OMB Control Number 2070-0038; EPA ICR Number 1188.09

ICR ATTACHMENT 5

Selection Criteria -- TSCA Section 8(a) Rule vs. SNUR

SELECTION CRITERIA: These criteria serve as guidelines and not as rigid standards for the regulatory selection process.

SECTION 8(a) Rules – REQUIREMENTS, TYPES OF DATA, USES:

– Statutory prerequisites: None (i.e., no required risk findings) other than a legitimate Agency need for such data "as the Administrator may reasonably require" and the use of notice and comment rulemaking for the establishment of reporting requirements.

- Scope: EPA can require reporting by manufacturers, importers, and processors of both new (PMN) and existing (initial Inventory) chemical substances.

- Types of data: EPA may use section 8(a) rules to obtain a variety of health and environmental data, including data on chemical identity and structure, uses, volume of production/importation/processing, byproducts, health and environmental effects, exposure, and disposal.

- Data support functions: Section 8(a) rules provide background exposure-related data to support chemical risk assessment; e.g., data support for section 4 testing decisions, voluntary testing decisions, section 6 rulemaking, section 9 referral actions, follow-up SNURs, and chemical advisories.

- Follow-up monitoring function: Section 8(a) rules can be used to monitor certain chemical activities which may cause significant new or ongoing exposures to the subject chemicals (i.e., section 8(a) reporting rules can be triggered by the commencement of certain prescribed chemical activities or by prescribed changes in chemical activities); this type of section 8(a) rule ensures that EPA will receive notification and information concerning the chemical activities described in the rule; however, the Agency can only take follow-up action through lengthy rulemaking (via section 4, 5(a)(2), or 6) or by civil action in cases of extreme and imminent hazard (via section 7).

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 8(a) RULE

- A need to gather data for chemical risk assessment, with no perceived need for immediate short-term control action: The basic data support function described above is the primary function of section 8(a) rules.

- Lesser health and environmental concerns: If EPA intends to develop a follow-up/monitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the

level of OPPTS concern regarding health and environmental effects of the chemical is not sufficient to require that follow-up action be immediately available (under section 5(e) or 5(f)) once the reporting requirement is triggered and notification is received by EPA (e.g., the substances is an eye or skin irritant; EPA lacks sufficient data on health and environmental effects for purposes of risk assessment; the substance may cause transient neurotoxic effects; the substances has moderate acute toxicity; the substance may persist in the environment; the substance may cause organ damage or reduced sperm counts; chronic exposure to the substance may result in health effects that generally are reversible).

- Activities are ongoing: If EPA intends to develop a follow-up/monitoring rule for a particular chemical substance, the Agency would favor a section 8(a) rule when the chemical activities in question are ongoing at the time of rulemaking (i.e., currently taking place or recently ceased and likely to resume) or are likely to be ongoing when the rule is proposed. By definition, a SNUR would not be possible under such circumstances.

- A need for long-term monitoring: A section 8(a) rule is favored if OPPTS needs to monitor industry-wide production and exposure trends on a long-term basis, as in the following examples:

(1) The rule may be triggered by a number of different firms over time, and the activity eventually may be considered ongoing (thereby preventing a SNUR);

(2) The rule may be triggered a number of times by the same firm, and the activity may be considered ongoing;

(3) Potential increases in exposure are expected to occur gradually over time and/or at a number of independent sites, making it necessary for the Agency to gather, aggregate, and analyze exposure-related data before making a decision about the potential for unreasonable risk.

SECTION 5(a)(2) SNURS – REQUIREMENTS, TYPES OF DATA, USES:

- Statutory prerequisites: TSCA does not require a risk finding for SNURs. The only statutory requirements are (1) that EPA consider "all relevant factors" (including the four exposure-related factors in section 5(a)(2)) before designating a significant new use, and (2) that the use not be ongoing at the time the SNUR is promulgated (i.e., not currently taking place or recently ceased and likely to resume).

- Scope: SNURs may be applicable to manufacturers, importers, and processors of both new and existing chemical substances.

- Types of data: EPA is authorized to require SNUR notice submitters to report the same types of data as may be required under section 8(a), plus certain types of test data in certain limited cases (note that health and environmental data must already be in the "possession or control" of the person submitting the notice (other health and environmental data which are known to or reasonably ascertainable by the person submitting the notice, which need only be described));

EPA generally requires SNUR respondents to complete the PMN reporting form.

- Follow-up monitoring function: SNURs can serve largely the same monitoring/notification/ information function as section 8(a) rules, with three important differences:

(1) A significant new use must be an activity that is not ongoing at the time the SNUR is promulgated;
(2) A SNUR respondent cannot commence the significant new use while EPA is evaluating the data in the SNUR notice;

(3) TSCA authorizes EPA to take immediate follow-up control action under either section 5(e) (the Agency lacks data but determines that the activity may present an unreasonable risk) or section 5(f) (the activity will present an unreasonable risk and section 6 action is necessary).

CRITERIA THAT FAVOR DEVELOPMENT OF A SECTION 5(a)(2) SNUR:

– Greater health and environmental concerns: If the potential health and environmental hazards posed by a chemical substance are of sufficient concern to OPPTS that the Agency wants to be able to do the following:

(1) Monitor potential exposure/risk which may be caused by non-ongoing activities involving the subject chemical;

(2) Prevent these activities from occurring until OPPTS has completed its assessment of the activities and has determined the potential for release and exposure;

(3) Take immediately effective control action (if necessary) via section 5(e) or 5(f) to prevent the activities from occurring (at least on an interim basis) after the completion of Agency review (e.g., the substance is a possible or probably human carcinogen; the substance may cause human teratogenic or reproductive effects; the substance has high acute toxicity; the substance tends to bioaccumulate in living tissue and is slow to biodegrade; chronic exposure to the substance may result in health effects that generally are irreversible).

– Likely that small businesses engage in the activities: Section 8(a) exempts small manufacturers, importers, and processors (as defined by EPA) from reporting requirements under that section. The Agency therefore may not receive adequate data from a section 8(a) rule in some cases if a substantial number of the firms subject to the rule qualify as "small." If EPA can determine prior to rulemaking that there is a likelihood that respondents will be small firms, the Agency may wish to ensure that it will have access to information from these key potential respondents by developing a SNUR for data-gathering purposes.

OTHER CRITERIA THAT MAY AFFECT THE REGULATORY SELECTION PROCESS (examined in every case):

- Federal regulatory action and state statutory/regulatory action involving the subject chemical: Relevant to the current need for OPPTS regulatory action, the likelihood of ongoing or future activities, and past experiences involving the subject chemical.

- Know past and present activities and projected future activities involving the subject chemical (including the size of the firms involved, the volume of production/importation/ processing, potential releases and exposures, etc.): If available, this information is a relevant supplement to all of the section 8(a)/SNUR criteria listed above.

- Concerns and objective of EPA and the technical staff responsible for the subject chemical: CCD regulatory staff relies heavily on continuing input from management (with regard to long-term regulatory objectives for the subject chemical) and technical staff (with regard to health and environmental concerns and short-term regulatory objectives).