Risk-benefit assessment of foods

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Opinion of the Director of the Office for Risk Assessment of the Food and Consumer Product Safety Authority (VWA) to the directors of VD (Ministry of Agriculture, Nature and Food Quality) and VGP (Ministry of Health, Welfare and Sport) and the Chief Inspector for food and tobacco and the Inspector-General of the VWA.

Summary
There is a growing need for risk-benefit assessments of foods, or components thereof, which may have health-threatening as well as health-promoting properties. The process of determining negative (risk) and positive (benefit) aspects consists of several steps. In collaboration with RIVM, the Office for Risk Assessment has designed a decision tree that describes the four steps and indicates when choices must be made in consultation with the risk manager. The four steps are: identification of negative and positive effects, estimation of exposure, characterisation of risk and benefit and integration of risk and benefit in a common measure. The introduction of specific 'stops' in the decision tree is innovative and indicates that it is not always necessary to carry out a full risk-benefit assessment. In this way, choices can be made in a transparent way. An example illustrates the use of the decision tree.

Introduction
In addition to health-promoting properties, foods, or components thereof, often also have health-threatening properties. The current system of risk assessment evaluates the health-threatening compounds and does not consider health-promoting compounds. A risk-benefit assessment compares the disadvantages (risks) of a given situation with the related advantages (benefits) to achieve a balanced response to the question whether the risk is acceptable given the benefits.

A risk-benefit assessment may be considered in one of the following situations:

- when both negative and positive compounds are present in a food. For example: methyl mercury and dioxin versus iodine, n-3 fatty acids and vitamin D in (oily) fish.
- when an adverse interaction occurs between compounds from different foods. The formation of nitrosamines at simultaneous consumption of fish and nitrate-rich vegetables is an example.
- when a compound has negative effects in a subpopulation while it has positive effects in another subpopulation; for example, folic acid.
- when a compound has negative effects when administered at a certain dose while it has positive effects at another dose; for example, fortification of foods with vitamins.
- when substituting or fortifying; examples, sweeteners replacing sugar or using fat replacers instead of fat.

Presently there is no consensus on how to carry out a risk-benefit assessment. In addition to an EFSA Working Group (1) there are also European FP6 projects (Qalibra, Beneris and BRAFO; www.qalibra.eu, www.beneris.eu, www.brafo.eu respectively) and national projects (such as 2-4), which study aspects of risk-benefit assessments.

This opinion is based on a collaborative project between the Office for Risk Assessment and the National Institute for Public Health and the Environment (RIVM) (5). It describes a tool that assists in deciding how and to what extent a risk-benefit assessment should be carried out. The subject fits into the efforts of the Office for Risk Assessment to take all relevant issues into account when delivering opinions.

Aim of the opinion
This opinion provides an instrument, a decision tree, to assess to what extent and how a risk-benefit assessment should be carried out (see Annex). The decision tree is a suitable tool for decision-making by the risk assessor in consultation with the risk manager. This opinion focuses on health, however, if required, other values such as cost or animal welfare, can also be considered in the final decision-making. It is a political decision how to weigh the various values.

Important issues
In a risk-benefit assessment, the negative effects (risks) are weighed against the positive effects (benefits). The starting point for the assessment is that the total daily intake of compounds will be considered. Also positive and negative effects of possible replacements of one food by another must be taken into account. Assumptions and uncertainties of each step and availability and reliability of the data used should be accurately described. The decision tree uses the same steps as in the generally accepted model for risk assessment (6), namely hazard identification, hazard characterisation, exposure estimation and risk characterisation. As noted by the Dutch Health Council, policy-making is not a scientific but a political and legislative process (7). A risk-benefit assessment provides the (scientific) information that can serve as a basis for policy-making.

Decision tree
The decision tree for a risk-benefit assessment is described briefly below. The decision tree contains multiple points where the assessment can stop (see Annex). These are the points where the risk assessor, in consultation with the risk manager, takes decisions. Leading here is always whether there is sufficient information for a conclusion to be drawn.

The decision tree includes the following steps:

0. Formulating the risk-benefit question, which clarifies the nutrient, chemical compound or food and the population (group) to be studied. The risk assessor formulates the question in consultation with the risk manager.
1. Identifying all negative and positive effects of the compounds or the food under consideration.
2. Estimating the total intake(s). This step in the decision tree comes earlier in our decision tree as compared to the generally accepted risk assessment model (6). This is done because the following steps are very time- and labour-intensive, and perhaps not always necessary. A qualitative comparison is made between the probability of negative and positive effects at the estimated exposure. This will result in one of the following situations:

    a) If the intake remains under the for the situation relevant health standard value, or if an intake below this level can be easily achieved (e.g., by replacing with another food), then a continued assessment is not required.
    b) If the intake (largely) exceeds the health standard value and is likely to have a serious negative health impact, the risk is not acceptable and the assessment will stop here.
    c) If the intake is likely to have a limited negative impact and there is a positive effect (benefit), the risk should be carefully weighed against the benefit and the risk manager may decide to continue the assessment with a quantitative assessment.

3. Characterising risk and benefit. In this quantitative part of the risk-benefit assessment dose-response relationships will be studied for both the negative and positive effects. The necessity of this step should be clear because this is a labour-intensive process.

4. Integrating risk and benefit. By converting the effects into a common measure, for example, a QALY or DALY (Disability- or Quality-Adjusted Life Years) (8), risks and benefits are weighed against each other and conclusions can be drawn.

Using the decision tree

How to use the decision tree is illustrated with the case of nitrate in vegetables. The question is whether the (possible) negative health effects of nitrate intake from leafy vegetables outweigh the recognised positive health effects (benefits) of vegetables for the European population. The EFSA report (9) shows that 2.5% of the European population that consumes leafy vegetables is at risk to exceed the ADI for nitrate. Application of the decision tree shows that the exceedence of the ADI by a small proportion of the population, combined with the demonstrated positive health effects for the whole population, may lead to a decision of a risk manager, already after the qualitative assessment, that the positive effects outweigh the negative effects. The assessment can stop. Another management decision might be to continue the risk-benefit assessment with a quantitative assessment.

Conclusions

The proposed decision tree is a tool for structuring the decision whether or not to carry out a risk-benefit assessment, thereby taking into account that:

- the decision tree is based on the same steps used in the 'classical' risk assessment process, but the order of steps has been changed for practical reasons: estimating the exposure is done earlier in the process;
- specific 'stops' are introduced in the decision tree to clearly indicate that it is not always necessary to complete a full risk-benefit assessment;
- using the decision tree calls for repeated interactions between risk assessor and risk manager. This will result in a transparent assessment with clearly defined assumptions and uncertainties;
- the decision tree is based on a risk-benefit assessment of public health, but can also be applied to other policy-relevant, social values.

Opinion

I advise you to:

- use the decision tree together with the Office for Risk Assessment for decisions about risk-benefit studies in relation to risk assessments of foods or compounds in foods that may have health-threatening as well as health-promoting properties; and
- evaluate the decision tree after using it to determine whether adjustments are needed to support policy-making decisions.

Yours sincerely,

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Director

Literature

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Annex. Decision tree for a risk-benefit assessment of (compounds of) foods