White Paper

Towards Inclusive Risk–Benefit Assessment: Integrating Co-Creation for Trustworthy Decision-Making in Biotechnology

Introduction

Emerging biotechnologies and innovations in the agri-food and bio-based sectors hold significant potential to address pressing societal challenges, including sustainability, food security, and climate resilience. At the same time, their development and deployment often raise complex questions regarding risks, benefits, and public acceptance. Traditional risk–benefit assessments (RBAs) provide a strong scientific basis for evaluating such innovations, but they are typically expert-driven and may not fully capture the perspectives, concerns, and values of those directly affected.

In recent years, there has been growing recognition that inclusive and transparent decision-making processes are essential to building public trust and ensuring the sustainable uptake of new technologies. The B-Trust project has responded to this need by developing a structured co-creation programme that actively involves stakeholders—such as consumers, producers, industry, and regulators—throughout the innovation cycle.

This white paper presents an approach that integrates stakeholder-driven co-creation into the analytical framework of risk–benefit assessment. By combining evidence-based methodologies, such as multi-criteria decision analysis, with participatory processes, the approach enables a more comprehensive understanding of both direct and indirect consequences, including socio-economic and cultural dimensions.

The resulting framework supports decision-makers in developing more robust, transparent, and widely accepted policies and regulatory solutions, while also identifying barriers and opportunities for implementation. By bridging scientific assessment and stakeholder engagement, the B-Trust approach helps strengthen trust in biotechnology and foster more sustainable innovation pathways.

Co-creation meets risk-benefit assessment: an inclusive B-Trust approach

A risk-benefit assessment or analysis (RBA) is a systematic evaluation process used to map the potential negative outcomes (risks) and anticipated positive outcomes (benefits) of a situation, innovation, technology or policy, often to compare them with the current practice. The goal is to provide a comprehensive analysis that can guide informed, evidence-based decision-making (1). This type of multi-disciplinary, integrative assessment can be widely applied across several sectors. In food regulatory science, it's a relatively new field that is based on practices developed for human health (2). RBAs often utilize specialized guidelines and frameworks, such as the Multi-Criteria Decision Analysis (MCDA) method, which is commonly used in food health and safety contexts (3, 4).

The B-Trust project set out to investigate and develop tools to address hurdles for public trust and acceptance in the context of biotechnology for the agri-food and bio-based sectors. Trust and acceptance can be greatly improved by listening to and addressing the concerns and doubts of all those who will be affected by an innovation, such as consumers or farmers. The B-Trust project developed a concrete programme (based on co-creation) with overarching methodologies and practical tools for engaging these stakeholders in the research, development, implementation and regulation of new innovations in a transparent, inclusive, and systemic manner. This process allows us to capture risks and benefits from a broader, stakeholder-centric perspective, including more indirect, socio-economic and cultural aspects. It also helps provide a different perspective on the severity (weights) of the risks and benefits, as perceived by the affected stakeholders.

Integrating such stakeholder perspectives in the analytical process of risk-benefit assessments can enrich the mapped risks and benefits while simultaneously identifying barriers and opportunities for implementation. This inclusive approach to RBA processes is becoming increasingly important (5) and supports evidence-based, transparent and trustworthy regulatory and policy decisions, ultimately contributing to a more sustainable uptake of innovations.

The B-Trust co-creation programme as a tool for setting up stakeholder interactions

The B-Trust co-creation programme lies at the center of the project's trust-building methodologies. Its general outline comprises four consecutive phases that can be applied partly or fully across the biotech innovation cycle (Figure 1).

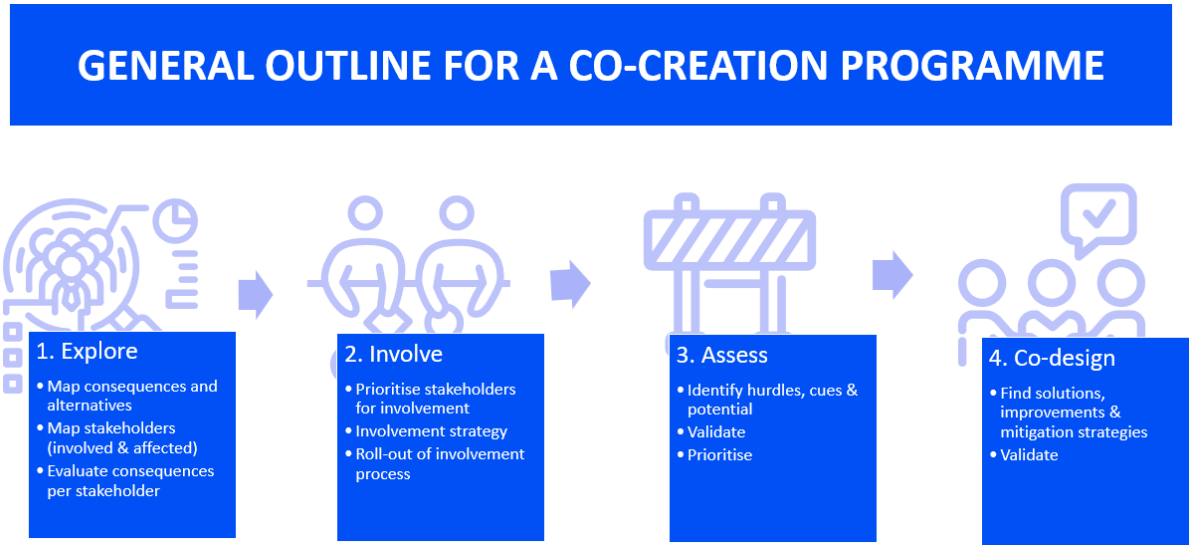

Figure 1: the different phases of B-Trust's co-creation programme

The programme is set up in four phases, of which two are analytical and two engaging:

- Step 1: Explore phase (analytical). In this step, we thoroughly analyze the context of our innovation and the expected impact on stakeholders, primarily drawing on the literature/existing knowledge. Specifically, we analyze the evidence-based consequences of innovation and its alternatives. These consequences can be positive (benefits), negative (risks), or neutral (changes), and can be direct or indirect, short- or long-term. Mitigation measures for the potential negative consequences are mapped accordingly. Additionally, we map the stakeholders who are either affected or influencing the innovation, and we evaluate the consequences per stakeholder.
- Step 2: Involve phase (engaging). Next, we explore this context further together with our stakeholders to gain a broader understanding of our innovation and its implications in real life. To do this, we first prioritize the stakeholders based on step 1, to make sure we engage with the most relevant stakeholders. Then we develop an involvement strategy, and we roll out the process to start co-creating with the selected stakeholders.
- Step 3: Assess phase (analytical). We now analyze this input to pinpoint critical issues and use these for step 4. Concretely, we identify the hurdles for implementing the innovation and the cues to overcome these hurdles (= an extended list of consequences), we validate these findings and we prioritize the elements that are most crucial to take to step 4.
- Step 4: Co-design phase (engaging). Finally, we co-design solutions and improvements with relevant stakeholders. First, we set up a co-design plan by identifying the relevant stakeholders and setting up a strategy for engagement, then we co-design solutions/mitigation strategies, we validate or test these and finally we provide feedback to all involved stakeholders (steps 2-4).

This programme can be partly or fully integrated into decision-making processes, like the inclusive approach to risk-benefit assessments to guide regulatory frameworks and decisions for new innovations as described in this white paper.

Risk-benefit assessments provide a strong scientific basis for regulatory advice

A risk-benefit assessment (RBA) is a key component of a comprehensive analysis that includes the assessment, management, and communication of risks and benefits for specific use cases. Such RBAs must be conducted in a systematic and transparent manner to ensure that outcomes are evidence-based, reproducible, and well-documented (1). RBAs often use different steps in a multi-criteria decision analysis (MCDA), a method that provides a structured and iterative framework to facilitate complex decision-making (3). A typical MCDA involves a sequence of steps, which are illustrated below (Figure 2). The delineated steps refer to the method of Schrijvers et al. (6), which was also based on the FAO guidelines on evidence-informed decision making (1):

- Steps 1 & 2: Initially, a decision problem and a set of possible interventions, or alternatives, are defined. The risk-benefit decision problem is generally formulated as a concrete question, that specifies and compares a set of alternatives against an existing reference.
- Step 3: Next, a risk-benefit tree is constructed using a set of evaluation criteria. These criteria reflect potential adverse (risks) or positive (benefits) outcomes associated with each alternative compared to the reference.
- Step 4: Once the risk-benefit tree is established, a performance matrix is constructed to evaluate how each alternative measures up against the defined reference. In this matrix, performance scores are assigned to each criterion. MCDA methods are well-equipped to handle diverse qualitative and quantitative scores, enabling a broad spectrum of criteria metrics.
- Step 5: A traditional MCDA approach allows a group of pre-selected, often expert stakeholders to assign weights to evaluation criteria so that different value judgments or preferences can be captured.
- Step 6: The assessment of the alternatives' performance is calculated through aggregation methods, of which several are available. The higher the net ranking, the ‘better’ the alternative.
- Step 7: Next, uncertainty analysis is performed to report and characterize knowledge gaps, whereas sensitivity analysis is used to check the stability of the results obtained through the MCDA (7).
- Step 8: Finally, results can be presented in bar graphs, tables and many more. This allows decision makers to quickly visualize and evaluate the impact of different scenarios on the final ranking of alternatives.

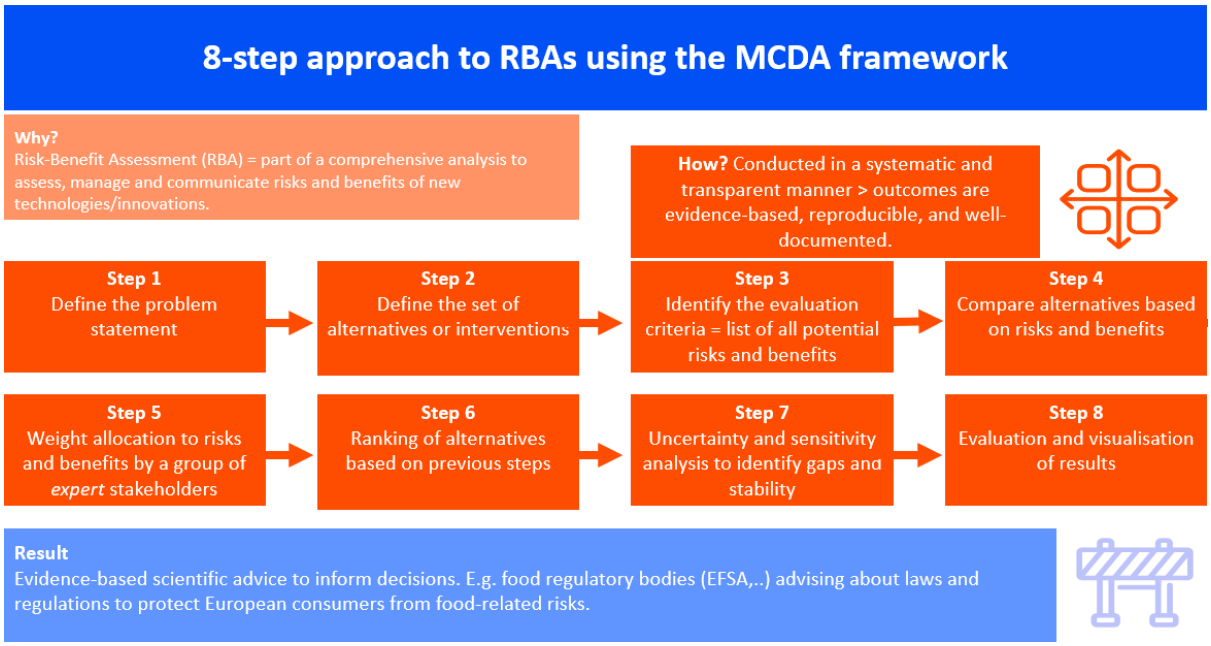

Figure 2: 8-step approach to a risk-benefit assessment using multi-criteria decision analysis (based on (6))

This multi-step approach integrates quantitative and qualitative criteria along with expert stakeholder perspectives, leading to an evidence-based, reproducible, and well-documented evaluation (3). Comprehensive RBAs using the MCDA framework provide an important scientific basis for policy or regulatory advice, for example, food regulations, as exemplified by the role of the European Food Safety Authority (EFSA) in providing scientific advice for laws and regulations to protect European consumers from food-related risks (4). While very robust, traditional RBA approaches can be top-down, linear, and limited to expert input.

Towards inclusive RBAs using B-Trust's participatory approach

Inclusive RBAs represent a holistic approach that complements the scientific, evidence-based risks and benefits from traditional RBAs with stakeholder-centric consequences. Integrating the Explore (step 1), Involve (step 2), and Assess (step 3) steps of the B-Trust co-creation programme into the 8-step procedure of the traditional RBA analysis (using the MCDA framework) allows for a comprehensive analysis to assess, manage, and communicate risks and benefits of new technologies and innovations, identify barriers and drivers for trust in society, refine solutions, and optimize communication strategies.

The resulting process consists of the following steps (Figure 3):

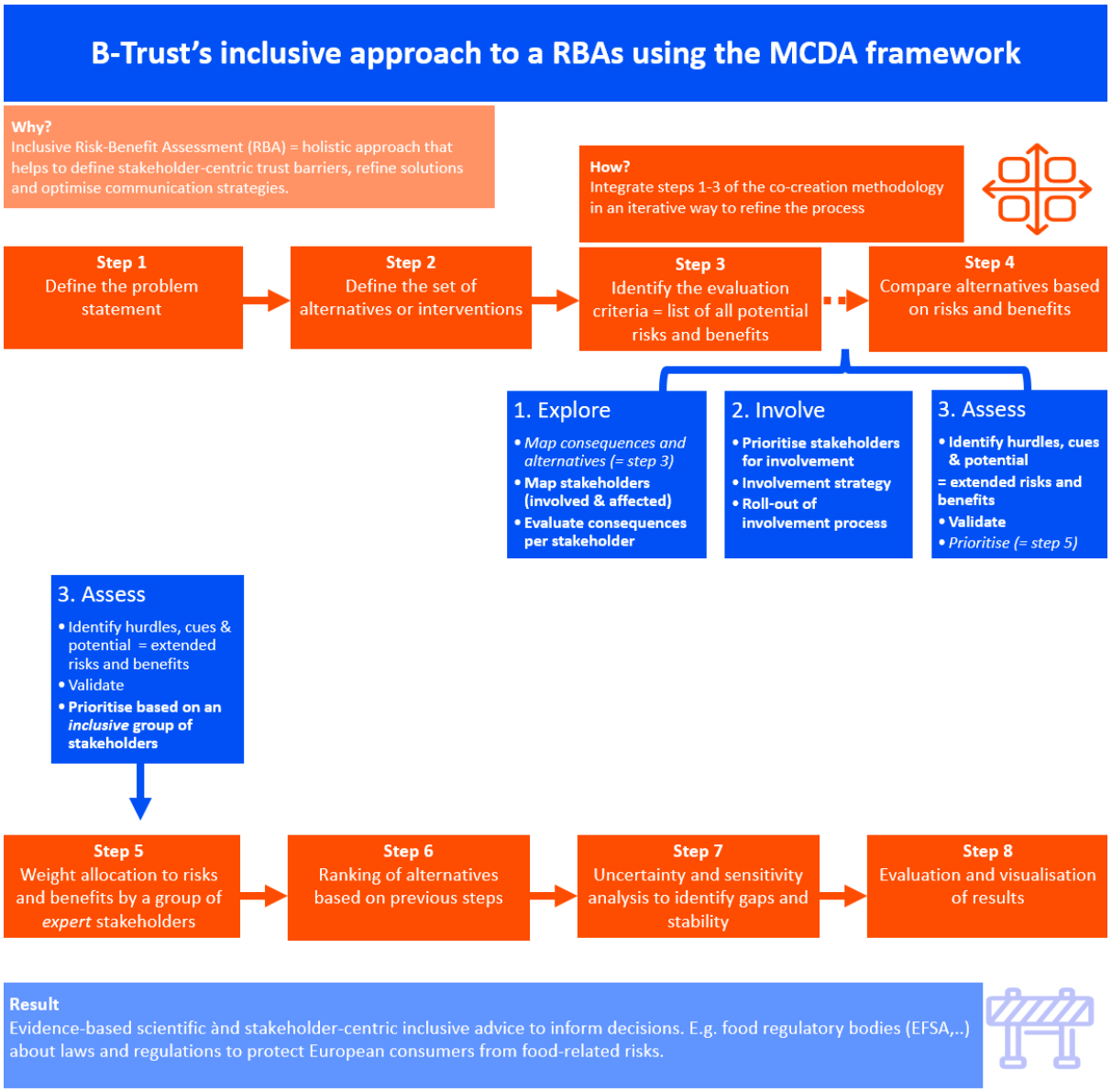

Figure 3: B-Trust's inclusive approach to RBAs using the MCDA framework

- Steps 1 & 2: Definition of a problem statement and a set of alternatives. These MCDA steps will stay the same.
- Step 3: Sketching of a risk-benefit tree. This step overlaps with the consequence mapping of the Explore phase (step 1 of the co-creation programme) and will thus mostly stay the same, except for the suggestion to focus on positive, negative and neutral consequences instead of purely risks and benefits.

Integration of the Explore, Involve, and Assess steps of the co-creation programme

- Explore step (step 1 co-creation programme): Mapping involved and affected stakeholders and evaluating the consequences (cf. step 3) per stakeholder.
- Involve step (step 2 co-creation programme): Prioritizing stakeholders for future involvement and developing and rolling out the involvement process.
- Assess step (step 3 co-creation programme): Identifying the hurdles and cues for acceptance (= extended list of consequences based on co-creation) and

validation of the data. The prioritization part of this step integrates with step 5 of the MCDA framework and will thus be tackled later in the process.

Returning to the MCDA framework based on (1, 6)

- Steps 4: Comparison of the alternatives based on the extended list of consequences
- Step 5: Weight allocation/prioritization of consequences based on an inclusive group of stakeholders. This step integrates with the prioritization part of the Assess step (step 3 co-creation programme).
- Step 6: Ranking of the alternatives.
- Step 7: Uncertainty and sensitivity analysis.
- Step 8: Evaluation and visualization of the results.

This inclusive approach will result in evidence-based ànd stakeholder-centric advice to inform decision-making. Policymakers and regulators who will work with this advice are encouraged to do so by continuing with the Co-design phase (step 4 of the co-creation programme). Together with the relevant stakeholders, they will co-design solutions, improvements, and mitigation strategies in the form of regulations or policies. These can be validated in an inclusive way by engaging the relevant stakeholders before implementation, thereby closing the loop.

Conclusion

This approach demonstrates how integrating stakeholder perspectives throughout the analytical risk-benefit assessment process can enrich the understanding of potential consequences while simultaneously identifying barriers and opportunities for implementation. Therefore, the proposed approach provides a strong foundation for evidence-based, transparent, and inclusive regulatory and policy decisions, ultimately contributing to a more trusted and sustainable uptake of biotechnology innovations.

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