"manufactured with" a controlled substance?

The final rule states that a controlled substance that is inadvertently produced or remains as a residue from a chemical reaction, leaving trace quantities of that substance in the final product, does not trigger the labeling requirements. However, there may be cases where a product is exempt from being labeled a product "containing" (in this case because it is only present in trace quantities), but where a product may still require labeling because it is considered to be "manufactured with" that controlled substance.

The introduction of carbon tetrachloride as an explosion suppressant in the manufacture of certain chemicals serves as an example. The carbon tetrachloride is introduced, then withdrawn from the chemical product. Trace quantities of the carbon tetrachloride remain in the chemical; however, such quantities serve no useful purpose in the final product. As a result, the product is exempt from being labeled as a product containing carbon tetrachloride. However, because the carbon tetrachloride is introduced into the chemical product directly in the manufacturing process, actually having physical contact with the product, the product would need to be labeled as "manufactured with" carbon tetrachloride, unless other exemptions

In order to be consistent with this view, EPA proposed to revise the definition of "manufactured with." The original regulations stated that a product is manufactured with a controlled substance if the manufacturer used a controlled substance directly in the product's manufacture, "but the product itself does not contain a controlled substance at the point of introduction into interstate commerce." However, to further clarify that trace quantities may actually be contained in a product manufactured with a controlled substance, EPA proposed to revise the definition of "manufactured with," to state that a product "does not contain more than trace quantities of the controlled substance.* * *

Six commenters agreed with these proposed changes. One commenter disagreed with EPA's position that carbon tetrachloride should trigger labeling unless the substance is subsequently destroyed or transformed, because the carbon tetrachloride is withdrawn from the product and only trace quantities remain. EPA supports it's original position, based on the fact that the introduction of carbon tetrachloride, which is used on a routine basis, constitutes use as part of the

direct manufacturing process. As a result, today's rule establishes the modified definition of "manufactured with" as proposed.

VI. Exemption for Trace Quantities

The preamble to the original labeling rule discussed the applicability of the labeling requirements for products containing trace quantities of controlled substances. However, some confusion over when labeling is required for such products has arisen since the publication of that rule.

The regulatory text in section 82.106, referring to the warning statement requirements, lists certain exemptions from these requirements. The first of these addresses "Products in which trace quantities of a controlled substance remain as a residue or impurity.* * *" EPA has determined that a trace quantity remaining in a product can only be contained within a chemical product; therefore, it is logical that this exemption specifically applies to products "containing" rather than products "manufactured with. Products that are manufactured using a controlled substance, but that contain only trace quantities of the substance, are not required to be labeled as a 'product containing"; however, they are required to be labeled as a "product manufactured with." To clarify this point, EPA proposed to amend section 82.106(b)(1), which provides exemptions from the labeling requirements, to read: "Products containing trace quantities of a controlled substance remaining as a residue or impurity due to a chemical reaction, and where the controlled substance serves no useful purpose in or for the product itself." However, if such a product was manufactured using the controlled substance, such product is required to be labeled as a "product manufactured with" the controlled substance.

There was also some confusion as to whether a container containing a trace amount of a controlled substance must be labeled. EPA understands that to determine whether a container contains a trace amount of a controlled substance, where such a determination falls outside of normal procedures, may be difficult and costly. For example, a container of a non-controlled substance that may hold a trace amount of a controlled substance as an impurity of the manufacturing process would be subject to labeling under current labeling requirements. As a product, however, that same container would be exempt from the labeling requirements. In many cases, expensive testing must be conducted to determine if a trace

quantity of the controlled substance is in fact contained in the container. Requiring the labeling of containers containing trace quantities of a controlled substance is inconsistent with the trace quantities exemption of the current labeling rule and with the intent of the Agency to require labeling of "containers of" controlled substances.

EPA received three comments agreeing with the exemption for trace quantities. One commenter asked for clarification of the definition of trace quantity. Another commented that trace quantities should be defined with a quantifying limit above which labeling would be required. Another commenter recommended that EPA publish guidance on what constitutes a "trace quantity", and suggests using analytical detection limits for the exemption level. Because the labeling rule covers a multitude of substances, products, and volumes, EPA believes it cannot responsibly put forth a standardized threshold for "trace quantity." However, EPA believes that the term "trace amounts" should be interpreted consistently with Webster's Ninth New Collegiate Dictionary (copyright 1990), which defines trace amounts to mean "a chemical element present in minute quantities." Reasonable interpretations of what constitutes a trace amount will likely be parallel to reasonable interpretations made by EPA. EPA is today revising its regulations, as proposed, to make the exemption clear. EPA will add the new 82.106(b)(2), (discussed above), stating that containers containing trace quantities of a controlled substance, which remain as a residue or impurity, are exempt from the labeling requirements.

VII. Labeling Requirements of Containers of 55 Gallons and Smaller Containing Controlled Substances

The original labeling regulations indicated that the use of supplemental printed material may be used to label containers of controlled substances that are larger than 55 gallon drums, as long as the information is viewed at the time of purchase or time of delivery, provided the purchase is not considered complete until delivery is accepted. EPA reasoned that such information, rather than the containers themselves, is usually viewed by the recipient of such containers. The regulations also indicated that the warning statement must be placed directly on containers of controlled substances that are smaller than 55 gallon drums.

EPA proposed in the December 30, 1993 amendment that supplemental printed material may also be used to