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A new global scientific tool for the assessment and prioritization of chemical hazards in food raw materials

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ABSTRACT

The purpose of this study is to develop a globally valid chemical risk assessment tool that provides the user with a priority rating in terms of which chemicals are important to manage in raw materials. The process entails the use of decision trees that enable the determination of risk (or "likelihood to cause harm"), and severity using objective and transparent selection criteria. Taken together, severity and risk are positioned in an HACCP-like matrix informing on the prioritization level of each combination of chemical hazard and raw material. The proposed model is intended to be adequately protective for consumer's health, as it considers a conservative food intake scenario, as well as various sources of contaminant exposure. The model's design is flexible and can easily be adapted to the needs of different food product categories and scenarios. Case studies are presented to illustrate the feasibility of the approach, and the model was tested using several examples, the results of which are consistent with existing data in the literature.

1. Introduction

Food commodities can contain undesirable compounds for a number of reasons: some are intrinsically present in the raw material (RM), such as for example glycoalkaloids in Solanaceae plants (Friedman & McDonald, 1997), whilst others may enter the RM through external, environmental sources, exemplified by mycotoxins. A number of chemical contaminants originate from anthropogenic activity, for example PCBs and pesticides (Peshin, Lall, & Gupta, 2002; Silano & Silano, 2015). The entry of many contaminants into our food RMs is efficiently prevented or managed by the application of good agricultural or manufacturing practices (GAP or GMP, respectively) (van der Fels-Klerx et al., 2014). In addition, local or international regulations help to limit the exposure to many of these contaminants. However, the setting of legal limits is a complex procedure; it requires a wealth of information and in-depth discussions with various stakeholders and can therefore be a lengthy process. Therefore, for some chemical contaminants regulatory limits do not exist for all relevant raw materials (e.g. perchlorate, nickel, aluminium). It is also important to remember that regulations consider "other legitimate factors" such as trade and food availability, and are therefore not exclusively based on consumer safety. Classical examples are regulatory limits for certain mycotoxins, that are set as to ensure the continued availability of foods for the local population where seasonal climatic and agricultural conditions may lead to fungal infection and consequently inadvertent mycotoxin contamination of crops. In such cases the setting of limits is also influenced by risk-benefit considerations (Duarte, Lino, & Pena, 2010).

Usually, limits are set for the RM (e.g. Codex Maximal Residue Limits for pesticide residues, MRLs), but in some cases they can be set for finished products (FP), as in the case of infant formulas. The starting point for defining MRLs is the establishment of health based guidance values (HBGVs), i.e. the acceptable daily intakes, conducted by food safety authorities/bodies such as the JMPR (Joint FAO/WHO Meetings on Pesticide Residues) or EFSA (European Food Safety Authority). HBGVs consider human lifetime exposure to a chemical, and food manufacturers need to properly manage the ingredients and manufacturing processes to ensure that the exposure will not exceed the HBGV. These assessments must take into account all other possible sources of exposure, including non-dietary sources for a particular chemical such as inhalation for PAHs, in other words not exclusively originating from a particular RM or FP.

Continuous improvements of analytical methods, equipment

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and detection capability may surface issues that reflect more a public perception risk rather than an actual food safety risk. Public perception and media attention can generate pressure to initiate management activities on specific non-regulated chemicals. As a result, the mere identification of a contaminant no matter at what (low) level, may be perceived as a health risk regardless if, from a risk assessment perspective, it would not present a concern to the population. This can result in a hazard-based management rather than a risk-based management of food safety (Barlow et al., 2015).

Therefore, the presence of chemical contaminants in food is not uniformly and scientifically managed and it may be difficult to determine their relative health significance. Consequently, prioritization of management actions concerning one chemical contaminant that is exceeding a RM limit versus another one to which consumers are exposed above their HBGV, or where neither HBGVs nor limits exist but can be expected to represent a possible public health concern, is a challenging exercise.

Although chemical food safety assessment is a well-established scientific process, the complexity of modern food supply chains, the number of food items, the geographical differences in human diets and the variety of potential sources of exposure require considerable efforts and diligence to effectively apply this process.

Therefore, the approach proposed in the present publication follows the scientific risk assessment paradigm for chemical contaminants in foods, based on the four steps: (1) hazard identification, (2) hazard characterization, (3) exposure assessment and (4) risk characterization (IPCS, 2009). It is uniformly used in a simplified way for all chemicals included in our study. Where critical information was missing, alternative approaches and assumptions were used that are described in the relevant sections. Ultimately this risk assessment process is used to derive a safety based guidance value (SBGV) which corresponds to the contaminant level per RM category ensuring that overall exposure is not exceeding the HBGV. The comparison between the actual contaminant levels and the SBGV is, together with the estimation of overall exposure, the critical input for setting the risk level (the likelihood to cause harm). The combination of the risk level with a severity grade is the basis for defining significance levels in the HACCP matrix, used to support the establishment of management actions.

2. Material & methods

2.1. Health based guidance value

A health-based guidance value (HBGV) is defined as the level of human exposure considered to be without appreciable health risk for lifetime exposure (IPCS, 2009). The term acceptable daily intake (ADI) is applied to food additives, residues of pesticides or veterinary drugs in food, while the term tolerable daily intake (TDI) is applied to compounds non-deliberately present in foods, such as chemical contaminants (IPCS, 2009). HBGVs can be defined by international food safety authorities such as EFSA or JECFA (Joint FAO/WHO Expert Committee on Food Additives), and by local/national authorities or individuals, including academics and members of the food industry.

In the present study HBGVs were taken as established by competent authorities (i.e. JECFA, EFSA, and US EPA). When several HBGVs (from different authorities) were available, the selection depended on the scientific rationale used for its determination. In general, HBGVs from most recent evaluations, using a most comprehensive database were preferred over more local or simply conservative assessments.

A prerequisite for establishing HBGVs is that sufficient toxicological data is available for dose-response assessment and extrapolation to the human exposure situation. This information is not available for all known food chemical contaminants. Therefore, in the absence of available HBGVs, an alternative approach was applied (see below).

2.1.1. Process in the absence of HBGVs

A HBGV for a particular chemical may not have been established by an internationally recognized authority because:

1. The compound is considered to act through a non-threshold effect, i.e. a genotoxic carcinogen, for which usually no safe level of exposure can be derived. However, toxicological and dose response data are often available for such compounds. More recently, these compounds are evaluated using the margin of exposure (MOE) approach, which estimates the margin between a dose that is reasonably close to doses that have caused effects (i.e. cancer) in long term animal studies, usually determined by benchmark dose modelling (BMD), and estimated human exposure (Benford et al., 2010; EFSA, 2005, 2009c).
2. The compound is considered to act through a threshold mechanism, but a HBGV has not been established due to gaps in the toxicological database.

In both cases, an alternative toxicological reference value (Point of Departure, PoD) (Izadi, Grundy, & Bose, 2012) was defined, to which a factor was applied corresponding to (i) a desired/targeted margin of exposure in humans, or (ii) a factor accounting for extrapolation e.g. from animal studies and/or other uncertainties in the toxicological database. The resulting value was used as a surrogate to the HBGV (sHBGV). The procedure is outlined in Fig. 1.

2.2. Exposure assessment

2.2.1. Occurrence

Levels of contamination in food RMs were extracted from the Nestlé internal database that collects analytical data that are routinely generated in Nestlé accredited laboratories on food RMs. The database counts more than 6'000'000 data on almost 3'000 chemical compounds. Information such as material identity, batch information, origin, the chemical contaminants analyzed, the testing laboratory, the analytical method used, etc., are all captured in the database. In order to ensure that the data extracted are relevant, a four-step data refinement workflow was developed:

1. **Collect**. All RM quantitative analytical data available were extracted and collected.
2. **Select.** Only data relevant to the target population (healthy adults) were selected. All data relative to RMs intended for infant nutrition or pet food were removed.
3. **Harmonize.** All data were expressed in mg/kg. Outliers were identified as values that were at least 10 times the interquartile range (Q3 − Q1) from the upper quartile.
4. **Refine.** Analytical results below the reporting limit (RL, i.e. LOD − limit of detection, LOQ − limit of quantification) were treated according to the criteria in Table 1, adapted from EFSA (2010b). EFSA specifies options to treat analytical data below the LOD or LOQ, depending on certain characteristics of the database (e.g. sample number, among others). A simplified substitution method was used to estimate the median occurrence level of a contaminant, ignoring constraints indicated by EFSA, e.g. the existence of multiple LODs (due to different analytical methods used by different laboratories on different matrices). At least 25 data points were considered necessary for the estimation of level of contamination to be significant and to be able to perform an assessment.