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A framework to determine the effectiveness of dietary exposure mitigation to chemical contaminants

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ABSTRACT

In order to ensure the food safety, risk managers may implement measures to reduce human exposure to contaminants via food consumption. The evaluation of the effect of a measure is often an overlooked step in risk analysis process. The aim of this study was to develop a systematic approach for determining the effectiveness of mitigation measures to reduce dietary exposure to chemical contaminants. Based on expert opinion, a general framework for evaluation of the effectiveness of measures to reduce human exposure to food contaminants was developed. The general outline was refined by application to three different cases: 1) methyl mercury in fish and fish products, 2) deoxynivalenol in cereal grains, and 3) furan in heated products. It was found that many uncertainties and natural variations exist, which make it difficult to assess the impact of the mitigation measure. Whenever possible, quantitative methods should be used to describe the current variation and uncertainty. Additional data should be collected to cover natural variability and reduce uncertainty. For the time being, it is always better for the risk manager to have access to all available information, including an assessment of uncertainty; however, the proposed methodology provides a conceptual framework for addressing these systematically.

1. Introduction

Risk management measures are an important tool in ensuring the safety of food. A variety of approaches can be applied, ranging from consumer advice, codes of practice and, ultimately, regulatory limits for the maximum permitted concentration of chemical contaminants in food. Such measures are intended to reduce consumer exposure to contaminants in the food that may occur either naturally e.g. mycotoxins, result from environmental contamination e.g. heavy metals, or are formed during food processing e.g. acrylamide and furan. The determination of the success of any risk management measure can often be overlooked in the risk analysis process but is as important a step as the risk assessment or the risk management intervention itself. Indeed, the outcome of any risk management measure should feed into a revised risk assessment. Assessing the impact of risk management measures, if done correctly, can lead to more effective risk reduction by identifying measures that are having the biggest impact or no impact at all.

The effectiveness of a risk management measure is typically measured by changes in the intake of a particular contaminant by consumers or certain subgroups within the consumer population which can involve changes in dietary consumption or a reduction in the concentration of a particular contaminant in the foodstuff itself. However, there can be many sources of variation and uncertainty involved – from measuring the chemical contaminant itself to the availability of consumption data – that will have an impact on any conclusions drawn. It is also important to recognise that some individuals will be impacted more than others, and the inter-individual variability must also be considered. These uncertainties should be identified and their impact should be considered in the context of both the exposure assessment and the conclusions drawn on the success of the exposure mitigation measure. It is also becoming evident that some risk management measures can have second-

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ary or unintentional consequences. To include such consequences may require additional consideration and the application of approaches like risk–benefit analysis.

The aim of the current study was to develop a science based approach for determining the effectiveness of mitigation measures on dietary exposure to chemical contaminants in food.

2. Methodology

A general framework for estimating the effectiveness of mitigation measures to reduce human exposure to food contaminants has been developed. The framework was assessed and refined using three different case studies related to certain contaminants in certain food products. The following case studies were chosen so that they cover chemical contaminants having a different nature of occurrence, and the product was deemed very relevant for presence of the particular contaminant: 1) Methyl mercury in fish and fish products, 2) Deoxynivalenol in small grain cereals, and 3) Furan in heat treated foods. Methyl mercury in fish and fish products was selected because of the variation of presence of this contaminant within different species, and the potential high exposure of high fish consumers. The balance of risks and benefits to different sub-populations through their consumption of oily fish is of particular interest, in order to assess what is the best guidance for consumers. Deoxynivalenol in cereal grains was chosen because of the natural occurrence of this contaminant and the large annual variation in the presence and concentrations of this mycotoxin in cereal grains. Furan was chosen because this compound is only formed during heat treatment of food products.

The three case studies have been completed to look at the types of dietary mitigation measures that have been or could be used and the challenges associated with assessing the effectiveness of these measures.

3. Results and discussion

3.1. General framework

The general framework for estimating the effectiveness of mitigation measures to reduce human exposure to food contaminants is presented in Fig. 1. The scheme and results of its application to the three case studies is further detailed in the following sections.

3.1.1. Risk assessment

The basis for any risk management intervention should be a risk assessment demonstrating the need to reduce dietary exposure. The need to reduce dietary exposure may apply across the population or may be targeted at certain population subgroups e.g. pregnant women. The risk assessment may have resulted in a health based guidance value such as a Tolerable Daily Intake (TDI) or, in the case of substances that are both genotoxic and carcinogenic, a margin of exposure (MoE) with – if needed – a recommendation to reduce exposure to as low as reasonably achievable, the so-called ALARA approach. The challenge with ALARA often is in defining what is "reasonably achievable". In preparing the exposure assessment a number of approaches may be used from simple deterministic approaches

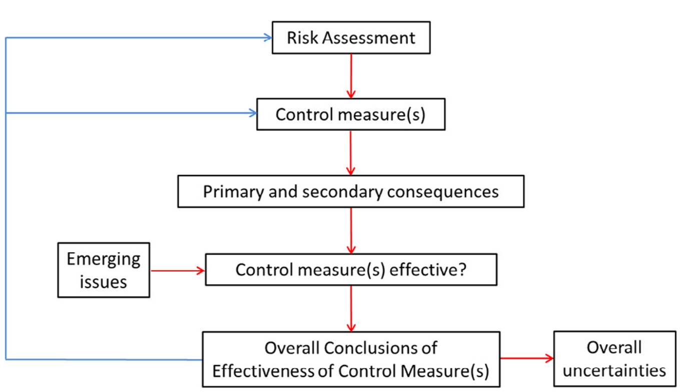

Fig. 1. A stepwise approach to assess the application and impact of any dietary exposure mitigation measure(s) to chemical contaminants in food.

to more complex probabilistic modelling. If the contaminant of interest is found in several dietary sources then conservative (worst case) intake scenarios may be used or more detailed modelling approaches that give more realistic intake estimates. Any intake assessment has a number of associated uncertainties. The main problem is that the collection of data on food consumption and on the presence of nutrients/contaminants is expensive and, therefore, is often limited. This leads to (sampling) uncertainties, as small datasets are not fully representative of the true distributions (of food consumption and/or contaminant concentrations) of all (sub)populations concerned. Risk is typically associated with intake values occurring in the extreme tails of the distributions. Consumption diaries are often used to capture dietary habits. Typically these diaries cover a short period, e.g. 1–7 days, for around 1000–2000 individuals, but investigations using intake diaries are not regularly updated. Problems can arise when rarely consumed items are of interest, or if more detailed patterns are required such as combinations of foods or consumption amongst specific subpopulations, as these will not be well represented. Assumptions are necessary in practice, such as extrapolating from countries/sub-populations/seasons for which information is available, and assuming typical or average levels for model parameters rather than accounting for the true range of variation. Sampling and measurement uncertainties and simplified model approximations also give rise to uncertainties (Kennedy, 2010). These uncertainties are being made more and more explicit in such assessments (EFSA, 2012a) and must be carefully considered when looking at the impact of any dietary exposure mitigation approach. It is important to consider quantifying the uncertainties in both measured concentrations of the contaminant and consumption data and to generate confidence (or credible) intervals around those exposure estimates. More research is required to quantify complex uncertainties, including the joint distribution of contaminants in cumulative assessments or multivariate modelling of food combinations (Kennedy, 2010). These are relevant for assessing secondary impacts of dietary risk mitigation measures (e.g. likely replacement foods for assessing secondary impacts) but are often unquantified in standard models. The impact of unquantified uncertainties may be evaluated using expert judgement (EFSA, 2006). The same approach should be applied when repeating the intake assessment after the mitigation measures have been applied.

3.1.2. Control measure(s)

The appropriate risk management or dietary intake mitigation measure will be determined based on the occurrence of the contaminant of concern, the processes that lead to its presence in food, and levels of consumption of foods containing the substance. In some cases the measure can be the advice to either the consumer (e.g. in the case of consumption of fish containing methyl mercury), or to growers and processors. For growers and processors this advice may take the form of good agricultural practice or good manufacturing practices. Similarly, toolboxes may be developed containing a number of approaches that can be used to reduce contaminant levels. This approach has been taken for process contaminants such as acrylamide (FoodDrinkEurope, 2014). In some cases, regulatory limits may be put in place to prevent food with high levels of contamination from entering the food chain.

For certain contaminants the goal of the exposure mitigation measure may be clear, e.g. to reduce human exposure below the appropriate health based guidance value such as a TDI. A related goal may be to reduce levels of a contaminant in food to the maximum concentrations specified in legislation. However, for contaminants for which the ALARA approach is used the challenge can be in determining when a reduction in exposure is adequate. The MoE has been developed as a mechanism for prioritising contaminants that require risk management measures and can provide some guidance on when exposure reductions may be considered