§ 1500.210

changed, using the \(\frac{1}{4}\) power instead of
the \(\frac{1}{3}\) power, as part of a unified Fed-
eral regulatory approach. If such an ap-
proach 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 ani-
mals 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 an-
ticipated for human use of a substance
is available, a study by another route
of exposure may be used. Pharmaco-
kinetic methods may be used if suffi-
cient data are available.

(vi) When exposure scenarios are dif-
ferent from those used in the under-
lying 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 with-
out taking the non-linearity into ac-
count.

(4) Acceptable Risks—(i) ADI for Car-
cinogens. The maximum acceptable
daily intake ("ADI") is that exposure
of a toxic (by virtue of its carcino-
genicity) substance that is estimated
to lead to a lifetime excess risk of one
in a million. Exposure refers to the an-
ticipated exposure from normal life-
time use of the product, including use
as a child as well as use as an adult.

(ii) ADI for Neurotoxicological and De-
velopmental/Reproductive Agents. Due to
the difficulties in using a numerical
risk assessment method to determine
risk for neurotoxicological or develop-
mental/reproductive toxicants, the
Commission is using a safety factor ap-
proach, as explained below.

(A) Human Data. If the hazard is
ascertained from human data, a safety
factor of ten will be applied to the Low-
est No Observed Effect Level ("NOEL")
seen among the relevant studies. If no
NOEL can be determined, a safety fac-
tor of one thousand will be applied to the
lowest LOEL. Both the NOEL and LOEL are
defined in terms of daily dose level.

§ 1500.211 Guaranty.

In the case of the giving of a guar-
anty or undertaking referred to in sec-
tion 5(b)(2) of the act, each person sign-
ing such guaranty or undertaking, or
causing it to be signed, shall be consid-
tered to have given it. Each person
causeing a guaranty or undertaking to
be false is chargeable with violations of
section 4(d) of the act.

§ 1500.212 Definition of guaranty; sug-
gested forms.

(a) A guaranty or undertaking re-
ferred 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 deliv-
ered, or caused to be shipped or deliv-
ered, by the person who gives the guar-
antity 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 un-
dertaking)

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 un-
dertaking)