportation and retain such logs for a period of one year.

II.3.1.9 Transfer of cannabis material to or from third parties including other Associations is strictly prohibited.

II.3.2 Distribution

II.3.2.1 Cannabis may only be distributed from facilities approved by the Authority. Distribution through other channels/mediums (e.g., vending machines, deliveries) is prohibited.

II.3.2.2 Cannabis may only be distributed by individuals approved by the Authority.

II.3.2.3 Distributed cannabis must be registered and assigned a unique identifier as stipulated by the Authority.

II.3.2.4 Members should be allowed to inspect the various species and phytocannabinoid profiles available and discuss their suitability in a harm reduction context with the aim of fostering community-based sharing of experiences. Small amounts of cannabis may be kept in clear containers in the area where cannabis is served to the members to achieve this aim. Cannabis held in these containers should be marked as not for distribution.

II.3.2.5 Distributors must verify the identity of individuals who request cannabis and confirm their membership status prior to each transaction.

II.3.2.6 Attempted purchases by unauthorized persons shall be immediately reported to the Authority.

II.3.2.7 The consumption or use of cannabis in any area managed by the Association is strictly prohibited.

II.3.2.8 Associations shall have in place policies and procedures to recall batches of cannabis which had already been distributed to the members.The Authority is to be notified immediately if cannabis must be recalled.

II.3.2.9 Complaints about the quality of the cannabis distributed must be immediately forwarded to the Authority.

STANDARD 3 – SECURITY

III.1 Purpose

III.1.1 This Standard defines the security control measures and compliance obligations requirements.

III.2 Responsibilities

III.2.1 The Key Officer and individuals in other designated key positions (where applicable) must ensure that sufficient security measures are in place, effectively managed and maintained at all times as established in this Standard.

III.3 Security Measures, Monitoring and Requirements

III.3.1 Premises Monitoring and Security Systems

III.3.1.1 Premises must be equipped with intruder and fire alarm systems. An adequate number of fire extinguishers are to be installed across the premises.

III.3.1.2 CCTV cameras must be installed both inside and outside the premises whilst adhering and complying to data protection laws and regulations.

III.3.1.3 Intruder and fire alarms, fire extinguishers and the CCTV system must be monitored to ensure that they are operating effectively on a 24/7 basis.

III.3.1.4 Images recorded by the CCTV system must be retained and stored for 60 days in full compliance with data protection laws and regulations.

III.3.1.5 Adequate security measures must be adopted to prevent the unlawful or inadvertent disclosure of recorded images. These must include:

a) CCTV recording systems including the NVR/DVR must be kept in a secure location.

b) Only the Key Officer and individuals in designated key positions (where applicable) shall have access rights to view live CCTV images or to make copies or recorded images.

c) Access to CCTV images must be registered.

d) Images may only be disseminated as provided in the Data Protection Legislation.

III.3.1.6 Entries to cultivation, processing and storage areas including controlled waste must be recorded. Associations with five employees or more must have an electronic system which identifies employees and automatically logs each access for each designated area.

III.3.1.7 Premises must be completely enclosed with sturdy materials and its main entrance accessible through a well-secured door.

III.3.2 Access to premises

III.3.2.1 Unless otherwise approved by the Authority, third-parties may only be allowed to enter the premises to carry out works done on an exceptional basis. Their presence shall be kept to the bare minimum and an employee shall accompany each third party. The presence of third parties must be recorded.

III.3.2.2 Theft and other suspicious events and attempts of unauthorized entries must be immediately reported to the Authority.

III.3.3 Security Risk Assessments

III.3.3.1 The Authority shall carry out a security risk assessment to indicate the required security features that the Associations must install in their premises to render them secure. Applicants may submit their own alternative assessment for the Authority's review, however the final decision on which assessment shall be followed will be taken by the Authority; and the applicants must implement it in full at their expense. Each processing room must be equipped with at least two cameras at opposite angles. Micro processing rooms such as grow tents may be equipped with a single camera. Additional cameras are to be installed in rooms with irregular layouts, or where equipment obstructs the view of the cameras.

III.3.3.2 A certification which confirms that the installation has been completed successfully is to be obtained from the provider of the security features.

III.3.3.3 Any major, high, or critical risk factors identified in the assessments must be addressed promptly, within the timeframe established by the Authority.

III.3.3.4 The assessment will be repeated at periodic intervals as deemed necessary by the Authority.

III.3.3.5 A recovery plan must be in place covering (but not limited) premises, operations, IT systems, communication networks, security measures and key personnel.

STANDARD 4 – WASTE MANAGEMENT AND HANDLING

IV.1 Purpose

IV.1.1 This standard stipulates how the waste generated from cultivation activities, processing, movement, and distribution of cannabis shall be handled and disposed.

IV.2 Responsibilities

IV.2.1 The Key Officer and individuals in other designated key positions (where applicable) are responsible to ensure that materials defined as contaminated with cannabis in this standard are only disposed as indicated.

IV.3 Management and Handling of Cannabis Waste

IV.3.1 Any unused part of the cannabis plant shall be considered as waste.

IV.3.2 Waste is to be recorded and accounted for at all times. Details kept must include the weight, source (cultivation batch number or other description) and composition (leaves / stems or failed production cycle which includes flowers) of all additions to the waste compound.

IV.3.3 Waste is to be weighed using calibrated equipment which shall be calibrated at least once a year.

IV.3.4 Waste must be weighed and stored in secured containers which prevent escape of odours prior to its disposal as stipulated in clause 3.6.

IV.3.5 Cannabis waste containers must be placed in a secure location. Access shall be recorded.

IV.3.6 Cannabis waste may be disposed of in accordance with any of the following three options:

1. A service provider licensed by ERA may be engaged to dispose of the waste. The association must verify that the selected service provider is authorized before engaging it. A service agreement which indicates both parties' responsibilities must be signed before commencement of operations. The agreement must stipulate that the service provider will not store waste at its own facility or other third-party premises and that the waste will be taken directly to an approved incineration site. The agreement must also stipulate that the service provider must take the waste from within the premises. Vehicles used for the transportation of waste should be enclosed, adequate for such purpose, and secured throughout the entire process. The association should obtain a destruction certificate from the service provider detailing:

a) Arrival date of material at the incineration site.
b) Quantity of waste received and incinerated.
c) List of seals and corresponding serial numbers.
d) Disposal Certificate. A copy of the certificate is to be sent to the Authority.

2. Waste may be shredded and inserted into an enclosed composting container or other equipment suitable for composting placed in an adequately secured location. The container must prevent the escape of odours. The resultant compost must be sterilized through a procedure approved by the Authority prior to its use in the cultivation process. The association must record:

a) The date when the material was inserted into the container and details of the individuals who inserted the material.
b) The weight of the material added.
c) The date when the compost was taken out of the compost container and details of the individuals involved.
d) The weight of the compost taken out of the container.
e) The intended use of the compost produced. Compost may only be used within the association's property or disposed of if deemed unsuitable.
f) Date of sterilization of the compost prior to its use in the cultivation process.
g) Compost which is not used in the cultivation process may be disposed of:

i. within the association's property in areas not used for the cultivation of cannabis.
ii. as organic waste following quality testing which confirms that its THC level does not exceed 0.2%. The Authority may waive this requirement for subsequent tests if the results consistently indicate negligible THC levels.
iii. as indicated in clause 1 above.

h) Any other access to the container and details of the individuals involved.

3. Waste may be incinerated in an incinerator located within the premises. The association must record:

a) date when material was incinerated,

b) weight of material.

IV.3.7 The association shall include details about its intended waste disposal method in its proposed operational plan and request the Authority's approval whenever it desires to change or modify its methods.

IV.3.8 Excess and contaminated water and all other waste generated by the association shall be disposed of as permitted by law, including any specific requirements set by the ERA in the permit granted for the cultivation site.

IV.3.9 Any discrepancies or deviations noted throughout the process must be immediately reported to the Authority.

STANDARD 5 – RECONCILIATION PROCESS

V.1 Purpose

V.1.1 This standard specifies how reconciliation of all cannabis material held shall be performed to detect, investigate, resolve, and document any differences between the actual amount of physical stock counted ("on-hand") with the expected amount of stock that should be on-hand.

V.2 Responsibilities

V.2.1 The Key Officer must ensure that all activities from the acquisition of seed to the distribution of cannabis to the members including waste disposal are properly recorded and that all material is accounted for at all processes and stages.

V.3 Reconciliation Process

V.3.1 Incoming Cannabis Material (Seeds)

V.3.1.1 The Key Officer shall notify the Authority upon receipt of any cannabis seeds acquired. The notification shall include the quantity, source and product details including strain and potency.

VI.3.1.2 In cases where multiple Associations operate within the same compound, the cultivation of the same strain by different Associations within the compound is not allowed.

V.3.1.3 Seeds must be verified for tampering, integrity, authenticity, and quantity upon receipt.

V.3.1.4 Cannabis seeds received shall be registered.

V.3.2 Processing

V.3.2.1 Processing includes the plantation of cannabis seeds, propagation by other means including clones, cultivation, harvesting, drying, curing and packaging.

V.3.2.2 The four-eye principle must be applied when performing reconciliation. Personnel involved in the process must log findings.

V.3.2.3 Reconciliation must be carried out upon the completion of each process, that is:
a) the number of seeds planted / clones introduced,
b) the number of seedlings sprouted,
c) the number of mature plants – to be calculated upon initiation of the flowering phase,
d) amount of fresh flower harvested,
e) amount of dried cannabis obtained,
f) amount of waste generated (stems, leaves, flower) throughout the process,
g) amount of cannabis distributed from the batch.

V.3.2.4 Data obtained from the reconciliation process is to be submitted to the Authority by no later than two days following the completion of the reconciliation process, i.e. from the completion of each process.

V.3.2.5 A thorough review of any discrepancies should include a review of the records, ordering/receiving systems, security systems, storage systems, present and previous inventory.

V.3.2.6 Any suspicions of theft must be immediately investigated and reported to the Authority.

V.3.3 Finished Product

V.3.3.1 An inventory count of the cannabis material in finished state should be done at least once a month.

V.3.4 Other Measures

V.3.4.1 A reconciliation report must be compiled on a quarterly basis and sent to the Authority.

V.3.4.2 The report should include stored inventory being raw material, intermediate product or finished product, sold inventory (finished product) and cannabis material waste.

V.3.4.3 Any discrepancies resulting from processing activities (e.g. loss on drying, losses during processing activities etc.), must be justified and documented in the report.

V.3.4.4 Substantial non-compliance or breaches in the reconciliation process shall be deemed a serious offence which may lead to the suspension or revocation of the permit.

V.3.4.5 Associations shall have in place detailed policies and procedures which indicate how the reconciliation process shall be carried out.

STANDARD 6 – CULTIVATION AND PROCESSING

VI.1 Purpose

VI.1.1 This section stipulates the standards that must be adhered to in the cultivation and processing of cannabis.

VI.2 Responsibilities

VI.2.1 The Key Officer and individuals in other designated key positions (where applicable) are responsible to ensure that the cultivation and processing methods adhere to this Standard.

VI.3 Specific Requirements

VI.3.1 Seeds and propagation material

VI.3.1.1 Seeds and any propagation material (e.g. clones) must be botanically identified as to species, variety, chemotype and origin. The materials used must be traceable. Seeds must be free from pests and disease.

VI.3.2 Soil and fertilisation

VI.3.2.1 Cannabis must not be grown on soil contaminated with sludge, heavy metals, pesticide residues or other chemicals.

VI.3.2.2 Manure applied should be thoroughly composted.

VI.3.2.3 Fertilisers, nutrients and organic additives are to be approved by the Authority

VI.3.2.4 The use of fertilisers or nutrients which are not indicated as suitable for the cultivation of cannabis products is prohibited.

VI.3.2.5 Fertilisers and nutrients shall be used at the minimum effective dose, and in any case the dose shall not exceed that recommended by the supplier.

VI.3.2.6 The use of precision growth regulators is prohibited.

VI.3.2.7 A log is to be kept to record all activities related to the addition, application and removal of soil, nutrients and fertilisers.

VI.3.3 Pest control products

VI.3.3.1 Inorganic chemical herbicides and pesticides must not be used at any time. A declaration to this effect is to be submitted with the application and subsequently as requested by the Authority.

VI.3.32 A log detailing pest control activities is to be maintained.

VVI.3.4 Cultivation methods and processes

VI.3.4.1 Applications for a permit must be supported by an operational plan which includes:

a) the cultivation methods to be used,

b) all processes from seed to packaging listed sequentially,

c) the role of each employee in these roles,

d) details about the quantity and type of nutrients, organic pesticides (if any), and any other methods which shall be used to take care of the cannabis plants.

e) details about each item of equipment which shall be used and their role in the processes.

f) a one-year schedule of the number of cultivation cycles and the number of plants to be grown in each cycle. The first cultivation cycle is to be broken down by the cannabinoid profiles to be used.

g) a floor plan of the cultivation site which shows the location of each cannabis plant and each item of equipment, including sanitary facilities.

VI.3.4.2 Proposed revisions to processes, methods, number of plants grown, and surface area occupied following commencement of operations must be submitted to the Authority for approval.

VI.3.4.3 The association shall record all the methods, processes and number of plants grown and surface area occupied.

VI.3.5 Drying

VI.3.5.1 Crops must not be dried directly on the ground or under direct sunlight.

VI.3.5.2 Uniform drying speed and prevention of mold growth must be assured.

VI.3.6 Storage

VI.3.6.1 Following repeated controls and removal of any material not meeting its requirements or of undesired objects, the product must be packed and stored in clean, dry packaging. Further processing and enhancement of the product, except as provided for in Standard IX, is strictly prohibited.

VI.3.6.2 Cannabis must be clearly labelled.

VI.3.6.3 The packaging material must not contaminate the product.

VI.3.6.4 Dried, packaged cannabis must be stored in a clean, dry, well-ventilated room in which daily temperature fluctuations are limited and good ventilation is ensured.

VI.3.6.5 Stored cannabis should be made available to the members as soon as it is certified for release following the quality testing. No attempt should be made to withhold stock for future availability.

STANDARD 7 – SAMPLING AND TESTING

VII.1 Purpose

VII.1.1 This Standard lists the permitted analytes and sets the acceptable limits for contaminants for each tested batch of cannabis. Testing shall detect:

(a) the phytocannabinoid profile of the cannabis product.

(b) the presence of contaminants including microorganisms, foreign material, metals, microbial impurities, moisture content and water activity, mycotoxins, pesticides, residual solvents, terpenoids, and any other analyte or group of analytes.

VII.2 Responsibilities

VII.2.1 The Key Officer and individuals in other designated key positions (where applicable) shall ensure that products are prepared and delivered for testing as required in this standard. The individual in the designated key position responsible for testing shall ensure that the testing process adheres to these standards.

VII.3 General Requirements

VII.3.1 A contractual agreement is to be signed between the association and the laboratory which shall test the Association's products in line with these Standards.The chosen laboratory must have the ISO/EC 17025 accreditation or be GMP certified. The agreement must be submitted to the Authority for approval. The agreement is to bind the chosen laboratory to send a copy of the test results directly to the Authority.Subsequent renewals or new agreements must be submitted to the Authority when they become effective.

VII.3.2 A qualified person must sign the documented specifications and test results and indicate whether the cannabis batch has reached the minimum stipulated requirements for release.

VII.3.3 Testing must be done on dried cannabis flowers prior to its release for packaging and distribution or further processing as provided for in Standard IX. Stock which is not distributed within six months must be withheld and re-tested prior to its re-release. This process is to be repeated every six months if the stock remains undistributed. The date when the testing was done for microbiological contaminants is to be taken if the phytocannabinoid profile is not assessed in the initial test.

VII.3.4 The sample must be representative of the entire batch and may not be altered by any means prior to the test.

VII.3.5 A written procedure must be recorded for all processes in the sampling operation. The procedure is to be approved by the Authority and is to indicate:
a)The individual responsible to collect the sample,
b)how the sample shall be selected and collected,
c)the quantity to be tested for each batch, which is to be sufficient to obtain meaningful results to ensure compliance with the specifications.
d)how the sample shall be delivered to the testing laboratory
e)Health and safety precautions and any other relevant information.

VII.3.6 Test results must be retained by the association. A copy must be forwarded to the Authority.

VII.4 Standards for test sampling

VII.4.1 Sampling process

VII.4.1.1 Containers should be cleaned prior to sampling.

VII.4.1.2 All sampling tools and implements should be made of inert materials and kept scrupulously clean.

VII.4.1.3 Before re-(use), they should be thoroughly washed, rinsed with water or suitable solvent, dried and stored in clean conditions.

VII.4.1.4 All cleaning procedures and activities should be documented and recorded.

VII.4.2 Sampling operation and precautions

VII.4.2.1 Closures and labels must be tamper-evident.

VII.4.2.2 Samples or parts thereof must never be reintegrated.

VII.4.2.3 Labelling of samples should provide appropriate details, including the batch number.

VII.4.3 Storage and retention

VII.4.3.1 The container used to store a sample should not interact with the sampled material nor allow contamination. It should also protect the sample from light, air and moisture, as required by the storage directions.

VII.4.3.2 The sample container should be sealed and tamper-evident.

VII.4.4 Definition of batches

VII.4.4.1 A batch shall mean a number of cannabis plants cultivated together as defined in this article.

VII.4.4.2 Plants cultivated in separate cultivation areas (grow rooms) must be kept as different batches, even if the same cultivation medium is used or if the plants have the same phytocannabinoid profile. Plants cultivated using different methods must be separated into different batches, even if grown in the same area.

VII.4.4.3 For the purpose of testing for the phytocannabinoid profile, plants of different genetic composition cultivated together in the same area shall make up different batches.

VII.4.4.4 For the purpose of testing for microbiological contaminants, water activity and moisture content and filth and foreign material, plants of different profiles cultivated in the same area (grow room) with the same cultivation medium shall consist of a single batch. A composite sample which is representative of all plants cultivated in the same area (grow room) must be prepared for testing in such case.

VII.4.4.5 An association may request that a batch is further subdivided (graded) according to the potency or aesthetic desirability of the product. In such case additional testing of each subdivided batch is to be carried out as directed by the Authority.

VII.5 Specification Requirements

VII.5.1 Phytocannabinoid Profile

VII.5.1.1 Specification is to be in the following format and must be reported as in percentage terms (% weight).

Total Tetrahydrocannabinol (THC) (including Delta9 / Delta8 / optical isomers of such substances)
Tetrahydrocannabinolic acid (THCA)
Cannabidiol (CBD)
Cannabinol (CBN)

VII.5.1.2 The report may include the individual results for Δ9-THC, Δ8-THC and Δ10-THC isomers but total THC must always be reported. Total THC is the sum of the percentage by weight or volume measurement of tetrahydrocannabinolic acid (THCA) multiplied by 0.877, plus the percentage by weight or volume measurement of THC.

VII.5.1.3 Phytocannabinoids must be corrected for moisture content and reported on a dry weight basis.

VII.5.1.4 Testing shall be done on the first three batches of any phytocannabinoid profile which the association intends to distribute to its members and repeated after every twentieth batch.

VII.5.1.5 Testing for additional cannabinoids such as Tetrahydrocannabivarin (THCV), Cannabinadiolic acid (CBDA), Cannabidivarin (CBDV), Cannabigerol (CBG) and Cannabichromene (CBC) must be done if such cannabinoids are known to be relevant for the composition of the selected cannabinoid profile (strain).

VII.5.2 Contaminants

VII.5.2.1 Regulated analytes shall not exceed the limits indicated in the table below.

Micro-organism Analyte	
Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, Aspergillus terreus	Absent
Salmonella enterica, Salmonella bongori	Absent
Escherichia coli	Absent
Bacteria, Yeast and Mold Count	
Total Aerobic Microbial Count (TAMC)	2,000 cfu/g
Total Yeast and Mold Count (TYMC)	1,000 cfu/g
* Batches with a TAMC count up to 10,000 cfu/g and TYMC count up to 5,000 cfu/g may be released following an investigation and additional environmental monitoring, however, where TAMC exceeds 9,000 cfu/g or TYMC exceeds 4,000 cfu/g, undistributed stock shall be retested after four months instead of six months as indicated in clause VII.3.3.	
Mycotoxins	
Total Aflatoxins (Sum of Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, and Aflatoxin G2, if determined individually)	0.020 µg/g
Ochratoxin A	0.020 µg/g

Trace / Heavy Metal Analyte (as a Total)	
Arsenic (As)	0.2 µg/g
Cadmium (Cd)	0.3 µg/g
Chromium (Cr)	110 µg/g
Copper (Cu)	30 µg/g
Lead (Pb)	0.5 µg/g
Mercury (Hg)	0.1 µg/g

VII.5.2.2 The presence of other toxins and chemicals which may be harmful to the human body when inhaled is prohibited.If toxins, chemicals or other non-regulated analytes are detected, they must be identified on the final report.

VII.5.2.3 Testing for Total Viable Aerobic Bacteria Count and Total Yeast and Mold Count shall be performed prior to the release of each batch for distribution.

VII.5.2.4 Testing for Heavy Metal Analytes shall be done prior to the introduction or replacement of the medium and nutrients used for cultivation.

VII.5.2.5 Testing for micro-organism analytes and mycotoxins shall be performed prior to the release of each batch.

VII.5.3 Water Activity and Moisture Content

VII.5.3.1 Moisture content must be between 5% and 15%. Results must be reported to the nearest tenth of a percentile.

VII.5.3.2 Testing for Moisture Content shall be performed prior to the release of each batch onto the market.

VII.5.4 Filth & Foreign Material

VII.5.4.1 Filth and foreign material include, but is not limited to hair, insects, faeces, manufacturing waste, packaging contaminants, and by-products. Stems with a diameter => 3mm must not exceed 5% of the sample by weight. Other foreign matter must not exceed 2%.

VII.5.4.2 Testing for filth and foreign materials shall be performed prior to the release of each batch onto the market.

STANDARD 8 – PACKAGING AND LABELLING

VIII.1 Purpose

VIII.1.1 This standard stipulates the packaging and labelling requirements for the final cannabis products.

VIII.2 Responsibilities

VIII.2.1 The Key Officer and individuals in other designated key positions (where applicable) must ensure that packaging and labelling materials sourced from third parties and the internal packaging and labelling processes comply with these standards.

VIII.3 Packaging & Labelling requirements

VIII.3.1 Cannabis may only be distributed in packaging approved by the Authority. Images and detailed technical specifications of the proposed packaging must be obtained from the proposed supplier and submitted for approval.

VIII.3.2 Packaging must be mostly plain and the use of logos, colours, branding and fancy display formats must be restricted. Packaging which is unduly attractive and / or appeals to youths, or which may transmit information which is not impartial will be rejected.

VIII.3.3 Cannabis must be packaged in weights of round gram figures (1g – 7g) or in a packet of 3.5g.The weight of the packet is to be indicated in the label.

VII.3.4 Variances between the actual net weight and the declared weight shall not exceed 0.2g, and the weight of packets of 7g shall not exceed said amount.

VII.3.5 Weighing instruments must be calibrated.

VIII.3.6 A packet may only contain one class of cannabis (seeds or dried flower). It may not contain cannabis and / or seeds with different phytocannabinoid profiles (strains).

VIII.3.7 The packaging material must keep the contents dry and prevent contamination of the stored cannabis.

VIII.3.8 The packaging material must be opaque.

VVIII.3.10 The packaging material must comply with food-grade packaging requirements.

VIII.3.11 The packaging shall be enclosed with seals as stipulated by the Authority. The seals must be placed such that they must be broken if the container is opened. Any seals which become damaged or otherwise remain unused must be documented, including through photographic evidence.

VIII.3.12 Labels must be affixed on the outermost layer of packaging as per standard requirements, design and size template provided by the Authority. The associations shall ensure that the printing material used is of good quality.

VIII.3.13 New labels must be affixed if the product is re-tested and re-released as provided in Standard VII.

VIII.3.14 If multilayered packaging is adopted all elements must meet the requirements of this standard.

STANDARD 9 – PROCESSING

IX.1 Purpose

IX.1.1 This Standard indicates the procedures and processes through which dried cannabis may be further converted into hash or resin.

IX.2 Responsibilities

IX.2.1 The Key Officer and individuals in other designated key positions (where applicable) shall ensure that products are prepared as required in this standard.

IX.3 General Provisions and Requirements

IX.3.1 This standard is to be read in conjunction with the other standards, and the provisions of the other standards shall be deemed to be also applicable for processed products.

IX.3.2 An operating permit to cultivate and distribute cannabis shall not be considered to include the processing of cannabis as allowed in this Standard unless a specific authorization to this effect is granted by the Authority.

IX3.3 The granting of an additional concession to process cannabis as allowed in this Standard shall be at the absolute discretion of the Authority. The Authority retains the right to refuse any request if it determines that the proposed processes and products are not consonant with the harm reduction principles of the reform, or if it is of the opinion that the operational setup of an association is not adequate to perform this additional process in full compliance with the legislation and the directives.

IX.3.4 Associations interested in obtaining a permit to process cannabis are to submit a proposed operational plan specifically for this purpose with the following details for each product offered:

a) The person who shall be responsible for this process.

b) A description of the finished product.

c) The method that shall be used to achieve the finished product, including the equipment and personnel used and the length of the process.

d) Revised layout plan showing the location where the processing shall be carried out and the equipment to be used.

e) The strain/s that shall be used for this process.

f) The estimated quantities of finished product to be produced.

IX.4 Allowed methods

IX.4.1 Only solventless methods of processing shall be allowed. The use of any liquid (except purified water), gas, solvent or chemical to facilitate or enhance or facilitate the process is not allowed. Production of distillates, typically in the form of highly concentrated oils is also not allowed.

IX.4.2 Only dried cannabis which has been successfully tested as stipulated in Standard VII may be used for processing. The Authority may, at its discretion, waive the requirement to perform the test for the cannabinoid profile if the entire batch is to be processed. In any case, the finished, processed product is to be tested as stipulated in this Standard prior to its release.

IX.4.3 No additional product, matter, liquid or gas shall be added to the dried cannabis flowers. The provisions of Standard VII regarding foreign material shall also apply for this Standard.

IX.4.4 The mixing of dried cannabis from different batches in the same processed product is not allowed unless they are of the same strain.

IX.4.5 The finished product shall be in solid form. The manufacture of oils and tinctures is prohibited.

IX.5 Distribution

IX.5.1 The daily and monthly limits of 7g and 50g respectively that may be distributed to the members as stipulated in the legislation shall be considered as applicable for dried cannabis flowers.

IX.5.2 A gram of processed product with a THC content exceeding 66% shall be considered as the equivalent of three grams of dried cannabis flowers. A gram of processed product with a THC content between 34% and 66% shall be considered as the equivalent of two grams of dried cannabis flowers. A gram of processed product with a THC content up to 33% shall be equivalent to a gram of dried cannabis flowers. This equation is to be rigorously adhered to in the calculation of the amount of cannabis that may be distributed to the members.

IX.5.3 Members may be provided a mix of dried cannabis flowers and processed products, provided that the total amount provided does not exceed the limits stipulated in this Standard and the legislation.

IX.6 Record Keeping

IX.6.1 Associations shall request the Authority to issue a new batch number prior to the commencement of the processing of a batch of dried cannabis. The request is to indicate the batch of dried cannabis from which the processed product shall be made and the amount of cannabis that shall be used.

IX.6.2 Records of the finished processed product and resultant waste shall be kept as stipulated in this Directive.

IX.6.3 Records of the register of members shall include the amount of finished products supplied and their equivalent in dried cannabis flowers.

IX.7 Quality Testing

IX.7.1 The finished processed product shall be tested according to the provisions of Standard VII. The following additional requirements apply.

IX.7.2 Upon completion of the process, the association shall request the authorized laboratory to collect a representative sample from the finished product.

IX.7.3 The authorized laboratory shall record the weight of the entire processed batch and the methodology used to take a representative sample.

IX.7.4 Great care shall be taken to ensure that the THC content of the sample is representative of the entire batch. The batch is to be split into multiple batches if substantial variances in THC levels are noted.


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