



Principles of Alternatives Assessment

Manufacturers routinely practice alternatives assessment (AA) as part of their R&D process to develop new and improved products for the marketplace. Protecting and improving public health and the environment is an inherent component of the product design process. As in the R&D process, an alternative should have not only an improved safety and environmental profile, but also should be technologically and commercially feasible; of comparable cost; maintain or improve product efficacy, performance, and usability; and result in consumer acceptance in the marketplace. The graphic below depicts how AA is integral to the typical product R&D process.

Product R&D Process – Continuous Improvement



As governments and others suggest alternatives to chemicals of concern, the product development process provides the most appropriate model to establish a practical and meaningful framework for AAs. Using best practices from the R&D process would achieve the objective while avoiding regulatory mandates that stifle innovation.

Principles – The product development and improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A sensible approach for conducting an AA should be built on the same approaches that underpin product R&D processes as follows:

- **Ensure Consumer Acceptance** – The alternative must be verified to provide the same or better performance and value as viewed by the consumer; i.e., the product must not simply possess the desired function, but must be perceived by the consumer as comparable or superior to the existing version of the product. Consumer acceptance will drive the market success that allows the alternative to achieve the goal of providing meaningful improvement to public health and/or environmental benefit.

- **Be Flexible** – Alternatives assessments may be undertaken by individual manufacturers, or by consortia representing an industry segment or an entire industry. However, each company's business model is different. Even for similar chemicals/products, the AA outcome may vary for different manufacturers due to manufacturing processes, design features or market niches, for example. Each manufacturer must be given the latitude and discretion to leverage existing tools and approaches to evaluate alternatives and make decisions for its products.
- **Be Modular** – The following evaluation topics with their corresponding list of key evaluation parameters are all considered in a multi-factorial matrix. Analysis of some parameters may not always be necessary in every AA, however, the most critical and relevant parameters for which there is a significant difference exhibited between the alternatives must be identified for in-depth alternative evaluation.
 - Safety (human and environmental) – Understanding chemical hazards and product use and exposure are essential to product safety via a comprehensive risk-based safety assessment of alternatives throughout the product lifecycle. Uncertainties and assumptions should be addressed.
 - Performance and Value – Beyond product safety, consumer acceptance is driven by a product's cost, performance and useful life and the alternative must not compromise these factors.
 - Lifecycle/Resource Utilization – Evaluation includes a number of parameters, especially resource consumption of materials, water and energy, during a product's manufacture, use and disposal.
 - Other – The alternative must be available at reasonable cost and in sufficient quantity, and the revised product must be manufacturable with acceptable yield in view of costs associated with equipment and process changes. There must never be an adverse impact on compliance with regulatory, patent or safety-related requirements.
- **Be Effective** – The alternative must provide meaningful improvement that delivers a significant benefit to public health or the environment.
- **Protect Confidential Business Information** – Trade-offs in decision-making must be understood and considered to avoid unintended consequences. Where necessary, due to the competitive nature of business innovations and value judgments, decision criteria, weighting and certain other evaluation information must be preserved as trade secrets and not be publicly divulged.
- **Allow for Gradual and Measured Evaluation and Implementation of Suitable Alternatives** – Adequate time is necessary to introduce a new product into the marketplace due to complex and lengthy design considerations, development of supply chains, compliance with regulatory requirements, and verifying consumer acceptance.
- **Include a Feasibility Check** – An opportunity for reassessment must be provided if new information or subsequent assessments or in-market surveillance uncover concerns with the alternative.
- **Avoid Duplicative Efforts** – Alternatives assessments are and will be performed by companies and industries around the world to comply with various regulatory requirements and as part of internal product safety commitments and continuous product improvement projects. AAs should be portable and readily accepted in various jurisdictions. Regulators should seek to harmonize requirements to internationally accepted best-practices in order to avoid unnecessary duplication.

Thus, a best practices alternatives assessment process follows the Product R&D paradigm – it is flexible and modular, focusing on parameters relevant to the product being evaluated. It should result in comparable or improved product safety, efficacy, value and consumer acceptance. It should include informed, risk-based decision making, protection of confidential business information, allowances for gradual and measured implementation, and feasibility checks to ensure that the proposed alternative actually meets the goal of the process – the design and manufacture of improved products that are safe, cost effective, regulatory compliant, desirable to consumers, and provide measurable improvements to public health and/or benefit the environmental.