DECISION INFORMATION SUMMARY

OVERVIEW: The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary module with the Social Benefits/Costs Assessment module to identify the advantages and disadvantages of the baseline and the substitutes from both an individual business and a societal perspective. The Decision Information Summary module does not include value judgements or recommendations. Instead, the trade-off issues and uncertainty in the data are summarized to enable decision-makers to make decisions that incorporate their own circumstances, while considering the results of a CTSA. A key point is that decisions about whether or not to use an alternative are made outside of the CTSA process.

GOALS:

- Compile the results of the Risk, Competitiveness & Conservation Data Summary and the Social Benefits/Costs Assessment modules for the baseline and the substitutes.
- Compile information on the uncertainties in the data that should be considered in the decision-making process.
- Identify the trade-offs among risk, competitiveness, conservation, and social benefits/costs associated with the baseline and substitutes.

PEOPLE SKILLS: The Decision Information Summary module requires the skills outlined in the previous module descriptions for the analytical components of a CTSA. Knowledgeable personnel and technical experts who completed the analytical modules are needed to evaluate results and identify uncertainties in the information. Completing this module should be a joint effort by all members of a DfE project team.

DEFINITION OF TERMS: Several terms from the Exposure Assessment and Risk Characterization modules are used in the Decision Information Summary module. Refer to these modules for definitions.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for preparing a decision information summary. Methodology details for Steps 1, 2, and 3 follow this section.

Step 1: Obtain data summaries from the Risk, Competitiveness & Conservation Data Summary module. The data summaries should describe any assumptions, scientific judgements, and uncertainties in the data.

Step 2: Obtain information regarding the net social benefits/costs of the baseline and alternatives from the Social Benefits/Costs Assessment module. Note any assumptions, scientific judgements, and uncertainties included in the assessment.

Step 3: Identify other factors that an individual business might consider when choosing among alternatives. Consider these additional factors when listing uncertainties in the data that should be considered in the individual decision-making process. For example, workplace practices data from large facilities may not be representative of the types of workplace practices at smaller facilities.

Step 4: Review the data and uncertainties for each alternative to determine the trade-off issues associated with any one substitute from both an individual business and a societal perspective. Note changes in trends from the baseline to the substitutes (e.g., the baseline performs well, is cost-effective, but consumes large amounts of water and has a high potential for worker exposure; an alternative performs well, is expected to be cost-effective if supply/demand relationships stabilize; and has greater net social benefits due to reduced water consumption and potential for exposure as compared to the baseline).

Step 5: In addition to publishing the Decision Information Summary in a CTSA, provide results to the communications and implementation work groups of a DfE project team. These workgroups typically prepare CTSA summary brochures that present the CTSA results in a user-friendly format. (For more information on the roles of these work groups, see the companion publication, *Design for the Environment: Building Partnerships for Environmental Improvement* [EPA, 1995a].)

METHODOLOGY DETAILS: This section provides methodology details for completing Steps 1, 2, and 3. In some cases, information on interpreting the significance of results can be found in the published guidance listed previously in other module descriptions.

Details: Steps 1, 2, and 3, Identifying Uncertainties and Other Factors Important to Decision-Making

Identifying Uncertainties in the Risk Characterization

Because information for risk characterization comes from the Environmental Hazards Summary, Human Health Hazards Summary, and Exposure Assessment modules, an assessment of uncertainty should include the uncertainties in the hazard and exposure data. There is also the issue of compounded uncertainty; as uncertain data are combined in the assessment, uncertainties may be magnified in the process. EPA guidance documents (e.g., *Risk Assessment Guidance for Superfund* [EPA, 1989a]; "Guidelines for Exposure Assessment" [EPA, 1992a]) contain detailed descriptions of uncertainty assessment, and the reader is referred to these for further information.

Uncertainties in the hazard data could include:

- Uncertainties from use of quantitative structure-activity relationships (QSARs) for aquatic toxicity.
- Using dose-response data from high dose studies to predict effects that may occur at low levels.
- Using data from short-term studies to predict the effects of long-term exposures.
- Using dose-response data from laboratory animals to predict effects in humans.
- Using data from homogeneous populations of laboratory animals or healthy human populations to predict the effects on the general human population, with a wide range of sensitivities.
- Assuming 100 percent absorption of a dose when the actual absorption rate may be significantly lower.
- Using toxicological potency factors from studies with a different route of exposure than the one under evaluation.
- Effects of chemical mixtures (effects may be independent, additive, synergistic or antagonistic).
- Possible effects of substances not included because of a lack of toxicity data.
- Carcinogen weight-of-evidence classifications; for any chemicals assessed as carcinogens (described in the Human Health Hazards Summary module), the weight-of-evidence classification should be presented with any cancer risk results.

Uncertainties in the exposure data could include:

- Description of exposure setting - how well the typical facility used in the exposure assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been included because they are minor or proprietary ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgment.
- Uncertainty in combining pathways for an individual.

In the CTSA, uncertainty is typically addressed qualitatively. Variability in the exposure assessment is typically addressed through the use of exposure descriptors, which are discussed in the Exposure Assessment module.

Identifying Uncertainties in Performance and Cost Data

The Performance Assessment module is typically designed to evaluate characteristics of a technology's performance, not to define parameters of performance or to substitute for thorough on-site testing. Thus, performance demonstration projects conducted during CTSA pilot projects are intended to be a "snapshot" of a substitutes performance at actual operating facilities.

Similarly, the Cost Analysis module evaluates the average cost of a substitute at a "typical" or "model" facility using data collected from performance demonstration sites, the Workplace Practices & Source Release Assessment module, and other sources. Neither the Cost Analysis nor the Performance Demonstration are intended to yield absolute cost or performance information, but they do result in comparative information on the relative cost or performance of the baseline and substitutes.

Uncertainties in the Social Benefits/Costs Assessment

Due to time and resource constraints, the CTSA process utilizes a qualitative assessment of social benefits and costs that does not provide monetary valuation of external benefits. A problem with qualitative descriptions is the difficulty in weighing the benefits and costs - there is a tendency to ignore those benefits or costs that are not monetized. The project team members who perform the social benefits/costs assessment may illustrate the magnitude of a qualitative description through the use of quantified aspects such as affected population size. The Decision Information Summary module should contain both the qualitative and quantitative results of the Social Benefits/Costs Assessment. The importance of social benefits/costs assessment is not to develop a precise numerical estimate of social benefits and costs, but to recognize that these benefits and costs exist and use a systematic form of analysis to identify the best alternative(s) among a choice of several possible options.

Other Factors Important to Decision-Making

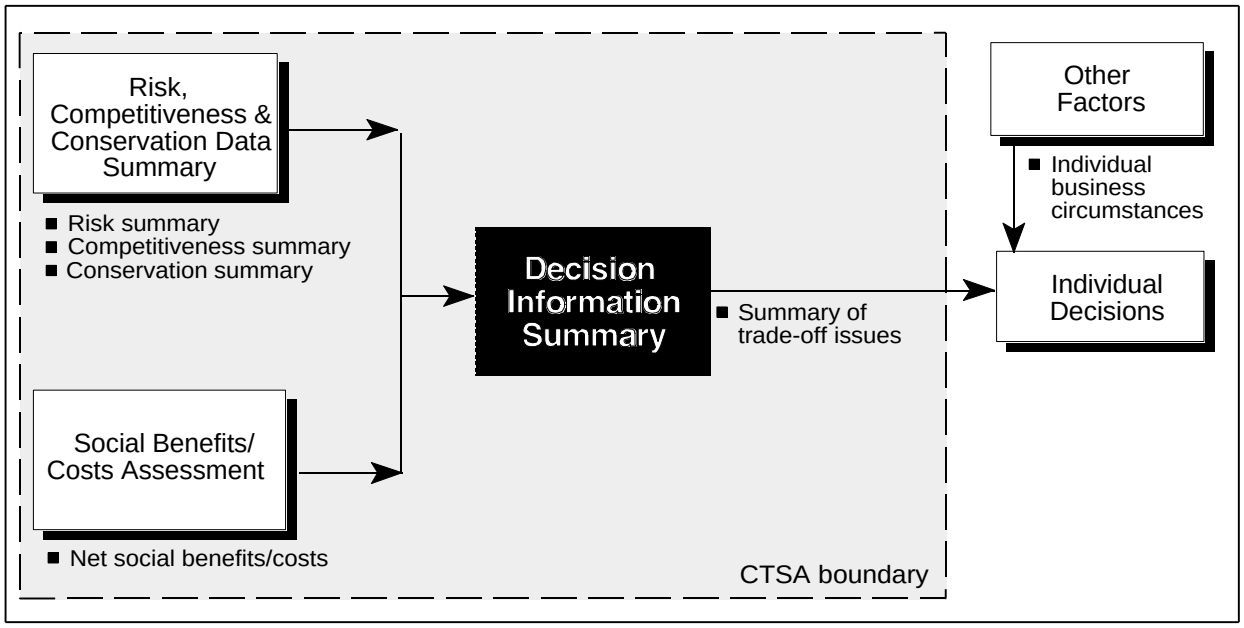
A CTSA provides comparative information on the relative risk, performance, costs and resource conservation of alternatives to individual decision-makers, but actual decisions about whether or not to implement an alternative are made outside of the CTSA process. Individual decision-makers typically consider a number of other factors before deciding upon an alternative. A few examples of these other factors include the following:

- The individual business circumstances, including cultural and political circumstances.
- The position of the business within the overall market it serves (e.g., steady, growing, shrinking).
- The status of the overall market for the product being delivered, including the outlook for long-term growth.
- The availability of funds for capital investments, if required.

FLOW OF INFORMATION: The Decision Information Summary is the final module of a CTSA. It combines the results of the Risk, Competitiveness & Conservation Data Summary with the Social Benefits/Costs Assessment modules to identify the overall advantages and disadvantages of the baseline and the substitutes from both an individual decision-maker's perspective and a societal perspective. The actual decision of whether or not to implement an alternative is made by individual decision-makers outside of the CTSA process, who typically consider a number of other factors, such as their individual business circumstances, together with the information presented in a CTSA. The relationship of the CTSA process to the actual

decision-making process and example information flows among the final modules of a CTSA are shown in Figure 10-3.p

FIGURE 10-3: DECISION INFORMATION SUMMARY MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: None cited.

DATA SOURCES: None cited.