Annex 1- Other sources of published guidance

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International Context

1. The working principles for risk analysis published by The Codex Alimentarius Commission (CAC) (FAO and WHO, 2023a) allows for the consideration of “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”. However, the Commission also specifies that “unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided”. There do not appear to be any precedents for the consideration of wider impacts beyond risk assessment in Codex decision-making. The 46th Meeting of CAC in 2023 stated that “there is a need for further clarity around other legitimate factors with particular relevance to other factors which can be accepted on a worldwide basis” (FAO and WHO, 2023b). The same meeting also debated whether consideration of environmental concerns fell within the scope and expertise available to Codex.

2. The Technical Barriers to Trade (TBT) Agreement (World Trade Organisation) requires members of the World Trade Organisation to avoid unnecessary

technical obstacles to international trade. The rules recognise the challenges presented by the proliferation of technical regulations and standards and the demands and interests of consumers. The categories of legitimate factors given by the TBT Agreement are broad: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. The use of agreed international standards, e.g., Codex standards, is likely to provide a better route forward to trade agreements than the setting of bespoke standards by individual partners.

Regulated Products: Food Additives, Enzymes and Flavourings

3. Current Retained EU Law on the authorization of food additives, food enzymes and food flavourings (EC, 2008) is clear that consideration of factors other than product safety are required in the approval process. The use of additives and food enzymes should always be technologically justified. Article 7 requires applicants to explain why the technological effect cannot be achieved by other economically and technologically practicable means. There is also a statutory requirement that products do not mislead the consumer. Applicants are required to provide an explanation that the intended uses do not mislead the consumer and, in the case of a food additive, the advantages and benefits for the consumer.

Non-Regulated and Regulated Products: Contaminants

4. The approach to food contaminants is somewhat different. Contaminants are not intentionally added to food and arise from a diverse number of sources that may include the environment, packaging, processing and cooking, mould growth, etc. Contaminants in regulated products (e.g., novel foods, food additives, etc), may be evaluated and risk management options put in place prior to marketing. Several regulations are applicable to contaminants (e.g., EC, 2006). These contain general principles for risk management which specify that contaminant levels should be kept as low as can reasonably be achieved. Regulations may also specify maximum levels in specific products or commodities. The principle of minimising contaminant levels and compliance with mandatory maximum levels, where applicable, would apply simultaneously.

5. Given the primacy of the management of risks, there is no basis for adjustment of tolerable contaminant exposures based on wider impacts. However, the evaluation of what “can reasonably be achieved” does depend on the context which would necessarily involve an evaluation of risk and wider impacts including costs, benefits, consumer interests, etc. Because precaution is an essential pillar

of food risk analysis, consideration of wider impacts would be secondary to assuring protection from identified risks.

Published technical guidance in the scientific literature

6. A number of papers are available on benefit-risk analysis in the context of food (EFSA, 2010, Boobis *et al*., 2013). These papers advocate a tiered approach and, where possible, the comparison of risks/benefits with comparable health metrics (Tier 3). Boobis *et al*. (2013) provide guidance on the evaluation of quality of evidence from different sources.

7. In addition to the BRAFO papers (e.g., Boobis *et al*., 2013), several papers have been published addressing food risk-benefit analysis including seafoods, micronutrients and packaging. It is possible to apply learnings from such examples to develop a framework for future evaluation of risks and benefits in different settings.

8. Renn (2006), provides a useful analysis of risk in a broader context including the challenges associated with risk communication in complex risk settings.

9. Whether in the context of regulated products or whole foods, a key consideration is that risks and wider impacts are not static. New food safety risks are emerging constantly, and wider impacts may change qualitatively and quantitatively depending on the context (for example, food security, economics or a variety of crisis situations). Therefore, any guidance on the consideration of wider impacts beyond risk assessment must allow for change, proportionality and adaptation (see PAGIT framework report; Tait *et al*., 2017). Responses to wider impacts should still be evidence based and the quality of evidence evaluated as a separate step.