

# **CLEANING AND MAINTAINING EQUIPMENT UNDER THE ACMPR**

Licensed Producers (LPs) striving to maximize their production capacity must have a strong grasp of Good Production Practices (GPPs), as defined under the Access to Cannabis for Medical Purposes Regulations (ACMPR). This document specifically addresses those GPPs that relate to the cleaning and maintenance of equipment used in the processing of cannabis products.

## **Background**

Cannabis is an exceptionally sticky, resinous plant and any equipment that is used to harvest or process cannabis will inevitably be coated in resin. To follow Good Production Practices, that resin must be fully removed from equipment surfaces during the cleaning cycle before the equipment is put back into service. To maintain compliance with the Regulations then, the selection and application of cleaners that effectively remove cannabis resin becomes one of the most critical aspects of an LP's sanitation program.

## **Cleaning Solution Selection**

Food-safe degreasers have proven to be particularly effective in removing cannabis resin from a variety of equipment surfaces and finishes. Unfortunately, a number of LPs have been reluctant to qualify degreasers on their list of internally approved cleaning products in the mistaken belief that only cleaning products explicitly 'approved' by Health Canada can be used in accordance with the ACMPR. In fact, the ACMPR and Health Canada are completely agnostic on cleaning methods and products that can be used for cannabis production. No cleaning products are specifically recommended nor are any cleaning products specifically prohibited. Rather, the regulation requires that whatever cleaners are used, no residual contamination by a cleaning product is transposed onto the end product.

Conversely, the Regulation does require that an LP establish a sanitation program that permits effective cleaning of the premises and equipment and prevents contamination. If residual cannabis resin remains on equipment after cleaning, this residual cannabis resin is a potential source of contamination (i.e. mould, bacteria, etc.) to future production batches.

Isopropyl and other disinfectants are in common use at many licensed production facilities but are just that – disinfectants. Disinfectants are not cleaners and are not effective for removing cannabis resin. When used exclusively to clean production spaces and equipment, disinfectants are very harsh and accelerate equipment deterioration.

**A Licensed Producer that is using only disinfectant to clean their processing equipment and space will be challenged to completely remove all cannabis resin, which would put them in violation of Sections 70, 71, 71 and 73 of the ACMPR.**

### **Summary of Key Points**

- A sanitation program that does not allow for the use of cleaners that effectively remove cannabis resin is very likely in violation of the regulations.
- Isopropyl and other disinfectants are not effective cleaners for removing cannabis resin, thus cannot be the sole cleaning substance(s) included in a sanitation program.
- Food safe degreasers are effective in removing cannabis resin and therefore need to be a part of equipment cleaning protocols.
- Provided that the equipment being used to process the plant material does not have cleaning solution residue on its surfaces, **any** cleaner may be used in accordance with the ACMPR.

The following table lists those sections of the ACMPR that specifically address cleaning and sanitation as per Good Production Practices.

Reference Section Under the ACMPR	Interpretation
<p><b>Premises</b></p> <p><b>70 (1)</b> Fresh or dried marihuana, cannabis oil or marihuana plants or seeds must be produced, packaged, labelled and stored in premises that are designed, constructed and maintained in a manner that permits those activities to be conducted under sanitary conditions, and in particular that</p> <ul style="list-style-type: none"> <li>(a) permits the premises to be kept clean and orderly;</li> <li>(b) permits the effective cleaning of all surfaces in the premises;</li> <li>(c) permits the substance to be stored or processed appropriately;</li> <li>(d) prevents the contamination of the substance; and</li> <li>(e) prevents the addition of an extraneous substance to the substance.</li> </ul> <p><b>Equipment</b></p> <p><b>71</b> Fresh or dried marihuana, cannabis oil or marihuana plants or seeds must be produced, packaged, labelled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that</p> <ul style="list-style-type: none"> <li>(a) permits the effective cleaning of its surfaces;</li> <li>(b) permits it to function in accordance with its intended use;</li> <li>(c) prevents the contamination of the substance; and</li> <li>(d) prevents the addition of an extraneous substance to the substance.</li> </ul> <p><b>Sanitation program</b></p>	<ul style="list-style-type: none"> <li>• No specific cleaning methods or cleaning products are required. What is required is that the cleaning methods and products applied are effective at cleaning the surfaces and at preventing contamination. If a cleaner does not fully remove all cannabis resin, this cannabis residue would be considered a potential source of contamination.</li> <li>• With respect to cleaning solutions, there is no risk of the addition of an extraneous substance to the end product if the cleaning solution is entirely rinsed off the equipment prior to putting it into operation. For example, the following three-step process would be an effective approach to apply: <ul style="list-style-type: none"> <li>Step 1. Clean the equipment with an appropriate cleaning solution (i.e. a food safe degreaser);</li> <li>Step 2. Rinse the cleaning solution off equipment surfaces;</li> <li>Step 3. Swab test equipment surfaces. If cleaning solution residue remains, either perform an additional rinse or wipe the surface with a disinfectant such as isopropyl.</li> </ul> </li> <li>• If a particular cleaning product is applied, followed by a rinse and swab tests show that no residual cleaner remains on the equipment, then logically there is no possibility of contamination by an “extraneous substance” and, hence, no risk in using that cleaning product.</li> <li>• Substances that have been registered under programs such as the NSF International/Nonfood Compounds Registration Program, have specifically been evaluated for their risk of contaminating the end product for human consumption and found to be safe when properly used. In this particular application, a substance would be assessed for both its cleaning efficacy <b>and</b> the user’s ability to rinse off the substance from the processing equipment to ensure that the cleaning solution would not itself pose a risk of contamination to the end product.</li> </ul>

**72** Fresh or dried marihuana, cannabis oil or marihuana plants or seeds must be produced, packaged, labelled and stored in accordance with a sanitation program that sets out

**(a)** procedures for effectively cleaning the premises in which those activities are conducted;

**(b)** procedures for effectively cleaning the equipment used in those activities;

**(c)** procedures for handling any substance used in those activities; and

**(d)** all requirements, in respect of the health, hygienic behaviour and clothing of the personnel who are involved in those activities, that are necessary to ensure that those activities are conducted in sanitary conditions.

**Standard operating procedures**

**73** Fresh or dried marihuana, cannabis oil or marihuana plants or seeds must be produced, packaged, labelled and stored in accordance with standard operating procedures that are designed to ensure that those activities are conducted in accordance with the requirements of this Subdivision.

## Section 68

Some LPs have misinterpreted Section 68 of the ACMPR as being applicable to the establishment of their cleaning protocols because it is titled 'Solvents'. This section is referring to the final cannabis oil product (i.e. what is sold to the consumer) – it is not a list of solvents that can and cannot be used to clean cannabis production equipment.

The correct application of Section 68 is, in fact, in the analysis of the cannabis oil end product. If a Licensed Producer is producing cannabis oil, the intention of this section is to address the chemicals used for extraction and the excipients used as carrier oils.

Below is the text of Section 68 and an interpretation of it if viewed through the lens of cleaning protocols.

Reference Section Under the ACMPR	Interpretation
<p><b>Solvents</b></p> <ul style="list-style-type: none"> <li>• <b>68 (1)</b> Cannabis oil must not contain residues of solvents other than Class 3 solvents listed in the <b>Guidance Document — Impurities: Guideline for Residual Solvents, ICH Topic Q3C(R5)</b>, published by the Department of Health, as amended from time to time.</li> <li>• <b>Residue limit</b> <b>(2)</b> Those residues must not exceed the limits established under that document.</li> <li>• <b>Non-application of section 64</b> <b>(3)</b> Section 64 does not apply with respect to those residues.</li> </ul>	<ul style="list-style-type: none"> <li>• This section is referring to the final cannabis oil product (i.e. what is sold to the consumer) – it is <b>not</b> a list of solvents that can and cannot be used to clean cannabis production equipment.</li> <li>• In practice, this means that when a Licensed Producer tests its cannabis oil, there cannot be any residual solvent in the end product.</li> <li>• When proper cleaning methods are applied, solvents can be used to clean, they just need to be rinsed off the equipment so that solvent is no longer present when the equipment goes back into operation.</li> <li>• Substances that have been registered under programs such as the NSF International/Nonfood Compounds Registration Program, have specifically been evaluated for their risk of contaminating the end product for human consumption and found to be safe when properly used. In this particular application, a substance would be assessed for both its cleaning efficacy <b>and</b> the user's ability to rinse off the substance from the processing equipment to ensure that the cleaning solution would not itself pose a risk of contamination to the end product.</li> </ul>