

with or alter absorption of the toxic substance, and

(D) Dose.

(3) *Assessment of Risk.* This section on quantitative risk assessment applies to estimates of risk for substances that are toxic by reason of their carcinogenicity.

(i) Generally, the study leading to the highest risk should be used in the risk assessment; however, other factors may influence the choice of study.

(ii) Risk should be based on the maximum likelihood estimate from a multistage model (such as Global83 or later version) unless the maximum likelihood estimate is not linear at low dose, in which case the 95% upper confidence limit on risk should be used.

(iii) For systemic carcinogens, if estimates of human risk are made based on animal data, a factor derived from dividing the assumed human weight (70 kg) by the average animal weight during the study and taking that to the $\frac{1}{3}$ power should be used. There is the possibility that this factor may be changed, using the $\frac{1}{4}$ power instead of the $\frac{1}{3}$ power, as part of a unified Federal regulatory approach. If such an approach is adopted, it will apply here.

(iv) When dose is expressed as parts per million, and the carcinogen acts at the site of contact, humans and animals exposed to the same amount for the same proportion of lifetime should be assumed to be equally sensitive.

(v) If no experimental study having the same route of exposure as that anticipated for human use of a substance is available, a study by another route of exposure may be used. Pharmacokinetic methods may be used if sufficient data are available.

(vi) When exposure scenarios are different from those used in the underlying study upon which estimates of risk are based, proportionality should be applied. If pharmacokinetic methods are used to adjust for risks at high versus low exposure levels, level-time measures should not be combined without taking the non-linearity into account.

(4) *Acceptable Risks*—(i) *ADI for Carcinogens.* The maximum acceptable daily intake (“ADI”) is that exposure of a toxic (by virtue of its carcinogenicity) substance that is estimated

to lead to a lifetime excess risk of one in a million. Exposure refers to the anticipated exposure from normal lifetime use of the product, including use as a child as well as use as an adult.

(ii) *ADI for Neurotoxicological and Developmental/Reproductive Agents.* Due to the difficulties in using a numerical risk assessment method to determine risk for neurotoxicological or developmental/reproductive toxicants, the Commission is using a safety factor approach, as explained below.

(A) *Human Data.* If the hazard is ascertained from human data, a safety factor of ten will be applied to the lowest No Observed Effect Level (“NOEL”) seen among the relevant studies. If no NOEL can be determined, a safety factor of 100 will be applied to the Lowest Observed Effect Level (“LOEL”). Both the NOEL and LOEL are defined in terms of daily dose level.

(B) *Animal Data.* If the hazard is ascertained from animal data, a safety factor of one hundred will be applied to the lowest NOEL. If no NOEL can be determined, a safety factor of one thousand will be applied to the lowest LOEL. Both the NOEL and LOEL are defined in terms of daily dose level.

[57 FR 46665, Oct. 9, 1992]

§ 1500.210 Responsibility.

The provisions of these regulations (16 CFR subchapter C of chapter II) with respect to the doing of any act shall be applicable also to the causing of such act to be done.

§ 1500.211 Guaranty.

In the case of the giving of a guaranty or undertaking referred to in section 5(b)(2) of the act, each person signing such guaranty or undertaking, or causing it to be signed, shall be considered to have given it. Each person causing a guaranty or undertaking to be false is chargeable with violations of section 4(d) of the act.

§ 1500.212 Definition of guaranty; suggested forms.

(a) A guaranty or undertaking referred to in section 5(b)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to

§ 1500.213

the invoice or bill of sale covering such shipment of delivery; or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered, or caused to be shipped or delivered, by the person who gives the guaranty of undertaking.

(b) The following are suggested forms of guaranty or undertaking referred to in section 5(b)(2) of the act. (1) *Limited form for use on invoice or bill of sale.*

(Name of person giving the guaranty or undertaking)
hereby guarantees that no article listed herein is misbranded within the meaning of the Federal Hazardous Substances Act.
(Signature and post-office address of person giving the guaranty or undertaking)

(2) General and continuing forms.

The article comprising each shipment or other delivery hereafter made by _____

(Name of person giving the guaranty or undertaking)

to, or on the order of _____

(Name and post-office address of person to whom the guaranty or undertaking is given)

is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not misbranded within the meaning of the Federal Hazardous Substances Act.

(Signature and post-office address of person giving the guaranty or undertaking)

(c) The application of a guaranty or undertaking referred to in section 5(b)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes misbranded within the meaning of the act.

§ 1500.213 Presentation of views under section 7 of the act.

(a) Presentation of views under section 7 of the act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 5(b)(2) of the act applicable to the article on which such notice was based, such

16 CFR Ch. II (1-1-07 Edition)

guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, reasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 7 of the act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Consumer Product Safety Commission that issued the notice.

§ 1500.214 Examinations and investigations; samples.

When any officer or employee of the Commission collects a sample of a hazardous substance for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Commission indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory not organized with a legislative body. Only samples so designated by an officer or employee of the Commission shall be considered to be official samples:

(a) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(b) The owner of a hazardous substance of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

§ 1500.230 Guidance for lead (Pb) in consumer products.

(a) *Summary.* (1) The U.S. Consumer Product Safety Commission issues this guidance to manufacturers, importers, distributors, and retailers to protect children from hazardous exposure to lead in consumer products.¹ The Commission identifies the major factors

¹This guidance is not a rule. It is intended to highlight certain obligations under the