36th EFFoST International Conference

Shaping the Production of Sustainable, Healthy Foods for the Future

7-9 November 2022
Dublin, Ireland

Abstract book

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EFFoST 2022 INTERNATIONAL CONFERENCE
7-9 November
Dublin, Ireland

Organised by: EFFoST

Hosted by: UCD DUBLIN

Co-event: NTP 2022

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Safety Assessment of Novel Foods from the Biorefinery of Olive, Grape, and Nut By-products

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Aim:
Upcycling for Health (Up4Health) is a H2020-funded project that is developing a sustainable and cost-effective process for the recovery of value-added ingredients from olive, grape and almond by-products for food, nutraceutical, and cosmetic applications. In the context of the European Novel Food Regulation (EU 2015/2283), Up4Health ingredients qualify as novel foods. A critical aspect of obtaining pre-market approval of novel foods is demonstrating their safety in compliance with existing legislation and standards. This research presents the approach for the safety assessment of the ingredients based on regulatory requirements and standards at the European and International level.
Method:
Reviews were conducted of relevant literature, European regulatory documents, scientific opinions by the European Food Safety Authority (EFSA), standards by the International Standards Organization (ISO), European Committee for Standardisation (CEN), CODEX Alimentarius, and toxicological test guidelines by the Organisation for Economic Co-operation and Development (OECD). Reports were compiled to inform the project of the relevant legal requirements and the standards available.
Results:
The review identified the relevant legislations and standards that support the application for pre-market approval of novel foods. These cover nutrition and health claims, labeling requirements, risk assessment and toxicological studies, extraction solvents, contaminant limits, among others. It was found that toxicological evaluation involves hazard characterization combined with a dose-response evaluation. Standard methods to assess the relevant chemical and biological hazards were identified. Biological hazards identified for Up4Health ingredients include *Salmonella, E. coli, Enterococcus, Enterobacteriaceae,* yeasts and molds, aerobic mesophilic count, and microbial toxins such as aflatoxins. Chemical hazards identified include pesticide residues, heavy metals (arsenic, lead, cadmium, mercury) and natural toxins (i.e., allergens). In the dose-response evaluation step, the following *in vitro* methods were identified to assess the safety of the extracts; the Ames and Comet assays for their genotoxicity evaluation, the MTT, Alamar Blue, and Trypan Blue assays for their cytotoxicity studies, and *in silico* models to predict their ADME (absorption, distribution, metabolism, and excretion) properties.
Conclusion:
A safety assessment approach that considers existing regulations and standards is critical to obtaining pre-market approval of the novel ingredients generated in Up4Health.