

IURA reporting, or that EPA should exempt certain fertilizers by CAS number. One commenter suggested that 20 substances be included in the fertilizer list (see list provided in Comment C4b-6 of the comment summary document, Ref. 18).

EPA does not believe the suggested IURA exemptions for fertilizers and fertilizer constituents are warranted at this time. The Agency does not agree with industry comments citing a 1999 EPA OSW risk evaluation on "non-nutritive" components in fertilizers as adequate justification for classifying fertilizers as "safe," and therefore eligible for exemption. The OSW report addresses trace quantities of metal contaminants in those fertilizers (i.e., the non-nutritive elements), not the fertilizers themselves. A review of basic hazard identification guides, such as the Merck Index, the Condensed Chemical Dictionary, and Dangerous Properties of Industrial Materials, shows that exposure to many fertilizers and fertilizer materials, including those cited in industry comments such as anhydrous ammonia, potassium sulfate, and urea, can cause both reversible and irreversible adverse health effects ranging from acute to chronic. The availability of IURA exposure-related data will allow for the risk screening of chemicals used as fertilizers and fertilizer constituents to extend beyond environmental effects and aid the screening of risks to workers, consumers, and the general population. The Agency therefore believes it is appropriate to require reporting for fertilizers under IURA.

iii. *Encapsulated substances.* A commenter stated that the import volumes of IUR reportable components contained within compounded imported polymers should be exempt from IURA reporting. The commenter indicated that volumes of these encapsulated components are difficult to determine. Such components include antioxidants, colorants, lubricants, and stabilizers that are commonly used additives in polymer products. The polymers are sometimes manufactured by a foreign company and imported into the United States. The commenter stated that these additives, which are encapsulated in a polymer matrix, are typically present in the matrix at a few weight percent. The commenter's understanding was that when chemicals are secured within a polymer matrix, the SNUR requirements no longer apply, thus their suggestion was for EPA to treat such substances similarly under IURA.

The SNUR requirements in 40 CFR part 721 do not exempt substances

encapsulated in a polymer matrix. Although chemicals incorporated into a polymer matrix are not subject to SNURs in certain limited circumstances, for example, when an individual SNUR specifically states that the SNUR requirements do not apply to such substances (see, e.g., 40 CFR 721.8160(a)), such chemicals are not otherwise generally exempt from SNUR requirements.

Although EPA appreciates the difficulty in ascertaining quantitative production information from manufacturers outside direct U.S. jurisdiction, exempting IUR reportable components encapsulated in a polymer matrix from IURA is not warranted. Not all polymers are inviolable. Additives such as colorants and lubricants, which can be hazardous to human health or the environment, can leach from the polymer matrix, resulting in subsequent exposures. Also, additives which are inherently insoluble in the polymer may migrate to the surface of the polymeric material and be released over time from the polymer. Under IURA, each non-exempted mixture component is reportable if imported above the stated thresholds. Reasonably ascertainable information can be used to estimate these import quantities.

iv. *Pesticides.* Some commenters stated that the Agency should exempt pesticide chemicals from reporting under the IURA, and also should exempt those substances outside the scope of TSCA, including drugs and cosmetics.

The original IUR did not require reporting for chemicals manufactured for non-TSCA purposes. Similarly, in IURA, amounts of an otherwise IUR-reportable substance that are intended at the time of manufacture to be used for non-TSCA purposes (e.g., as a pesticide, as a drug) do not have to be reported. For example, if a company were to manufacture 300,000 lbs. of an IUR-reportable substance, 170,000 lbs. of which were intended at the time of manufacture to be sold as a drug precursor, and 130,000 lbs. of which were intended at the time of manufacture to be used for a TSCA purpose, only 130,000 lbs. of the substance would have to be reported under IUR. The company would not have to report the processing and use information described in § 710.52(c)(4) of the regulatory text for that chemical at that plant site, since the company did not manufacture a total of at least 300,000 lbs. of the chemical at the site for TSCA purposes. Many substances, such as the pesticide active ingredient pentachlorophenol, are also used in industrial and commercial applications

regulated under TSCA. In those cases, the chemicals will continue to be reportable under IURA.

v. *Food additives.* Commenters stated that low hazard chemicals, such as food additives, should be categorically excluded from the new reporting requirements. The commenter stated that food use substances, for example, are regulated by the Food and Drug Administration (FDA) and must either be generally recognized as safe (GRAS), the subject of a prior sanction, or the subject of a food additive regulation promulgated by FDA.

According to FDA's Office of Premarket Approval (OPA), food use substances for FDA's purposes are those that are added directly to food, and could inadvertently contact and be incorporated into food because of use in packaging material or in food processing. FDA does not evaluate chemicals for environmental effects--only for human health effects. The chemicals subject to FDA rules are not inherently low hazard in many cases. For example, substances such as plasticizers, lubricants, release agents, acids (e.g., hydrochloric acid), boiler water additives, and solvents (e.g., acetone and hexane) are included as food use substances. Furthermore, even direct (i.e., listed) GRAS chemicals can be of concern when used at industrial concentrations, such as sulfuric acid. Thus, as is true with other chemical substances, food additives can present a risk to human health or the environment depending on use and the resulting exposure pathways. EPA does not believe a categorical exemption for chemicals that may be used as food additives is warranted at this time. Again, such chemicals are only reportable under IURA to the extent that they are intended at the time of manufacture to be used for TSCA purposes.

3. *Thresholds.* EPA requested comment on the 300,000 lbs. threshold for reporting industrial processing and use, and consumer and commercial use information (required under § 710.52(c)(4) of the regulatory text). Commenters generally were supportive of having a second, higher reporting threshold for this exposure-related information. However, one commenter stated that the 300,000 lbs. threshold is too low, and that it should be set at one million pounds to coincide with the HPV Challenge Program threshold.

EPA considered chemicals with aggregate, nationwide U.S. production and importation volumes of one million pounds or more (based on 1990 IUR data) for the HPV Challenge Program. That is, if one million pounds of a