

Risk analysis for the presence of pesticides in dry cannabis floss cultivated under indoor conditions

Maja Trenova¹; Tijana Serafimovska¹; Tanja Ivanova¹; Suzana Zafirova¹; Marija Darkovska Serafimovska¹

¹Faculty of Medical sciences, University "Goce Delcev", Krste Misirkov No.10-A, 2000 Stip, North Macedonia

Introduction

Prospective risk analysis methods have significant potential for risk reduction and should be an integral part of any patient safety improvement strategy (Stojkovic, 2021). Risk management principles are effectively utilized in many areas. In the pharmaceutical industry risk is defined as the combination of the probability of occurrence and the severity of the damage it can cost. To meet regulatory and quality control standards, cannabis products should be tested for all pesticides, especially high-risk pesticides to health (Sanka, 2020; Paul, 2020). Determination of pesticides in cannabis facilities is increasingly important as medicinal uses of cannabis products expand rapidly (Caley, 2021). Therefore, risk analysis as a systematic process for detection of probability occurrence of harm can improve the decision making if a quality problem arises (ICH, Q9, 2015).

Results and discussion

Quality risk assessments begin with a well-defined problem description or risk question. The criteria for risk assessment can be grouped in four categories:

- severity of consequences (great impact, medium, low impact)
- possibility of occurrence (often, occasionally, almost never)
- detection possibility (high, medium, low)
- risk classification on human health (high, medium, low)

Cultivation process

Cultivation part is consisting of severe phases: seeds to be plated, vegetation phase, flowering phase, harvesting, and drying. In these phases a possible source of pesticides can arise from water and feeding material. Checking the starting material that is used for cultivation is one step to

prevent contamination of cannabis plants with pesticides. There is no risk of contamination with pesticides during harvesting and drying if the process is going under indoor controlled conditions.

Environmental impact

Pesticides can come from outside in the growing rooms if non-adequate air filtering system is installed, or if inappropriate filters are used, or if changing of the filters is untimely. Not treated air can contaminate the plants with pesticides, so implementation of proper HVAC system is another step to prevent contamination of indoor cultivated cannabis plants with pesticides.

Personal related and quality control related risks

Personnel can have impact for contamination with pesticides if they do not follow the process as it is described in Standard Operating procedures (SOPs) for using only approved materials or if they are not properly trained or if they are unaware of proper behavior during the process. Thus, well trained employers in accordance with GMP requirements are another step to prevent contamination of indoor cultivated cannabis plants with pesticides.

All processes and materials used in the production/ growing part should be accurately described and specified in the SOPs as well as in the Batch protocols for each phase of the process.

In quality control laboratory the risk of not detecting pesticides is only if not adequate, not validated methods are used for quality testing. Training of the people who do analysis is also very important. Detection of the pesticides in reference standard material that is used is a confirmation that the method is adequate for pesticide testing.

Conclusion

Risk identification is a systematic use of information to identify hazards. Risk analysis is the estimation of the risk associated with the identified hazards, while risk evaluation compares the identified and analyzed risk against given risk criteria. FMEA analysis is recommended to be made for possible deviations that may arise because of the risk have been identified, the severity of the consequences, the frequency of occurrence, and the possibility of detecting the risk before the damage occurs. According to the conducted FMEA analysis it can be concluded that the risk of contamination the dry cannabis floss as a starting material used for extraction with —

pesticide residues is not possible in indoor cultivation if pesticides are not used in any phase of the process of cultivation, if starting material used for growing is purchased from approved suppliers and in the same time is regularly controlled, if employers are adequately trained and follow the process as it is described in SOPs.

FMEA relies on product and process understanding. Once failure modes are established, risk reduction can be used to eliminate, contain, reduce or control the potential failures.

References

- Caley B Craven, Afsoon Pajand Birjandi, Brigitte Simons, Ping Jiang, Xing-Fang Li, 2021. Determination of eighty-two pesticides and application to screening pesticides in cannabis growing facilities. *Journal of Environmental Sciences*, 104, 11-16. DOI: 10.1016/j.jes.2020.11.004
- ICH Q9 guideline on quality risk management. 2015, (EMA/CHMP/ICH/24235/2006) available at: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-3.pdf, last access: 29th May, 2022
- Paul C Jepson, Katie Murray, Oliver Bach, Maria A Bonilla, Lars Neumeister, 2020. Selection of pesticides to reduce human and environmental health risks: a global guideline and minimum pesticides list. *The Lancet Planetary Health*, 4(2), e56-e63. DOI: [https://doi.org/10.1016/S2542-5196\(19\)30266-9](https://doi.org/10.1016/S2542-5196(19)30266-9)
- Stojkovic Tatjana; Marinkovic Valentina; Manser Tanja, 2021. Using Prospective Risk Analysis Tools to Improve Safety in Pharmacy Settings: A Systematic Review and Critical Appraisal, *Journal of Patient Safety* 17(6), e515-e523 doi: 10.1097/PTS.0000000000000403
- Sanka N. Atapattu, Kevin R.D. Johnson, 2020. Pesticide analysis in cannabis products. *Journal of Chromatography A*. 1612, 460656. DOI: <https://doi.org/10.1016/j.chroma.2019.460656>