Review of: "Improving the Integration of Epidemiological Data Into Human Health Risk Assessment: What Risk Assessors Told Us They Want"

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Potential competing interests: No potential competing interests to declare.

The Authors do not say explicitly, but if I understand well, the topic is dietary exposure, i.e., substances potentially ingested and causing health problems.

The article would be interesting, but it is necessary to precisely describe how the information could be used because risk management is quite widely codified. Risk assessors should have been trained on this topic, including the appropriate use of epidemiological data. All kinds of data need to be used according to the type of information they were designed for.

So, I suggest revising the manuscript, considering some concepts I try to illustrate below.

Risk assessment is part of the risk management process mainly managed by national and international authorities like the Food and Drug Administration, which delivers guidance documents (see e.g., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9r1-quality-risk-management), and the European Food Safety Authority (https://www.efsa.europa.eu/), which has also provided tools (https://www.efsa.europa.eu/en/science/tools-and-resources/dietex).

Risk assessment requires specific methods depending on the substance patterns. As an example, the microbiological risk is related to hazards deriving from pathogens that are primarily harmful in acute scenarios, so the occurrence must be avoided by prevention procedures like hazard analysis and critical control points, and its evolution (see, e.g., https://globalfoodsafetyresource.com/haccp-evolution/). Conversely, other substances could cause health problems after exposure for a lag time.

Habitual dietary intakes are required to estimate long-term exposure. Not all, but mostly, dietary data are collected or referred to the short-term horizon. However, the method to estimate habitual from actual intake exists (see, e.g., Hoffmann K, Boeing H, Dufour A, Volatier JL, Telman J, Virtanen M, Becker W, De Henauw S; EFCOSUM Group. Estimating the distribution of usual dietary intake by short-term measurements. Eur J Clin Nutr. 2002 May;56 Suppl 2:S53-62. doi:10.1038/sj.ejcn.1601429. PMID: 12082518.).

This was acquired in the EFSA approach (European Food Safety Authority, 2014. Guidance on the EU Menu methodology. EFSA Journal 2014;12(12):3944, 80 pp. doi:10.2903/j.efsa.2014.3944).

Anyway, observational studies provide a picture of the interesting phenomena, and the reporting is crucial to

strengthening the reporting of observational studies in epidemiology (see e.g., https://www.strobe-statement.org/); this is particularly important for dietary studies (Lachat C, Hawwash D, Ocké MC, Berg C, Forsum E, Hörnell A, Larsson C, Sonestedt E, Wirfält E, Åkesson A, Kolsteren P, Byrnes G, De Keyzer W, Van Camp J, Cade JE, Slimani N, Cevallos M, Egger M, Huybrechts I. Strengthening the Reporting of Observational Studies in Epidemiology-Nutritional Epidemiology (STROBE-nut): An Extension of the STROBE Statement. PLoS Med. 2016 Jun 7;13(6):e1002036. doi: 10.1371/journal.pmed.1002036. PMID: 27270749; PMCID: PMC4896435.)

A total diet approach is also recommended for estimating dietary exposure to trace elements (European Food Safety Authority, Food and Agriculture Organization of the United Nations, World Health Organization; Towards a harmonised Total Diet Study approach: a guidance document. EFSA Journal 2011;9(11):2450. [66 pp.] doi:10.2903/j.efsa.2011.2450.).

To manage risk, a multidisciplinary, multi-layered approach involving multiple stakeholders is required, such as the mycotoxins required at https://www.who.int/health-topics/one-health#tab=tab_1.

Individual food consumption or total diet studies can be combined with occurrence in foods either at a deterministic level or, as mostly is currently done, in probabilistic modeling that includes uncertainties (see, e.g., https://mcra.rivm.nl/mcra/#/ and van Klaveren JD, Kruisselbrink JW, van der Voet H, Engel J, van Voorthuijsen T, van Lenthe MS, de Boer WJ, Chen G, van Donkersgoed G, de Jong E, 2023. The MCRA platform for EU regulatory actions: governance, user guidance and FAIRification. EFSA supporting publication 2023:EN-8251. 67pp. doi:10.2903/sp.efsa.2023.EN-8251)