

# FoRK Toolkit – Guidance for Use

## Support document for the Risk Assessment (Tool A) and Risk-Benefit Analysis (Tool B)

Tool A and Tool B are designed to be ‘thinking tools’ that will help research teams work through a problem or opportunity and assess risk specific to the context of their research. When we refer to risk we are referring to risk from conflicts of interest, which can result in biased research, but also reputational risk to individual researchers and research institutions, all of which may lead to public mistrust of science.<sup>1</sup> It is important to note that the definition of a conflict of interest – “situations where an individual has an obligation to serve a party or perform a role and the individual has either: 1) *incentives* or 2) *conflicting loyalties*, which encourage the individual to act in ways that breach his or her obligations”<sup>2</sup> – has the concept of *risk* at the heart of it.

### Who are these tools for?

These tools have been designed for population health researchers who study nutritional epidemiology, public health nutrition, and dietary behaviours at a population level. This narrow focus has been chosen as researchers who work in population health have research interests that are somewhat different from those of clinical or laboratory-based scientists. In population health the main point of concern is promoting and protecting the health of the population. Public policy, including regulation, is often a key focus. Consequently, recommendations from population health researchers regularly encourage government action that is in conflict with to the preferences of the commercial sector. Furthermore, the task of undertaking research to prevent disease and promote health may result in conflict with food companies whose products are associated with a raised risk of diet-related diseases. In addition, these tools focus on impact on human health and not on planetary health. Planetary health, which acknowledges the crucial links between ecological change, human health, and our ability to thrive,<sup>3</sup> is an important consideration for population health and researchers may wish to consider this in their assessment. It is not our intention to infer that these tools are *not* applicable or useful for other researchers concerned with food, nutrition or the food industry, but the tools may require adaptation for other groups of researchers who were not the specific focus of the FoRK Toolkit.

It is hoped that Tools A and B will increase the agency of population health researchers to assess potential risk when considering opportunities to interact with commercial food sector organisations. Tools C, D and E are designed to guide researchers in managing those relationships if interaction proceeds. These tools are *not* designed to be used to assess and guide policymaking activities, as the primary interests and challenges of governments and policy officers are somewhat different from the primary interests of researchers.

### Quantifying risks

It is often easy for researchers to list the benefits of interacting with the commercial food sector, for example, access to unique data or customers. However, considering the risks can sometimes be more challenging. Tool A is designed to increase the capacity of population health researchers to assess potential risk when considering opportunities to interact with the commercial food sector. It firstly assesses the level of risk associated with different types of organisations, and then the risk of different types of interactions. Tool B enables researchers to conduct a benefit assessment and to consider that in light of the risks identified in Part A to provide an overall assessment.

As some components of the Risk Assessment are subjective, this support document has been written to provide researchers with the background and evidence that underpins each component of the Risk Assessment and Risk-Benefit Analysis Tools.

The level of risk identified in these tools has been determined through using available evidence together with a consensus process undertaken with population health researchers involving an on-line Delphi study<sup>4</sup> an international workshop<sup>5</sup> and ongoing consensus discussions. Importantly, depending on a researcher's attitude to risk individual researchers may have a different tolerance for risk and so may choose to undertake research at different levels of risk to other researchers.

Risk assessments are inherently difficult as people tend to be overconfident about their ability to independently assess risk and the range of outcomes that may occur.<sup>6</sup> This is further compounded by confirmation bias, which drives us to favour information that supports our preferred position and suppress information that contradicts that position.<sup>6,7</sup> To assess risk adequately, it is important to be aware of and to try to counterbalance these biases. Ideally, a risk assessment would be undertaken by one or more (independent) professional colleagues with whom the researcher does not work directly. Within a university, this could be a role taken on by an ethical review committee or a legal advisor.

### **What is the 'commercial food sector?'**

When we use the term 'commercial food sector' in the document, we mean the complex, global system incorporating diverse businesses that support the production, processing and supply of most of the food consumed by the world's population. Only subsistence farmers, those who survive on what they grow, can be considered outside of the scope of the modern food industry.<sup>8</sup> Because the food industry often works through intermediaries, especially in its relationships with the academic sector, we will use the term 'commercial food sector organisation' throughout to include both food and beverage companies and any closely associated organisations (e.g. philanthropic foundations funded by the food industry, food and beverage retailers, trade associations or research institutes funded by the organisation or multiple commercial food organisations). Sometimes it is difficult to identify the organisation a researcher needs to interact with, for example, when there is a retail operator in a hospital – the researcher will almost certainly need to interact with both the hospital administration (as the contract holder) and the food retailer (as the organisation delivering a commercial food offering to the hospital community).

It is important for researchers to consider that the nature of a commercial food sector organisation and their involvement with it may change over time. For this reason it is important to reassess risk regularly (e.g. annually). Using the thinking tools in this toolkit provides a learning opportunity, which may enable researchers to improve their practice for the future. The systematic application of the tools may also help to change commercial behaviour in ways favourable to the independence of science.

## 1. Risk profile of commercial food sector organisation (Tool A, Part 1)

**Tool A** is a matrix designed to be used to assess risks associated with both the type of commercial food sector organisation AND the type of interaction. Researchers need to combine *both* parts 1 and 2 to assess risk adequately, except in certain cases where the risk is identified as too high in part 1.

Tool A, Part 1 is designed to assess the present activities of an organisation but a thorough assessment would also include an examination of past track-record and the direction of travel of an organisation.

The first step of the risk assessment is to determine the structure of the organisation with which a researcher is considering interacting. This will involve investigating whether the commercial food sector organisation is owned by another organisation. If it is owned by another organisation, assess risk based on the product portfolio of the parent organisation.

Many food brands are owned by a small number of very large, often multinational, companies. In the USA, the ten largest food companies account for more than half of all food sales.<sup>9</sup> Worldwide, the ten largest food companies account for 15% of sales.<sup>10</sup> The top ten soft drink companies account for 52% of sales worldwide.<sup>10</sup> Knowing which company ultimately owns the organisation is an important part of accurately assessing risk. This will involve some investment of time. The practices of transnational companies may differ in different parts of the world and researchers may wish their assessment of risk to reflect their practices beyond national boundaries.<sup>11</sup>

*1a. Does the organisation:*

- *Violate international human rights conventions or health-related international, national or regional laws or agreements (e.g. The WHO International Code of Marketing of Breast-milk Substitutes or the WHO Framework Convention on Tobacco Control)?*
- *Own, or is owned by, or has other structural links (such as financial links) to a tobacco or arms company?*

The actions and products detailed in this statement directly contradict the core values of public health practice. Not only do tobacco companies and arms companies make products that kill or disable millions when used as intended but there is strong evidence<sup>12</sup> of the tobacco industry's unethical scientific and publication practices, which result in substantive reputational risk for researchers interacting with them. These issues are covered by the WHO Framework Convention on Tobacco Control.<sup>13</sup>

The WHO International Code of Marketing of Breast-milk Substitutes, agreed to by all member states, sets clear guidance for breastmilk substitute manufacturers.<sup>14</sup> Violations of the Code by breastmilk substitute manufacturers continue in many countries around the world.<sup>15-17</sup>

*1b. Does the organisation:*

- *own or is owned by, or has other structural links (such as financial links) to a company that produces other commodities harmful to health (e.g. alcohol, gambling)?*

Alcohol and gambling can be harmful to health. Alcohol is responsible for 5.9% of all global deaths<sup>18</sup> and gambling is associated with significant negative health impacts on individuals but also communities and society.<sup>19</sup> Furthermore, alcohol and gambling companies have engaged in marketing and lobbying practices that undermine public health, and have provided funding for research designed to be sympathetic to their arguments.<sup>20</sup> However, as these commercial entities

are not subject to the same sort of legal frameworks as tobacco and arms, they have been classified as high risk rather than 'very high risk' in the toolkit.

*1c. Does the organisation produce, manufacture or retail any food or beverages considered 'unhealthy'?*

AND

*2a. Does the organisation promote through marketing strategies any products or eating practices considered 'unhealthy'?*

Interacting with a commercial food sector organisation may give the appearance that researchers or a research institute endorse that commercial food sector organisation's products or its marketing strategies. We define marketing as the process of exploring, creating and delivering value to meet the needs of a target market in terms of goods and services, which often involves aspects of the product, its placement, price and promotion.<sup>21</sup> Co-opting academic experts has been a deliberate strategy used by some commercial food sector organisation to neutralise criticism and promote the marketing of their products.<sup>22 23</sup> This practice is particularly apparent with organisations that manufacture products or promote practices that are not recommended for healthy and sustainable diets.<sup>23 24</sup> In addition, a survey of researchers and stakeholders has shown that the further removed an organisation is from producing/manufacturing healthy/unprocessed foods, the less agreement there is that researchers should interact with them.<sup>4</sup> Another challenge is that many commercial food sector organisations produce both healthy and less healthy foods and, therefore, while we have suggested a somewhat arbitrary cut-off for the proportion of unhealthy food produced, judgement will be required.

*2b Has the organisation actively lobbied or petitioned against public health policies, particularly those aimed at supporting healthy eating?*

Certain commercial food sector organisations have lobbied and used legal processes to oppose regulation or legislation aimed at helping the public reduce consumption of less healthy food products. For example, some commercial food organisations have employed lobbyists and made large donations to political parties to fight federal sugar or soda taxes.<sup>11 25-28</sup> Food and beverage multinational companies are also documented to have pressured governments to not pass legislation banning vending machines from schools, misleading food advertising, and a tax on the advertising budgets of food organisations promoting unhealthy eating.<sup>27 29</sup> Organisations undertaking these actions are acting in ways that are counter to public health evidence.

*2c Does the organisation have a commercial interest in the research topic/intervention?*

As a general rule, the highest risk of undue influence towards dietary and nutritional public health goals is when an organisation has a commercial interest in the production and sale of goods contributing to an unhealthy diet.<sup>30-32</sup> An example of this can be seen in relation to the International Life Sciences Institute (ILSI). ILSI-funded research reported that the advice to cut sugar by various national and international health bodies, such as the World Health Organization, could not be trusted.<sup>33 34</sup> However, the funders of ILSI include numerous food and beverage companies, including Kellogg's, Coca-Cola and Tate & Lyle, all of which have a clear commercial interest in maintaining high sugar consumption.<sup>34</sup>

In another example, a systematic review of studies examining the association between sugar-sweetened beverages (SSBs) and obesity found that studies in which scientists had received research funding from large SSB firms were five times more likely to conclude that there is no link between SSBs and weight gain.<sup>35</sup> Such research may then be used by SSB companies to respond to challenges regarding the health risks of its products and to lobby against potential regulation.<sup>34</sup>

## 2. Type of interaction (Tool A, Part 2)

The type of interaction a researcher or research institution has with a commercial food sector organisation may change over time and can have many components. Therefore, it is important to re-evaluate risk regularly and at every stage of the research, because what might start out as informal dialogue may later turn into formal collaboration, resulting in a different level of risk.

### ***Dialogue***

This type of interaction generally has the lowest risk as it constitutes participating in a discussion of some sort with a commercial food sector organisation with no subsequent commitment to action. This may be as part of a government committee that has commercial food sector representatives or participating in a formal or informal discussion directly with a commercial food sector organisation (e.g. regarding potential changes an organisation could implement to improve their internal policies or products to support healthier eating).

Some forms of dialogue may impact on the perceived integrity of researchers. This can occur when population health researchers participate in commercial sector-led or funded advisory groups. This is particularly the case if the aim of the advisory group is to produce guidance on decreasing nutrition-related disease and involves commercial food sector organisations that make, sell or promote products that contribute to nutrition-related diseases. For example, an examination of a commercial food sector funded scientific charity, which regularly produces nutrition evidence reviews and position statements, demonstrated that it actively attempted to influence research conferences, public messages and policy to promote industry-favourable messaging.<sup>34 36 37</sup> Furthermore the organisation actively attempted to thwart polices or leaders hostile to their interests.<sup>34 36</sup> When a scientific expert is engaged in a dialogue-related activity and acts in the interest of such a commercial food sector funded committee, his or her implicit ties to commerce may create a reputational risk and a perception that they will make biased decisions.<sup>38</sup>

### ***Developing or evaluating an intervention within a commercial food sector organisation (in-kind funding only)***

Depending on the requirements of the organisation, this level of interaction can lead to varying levels of risks. The lowest risk occurs when no restrictions are placed on the researcher (e.g. sales data is given freely to researchers to evaluate an industry intervention without restrictions on publication). This was the case with an evaluation of changes in sales of non-alcoholic beverages in Jamie's Italian, a national chain of commercial restaurants in the UK, following the introduction of a £0.10 per-beverage levy on sugar-sweetened beverages. Sales data were made available to the research team with no restrictions.<sup>39</sup>

If there is shared decision-making power between the researcher and commercial food sector organisation around the agenda, goals, strategies, resources, roles and responsibilities of the initiative, this also reduces risk as the researcher has greater control. However, if restrictions are put in place by the organisation, the level of risk increases as the level of control of the researcher(s) decreases, and accountability and transparency of the organisation decreases.<sup>40</sup>

Regardless of the level of restrictions mentioned in the previous paragraph, a further risk associated with developing and/or evaluating interventions with commercial food sector organisations is the issue of reciprocity and bias. While in-kind funding may be considered less problematic than accepting direct funding from such an organisation, acceptance of gifts, for example, lunch/dinner, stationary, conference registration, from an organisation creates a

relationship with them.<sup>41</sup> Researchers may then feel favourable towards, or even obligated to, that organisation.<sup>35</sup>

### ***Sponsorship and branding***

The strategy of co-branding allows the transfer of reputation and credibility between partner brands.<sup>42</sup> Research has demonstrated subtle biasing effects can result from branding where positive direct effects from one organisation can be transferred to another organisation or product through the presence of a logo.<sup>43</sup> The ultimate effect of this is that co-branding can lead to a 'halo effect' for commercial food sector organisations and subsequently results in increased sales.<sup>44</sup> Therefore it is important for researchers to consider the products that an organisation sells and understand that their involvement with the organisation may lead to increased sales of these products if their academic 'brand' is used by the organisation in any way.

There is also the potential for negative impacts, particularly if the combination of the two brands is perceived to be a poor fit. This results in negative value perceptions and dilution of reputation which has a greater impact on the brand with the higher popularity.<sup>45</sup> An example of this would be UNICEF partnering with McDonalds. Of concern is that these negative associations have been observed to continue to have an enduring effect 12 months after the event.<sup>45</sup>

It is important to recognise that a commercial food sector organisation willing to co-sponsor or co-brand with a research institute on a project, product, training or conference will likely use their association with the institute for additional marketing purposes.<sup>46 22</sup>

### ***Conference presentation (no funding received)***

Presenting research at a conference that receives commercial food sector sponsorship when the researcher has received no direct funding from the conference sponsors is generally considered low risk. However, there may be reputational concerns for those organising and attending conferences with sponsorship from organisations that have a poor fit with the researcher's goals and ethos. Of particular concern is if researchers are asked to be part of a panel or a session sponsored by a commercial food sector organisation that only highlights one side of an argument – usually in favour of the sponsor.<sup>22</sup>

Another issue researchers may want to consider is that commercial food sector organisations can use these events to gain advanced notice of research findings and publications, which may impact on their business. Commercial organisations are likely to use such knowledge to inform mitigating and other strategies.

### ***Funding: grant funding, travel costs, honorarium, prizes***

Direct grant funding from commercial food sector organisations can create a conflict of interest. There is strong evidence that receiving funding from a commercial organisation is associated with outcomes favourable to the sponsor's product(s).<sup>35 47-50</sup> The bias that may occur in favour of the funder often happens without the researcher realising it.<sup>50-52</sup> This is known as unconscious bias. It can manifest in the types of research questions that are asked, the way the data is gathered and interpreted and the way findings are reported.<sup>35 49</sup> It can impact on the credibility of the researcher and the research field, partly because of the generation of biased results and partly through a loss of trust in the scientific discipline among the media and general public.<sup>35</sup>

Direct funding to a researcher or a research institute can also result in conscious bias. This may occur through encouragement or even pressure on researchers from senior university executives to engage with or not be critical of products so as not to upset the funder, or by researchers yielding to the temptation to manipulate their research to ensure results they are acceptable to the commercial food sector organisation. In both scenarios, these actions are taken to avoid the risk of losing the funding.<sup>46 53</sup>

It is generally accepted that the greater the amount of funding from a commercial entity to a researcher, the greater the likelihood that professional judgment will be biased, and the more significant the conflict of interest.<sup>54</sup> However, there is also considerable evidence that in-kind funding, travel funding and even small gifts or the provision of meals from the commercial sector can influence the behaviour of researchers.<sup>41 55 56</sup> When a gift or gesture *of any size* is bestowed, it imposes on the recipient a sense of indebtedness.<sup>56</sup> Importantly, researchers who do not recognise the power of small gifts are the ones most likely to be influenced by unconscious bias, because their defences are down.<sup>55</sup>

### ***Manipulation of the research and policy agenda***

Research funded directly or indirectly by the commercial food sector is often designed to either explore only the potential health benefits of consuming certain foods and ingredients or as a way to garner evidence to oppose proposed regulation.<sup>22</sup> For organisations investing in research that will support particular products, this form of one-sided research can distort the research agenda of academic institutions (as well as individual scientists) and undermine the mission of institutions to explore the positive *and* negative associations between food and health.<sup>46</sup> Furthermore there is a danger that the funder may magnify or cherry-pick positive results or they may refuse permission to publish negative results.<sup>46 57</sup>

A well-known strategy of the commercial food sector when opposing proposed regulation is to accrue evidence in opposition to it.<sup>58 59</sup> This usually occurs through funding research to generate evidence via their own research teams or via external research institutions.<sup>37 59</sup> The evidence garnered is then used to reframe the problem and solution in favour of the commercial food sector organisation.<sup>58</sup> A more strategic use of research and researchers by commercial food sector organisations is to fund research that diverts attention from pressing public health issues, for example, funding research that shows physical inactivity, rather than a poor diet, is the primary cause of obesity.<sup>37 44 60</sup>

Generally the longer and closer the association between a commercial food sector organisation and a researcher, the higher the risk.<sup>40</sup> Concerns have been raised that once a researcher receives money from a commercial organisation they more easily become an ally of the organisation's position, more willing to compromise standards, less likely to oppose the actions and policies of the organisation, and they may become dependent on those commercial funds.<sup>61</sup>

### 3. Risk-benefit analysis (Tool B)

Tool B is designed to be used as a ‘thinking tool’ that can help researchers to identify the risks and benefits of interacting with a commercial food sector organisation and the likelihood of these risks and benefits occurring. It is often easy for researchers to list the benefits of interacting with the commercial food sector, for example, access to unique data or customers. However, considering the risks can sometimes be more challenging.

Undertaking a risk-benefit analysis can help to ensure the core research values of independence and integrity are preserved. Damage to one of these values will directly impact on the researcher’s reputation and that of their institution, from which it is generally hard to recover.<sup>31</sup> Reputational damage for researchers may result in exclusion from future research opportunities as well as questions around academic integrity and fitness to practice.<sup>62</sup>

***May provide a commercial food sector organisation with a ‘health halo’ (i.e. increases the perception that an organisation produces ‘healthy’ food or drinks).***

Studies have shown that commercial food sector organisations that claim their products to be ‘healthy’ in menus and marketing material confer ‘health halos’ on their food.<sup>63</sup> This results in consumers subsequently choosing more energy dense food from these organisations.<sup>63 64</sup> The effect may be even more powerful when the halo is conferred not by the organisation itself but by another entity perceived to be independent and trustworthy, such as a government body or research institute.<sup>65</sup> However, the formation and use of health halos is not just limited to the marketing of food, it can also be based on the organisation’s image or reputation.<sup>66</sup> In particular, positive information about an organisation’s corporate social responsibility has been shown to create a ‘health halo’. The term ‘health washing’ is also used in relation to such corporate activities. When people consider an organisation is responsible they assume it makes ‘better’ products and that these products are healthier, leading to overconsumption of these foods.<sup>66</sup> Researchers may need to consider that both research findings and the interaction of a research institute with a commercial food sector organisation may both increase the perceived responsibility and respectability of an organisation and therefore the perceived healthiness of their foods.

***Research could be used by an organisation to divert attention from pressing public health issues***

The issue of manipulating research and policy agendas was highlighted in relation to direct funding above. Researchers will need to decide whether there is a risk of such manipulation occurring in relation to the proposed interaction they are considering. Commercial funding for a particular research question is usually dictated for commercial reasons, and is likely to or may alter the research agenda.<sup>67</sup> This can create a dependence on this form of research funding which may then inhibit other independent research and inquiry.<sup>68</sup>

***Reputation – personal, professional and/or institutional***

Reputational risk for population health researchers may be determined by two factors:<sup>69</sup>

- *An expectation-experience gap:* e.g. if a researcher is promoting themselves as a high quality (methodologically rigorous) researcher then produces sub-standard work or their independence or integrity is questioned, this increases reputational risk.
- *A change in norms and beliefs:* e.g. if society is becoming more concerned with environmental impact of food choices and a researcher’s work does not take this on board or, worse, results in environmental degradation, this can increase reputational risk.



The reputation of a researcher is ultimately determined by others (e.g. peers, the public, the media). They all have certain expectations. When a researcher meets or exceeds these expectations, their reputation will increase. To maintain their reputation a key strategy is to determine whether the interaction a researcher is considering will do anything to adversely affect their (or their institution's) primary purpose and core values.<sup>69</sup> If it is likely to adversely affect either of these, it is recommended to avoid the interaction, as the risk is too high.

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