

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.

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§ 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 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.