

inconsistencies in the skin sensitization profiles ranging from strong, moderate, weak to non-sensitizer.

The aromatic aldehyde alert observed for vanillin and all possible analogues is characterized by a variety of skin sensitization outcome across the chemical class. Therefore, all chemicals are kept despite the shortcomings observed in the skin sensitization data for the two strongest sensitizers (poor documentation, no clear dose-response).

Step 2: The profiling was extended using predictions of physico-chemical properties, similarity score and simulated autoxidation/skin metabolism, but did not succeed in refining the selection of the analogues.

Step 3: This step includes several options. The analogue selection process can be completed either by application of the most conservative approach, i.e., selection of the strongest skin sensitizer chemicals, or by exclusion of chemicals with limitations in the skin sensitization studies or by integration of *in vitro* data strengthening the chemical grouping. This 3-step process enabled the identification of appropriate analogues as basis for an acceptable NGRA conclusion of vanillin.

References

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Exposure assessment of total DON in urine of Portuguese adult population under the HBM4EU aligned studies

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Mycotoxins are secondary metabolites of fungi that can be found in food commodities. Exposure to mycotoxins has been associated with several adverse health effects, including hepatotoxicity,

nephrotoxicity, immunotoxicity, mutagenicity and carcinogenicity. As such, from a public health perspective it is important to monitor and to assess the risk associated to mycotoxins' exposure.

In the scope of the European Human Biomonitoring Initiative (HBM4EU), exposure to mycotoxins, namely to deoxynivalenol (DON) was analysed in adults from several European countries, including Portugal.

Data was collected under the project "Exposure of the Portuguese Population to Environmental Chemicals: a study nested in INSEF 2015". INSEF-ExpoQuim, was an epidemiological study nested in the first Portuguese Health Examination Survey (INSEF), that enrolled individuals aged 28–39 years, living in Portugal for more than 12 months and able to follow an interview in Portuguese. Fieldwork was developed between May 2019 and March 2020 and first morning urine samples were collected along with data on socio-demographic characteristics, living conditions and residential history, habits/lifestyle, nutrition, health, occupation and substance specific information covering nearly all exposure pathways. Procedures followed the guidelines of HBM4EU. Total DON (sum of free DON + DON-glucuronides after deconjugation) was determined in 295 urine samples by a qualified laboratory and using a harmonized analytical method.

Results: showed that the Portuguese population was exposed to DON (mean = 9.8 mg/L; 95% CI: 8.7–10.9 mg/L). DON concentrations were significantly higher for samples collected in spring and summer. Individuals living in rural areas and with a lower education levels presented higher exposures to DON, as well as individuals with a higher bread consumption frequency (≥ 4 times per week). No differences were found regarding sex, age, occupation, income or consumption of other foods.

Comparing this study's data with the human biomonitoring guidance value (HBM-GV) determined for DON in the scope of HBM4EU (Total DON: 0.69 μg DON/kg bw/total 24 h \approx 23 μg DON/L urine) 12.5% of the participants presented values above the HBM-GV.

Overall, the results from this study showed that the Portuguese population is currently exposed to DON, with a significant proportion of individuals presenting exposures to values that warrant further assessment, including a close monitoring of exposure in the future and the development and implementation of policy measures aimed at minimizing exposure and improving the health of the population.

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Virtual human platform for safety assessment (VHP4Safety): assessing the safety of chemicals and pharmaceuticals based on human data

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Imagine a world in which we perform precision safety testing of chemicals and pharmaceuticals solely based on human data. Imagine that the safety of chemicals and pharmaceuticals can be assessed for