



U.S. CONSUMER PRODUCT SAFETY COMMISSION

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OFFICE OF THE
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Gentlemen:

This is in response to a request from the Chemical Specialties Manufacturers Association for an advisory opinion from the Consumer Product Safety Commission addressing the following question.

Do the signal word and principal statement of hazard "WARNING: This product contains a chemical known to the state to cause cancer (or birth defects)," when used in connection with the sale (e.g., shelf sign, brochure, display sign) of an FHSA hazardous substance constitute "directions for use" pursuant to FHSA § 2(n), 15 U.S.C. § 1261(n), thereby rendering them accompanying literature subject to the labeling requirements of FHSA § 2(p), 15 U.S.C. § 1261(p)?

This office has also received correspondence from the State of California concerning how the Commission interprets the Federal Hazardous Substances Act ("FHSA") as it concerns issues raised by California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65). Because the answer to CSMA's question is relevant to these concerns, this letter is also being sent to the California Department of Justice.

ADVISORY OPINION

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The FHSA provides a comprehensive scheme for ensuring that hazardous substances intended for use in the household or by children bear cautionary labeling. Included within the FHSA's definition of hazardous substances are those substances that are toxic because they present a risk of cancer or other types of chronic toxicity, such as reproductive toxicity. CPSC General Counsel's Advisory Opinion No. 309 at 1 (March 19, 1987). Thus, a product would be regulated under the FHSA if (1) it is intended or packaged in a form suitable for use in the household or by children and (2) if the exposure to the product creates a significant risk of cancer or reproductive toxicity as a proximate result of any customary or reasonably foreseeable handling or use.

Section 2(p)(1) of the FHSA requires hazardous substances to bear certain types of label messages. Included within the types of labeling required are:

1. The name of each component that contributes substantially to the hazard,
2. A signal word (in the case of chronic hazards, "WARNING" or "CAUTION"),,
3. An affirmative statement of the hazard or hazards (e.g., "Vapor harmful"),
4. Precautionary measures describing the action(s) to be taken or avoided,
5. Any necessary or appropriate instruction for first aid treatment,
6. Any required instruction for special handling or storage of the package, and
7. The statement "Keep out of the reach of children," or its equivalent.

FHSA Sec. 2(p) (1)(B), (D)-(J)(i), 15 U.S.C. § 2(p)(1)(B), (D)-... (i). Except for the signal word, the FHSA generally does not require particular label language and permits manufacturers to decide on the specific language. (In addition, the Commission may, by rule, require different or additional labeling where required by a special hazard presented by the substance. Section 3(b) of the FHSA, 15 U.S.C. § 1262(b). Where labeling cannot

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adequately protect the public, the Commission may ban a hazardous substance. **Sec.2(q)(1)(B)**, 15 U.S.C. § 1261(q)(1)(B).)

Section 2(n) of the FHSA defines "label." In addition to specifying that matter on the product or its container is part of the label, section 2(n) reads, in pertinent part:

a requirement [under the FHSA] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears ...
(2) on all accompanying literature where there are directions for use, written or otherwise.

15 U.S.C. § 1261(n) '(emphasis added). In other words, where accompanying literature contains directions for use, it must contain all the cautionary labeling required on the product label by the **FHSA**.

The Commission's regulations specify that:

"**accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance

16 C.F.R. § 1500.3(c)(9) (emphasis added). Shelf signs, brochures, and display signs are "**accompanying literature" under this definition.

A warning that a product can cause cancer or birth defects is not an express direction for use. Nevertheless, it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure. Stated another way, the warning itself can also **serve** as a direction for use. An example of the dual function performed by statements warning of hazards a product presents is in the Commission's regulations at 16 C.F.R. § 1500.123. That section states:

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p) (1)(E) [statement of principal hazard] and

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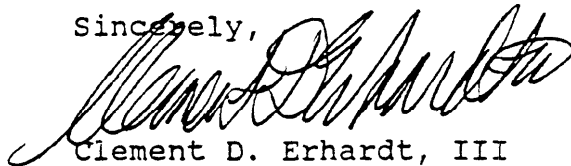
(F) [****precautionary measures describing the action to be followed or avoided**"] . . .

Thus, for example, a product having flammable vapors might have a statement of principal **hazard**, such as "**FLAMMABLE**," that could serve also as the **required** statement of action to be avoided, which, if stated separately, might read "**do not use near open flame.**** Similarly, the statement of principal hazard "**HARMFUL IF SWALLOWED**" could negate the need to state additionally "**for external use only.**" Also, the statement "**VAPOR HARMFUL**" could also serve instead of an additional statement to "**avoid prolonged inhalation of vapors.**"

Therefore, although the warning quoted in your inquiry does not necessarily convey specific actions to be taken in the use of the product, it does convey information about how the product should be used (steps should be taken to reduce exposure). Accordingly, this office views the statement as a direction for use. It follows, **therefore**, that signs and the like bearing such warnings are "**accompanying literature containing directions for use**" and thus are labeling under FHSA § 2(n). The fact that such signs are considered labeling, however, does not mean that the sign complies with any or all of the FHSA labeling requirements described above.

I trust that this information responds fully to your inquiry. Please contact me if you have further questions.

Sincerely,



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September 14, 1990

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Re: Request for CPSC Advisory Opinion Construing
FHSA Requirements for Accompanying Literature

Dear Mr. Erhardt:

The Chemical Specialties Manufacturers Association ("CSMA") requests an advisory opinion from the Consumer Product Safety Commission construing the accompanying literature requirements under the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-1276. Specifically, we seek clarification of the following issue:

1. Do the signal word and principal statement of hazard "WARNING: This product contains a chemical known to the state to cause cancer (or birth defects)" when used in connection with the sale (e.g., shelf sign, brochure, display sign) of an FHSA hazardous substance constitute "directions for use" pursuant to FHSA § 2(n), 15 U.S.C. § 1261(n), thereby rendering them accompanying literature subject to the labeling requirements of FHSA § 2(p), 15 U.S.C. § 1261(p)?

Our views on this issue are set forth in the enclosed memorandum. CSMA solicits your prompt guidance on this issue.

Sincerely,

Stephen S. Kellner
Stephen S. Kellner

**MEMORANDUM CONSTRUING FHSA
ACCOMPANYING LITERATURE REQUIREMENTS**

1. Statutory and Regulatory Definition of
Accompanying Literature

FHSA § 2(n) defines "label," inter alia, to include written, printed, or **graphic** matter upon the immediate container of hazardous substances (or for unpackaged materials a display of such matter on tags) and further states that "a requirement made by or under authority of [FHSA] that any word, statement, or other information **appear** on the label . . . [is not satisfied] unless such word, statement, or other information also appears on all accompanying **literature** where there -are directions for use, written or otherwise." 15 U.S.C. § 1261(n) (emphasis added). Necessarily, FHSA § 2(n) implies a broad meaning to the term "directions for use" because it can be "written or otherwise." Thus, even mere symbols: may convey directions for use. For example, a symbol for **fire** with a red slash through it on a butane lighter fluid container directs the consumer not to use the product near. flames. Thus, a consumer would know from the symbol not to squirt **the** fluid into a flaming barbecue grill.

The Commission's regulations also describe directions for use to include printed words, pictures, designs or any combination further implying that the term should be given a broad meaning. See 16 C.F.R. § 1500.125 ("When any accompanying literature includes or bears any directions for use (by printed word, picture, design or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the **information** required by Section 2(p) of the act") See also 16 C.F.R. § 1500.3(c)(9) ("Accompanying literature" means written or unwritten material containing directions for use that are used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.)

The obvious purpose of the accompanying literature provision is to ensure that the manufacturer does not give partial information about the use of a hazardous substance. If the manufacturer gives any information concerning the safety of the product which heightens the awareness of a consumer, whether written or otherwise, he must give the complete label information for the product required under FHSA § 2(p). Viewed in this

context, most of the § 2(p) information is either an express or implied direction for use.

2. Required Accompanying Literature Statements

The FHSA § 2(p)(1) label statements required for accompanying literature are as follows:

- (A) the name and place of business of the manufacturer;
- (B) the common name of the chemical;
- (C) the "signal word" "DANGER," for substances which are extremely flammable;
- (D) the signal word "WARNING" or "CAUTION" for other hazardous substances;
- (E) an affirmative statement of the principal hazard (e.g., "Flammable," "Causes Burns," "Vapor Harmful,");
- (F) a statement of precautionary measures describing the action to be followed or avoided;
- (G) appropriate instructions for first aid;
- (H) the word "Poison" for any hazardous substance defined as "highly toxic" under the Act;
- (I) instructions for handling and storing packages which require special care; and
- (J) the statement "Keep Out of the Reach of Children," or adequate directions for use by children if the product is so intended.

15 U.S.C. § 1261(p)(1) (A) - (J).

Obviously, the name of a business or name of a chemical conveys no direction for use, but a careful inspection of every other label statement reveals an express or implied direction of proper and safe handling or use. An FHSA signal word like "DANGER" or "CAUTION" alerts the user of a household product to use the product with care. Likewise, principal statements of hazard warn the user to handle the product in a certain manner and to avoid a particular hazard. For example, the principal statement of hazard for acetone is "DANGER: EXTREMELY FLAMMABLE." This statement warns consumers not to use acetone near sparks or flames. Although the statement does not expressly direct the user against exposing the acetone to sparks or flames,

the statement impliedly **gives** this direction. It necessarily implies that the user **must** take such **care**. The statement of hazard for ammonia (**3-5%**) is "WARNING - IRRITANT HARMFUL IF SWALLOWED.* It does not expressly state "do not drink ammonia," yet it clearly implies not to do so. Products containing **5-25%** ammonia must state "POISON - MAY CAUSE **BURNS**." This statement of hazard does not directly advise to "avoid contact with eyes or skin," but that implication is clear and unmistakable.

3. Typical Principal Statements of Hazard
Conveying Implied Directions for Use

The following typical statements of hazard are implied directions for use.

Butyl Alcohol: WARNING HARMFUL IF SWALLOWED COMBUSTIBLE.
VAPOR HARMFUL. IRRITANT;

Borax: CAUTION - EYE IRRITANT;

Calcium Hydroxide: CAUTION - INJURIOUS TO EYES PROLONGED
CONTACT WITH WET SKIN MAY PRODUCE BURNS;

Cadmium Silver Solders: WARNING - POISONOUS FUMES **MAY** BE
FORMED ON HEATING;

Charcoal Lighter Fuel: DANGER - HARMFUL OR FATAL IF
SWALLOWED COMBUSTIBLE;

Carbon Bisulfide: DANGER - MAY BE FATAL IF INHALED OR
SWALLOWED EXTREMELY **FLAMMABLE**;

4. Cancer and Reproductive Toxicity Principal
Statements of Hazard Conveying Directions for Use

The methylene chloride labeling enforcement policy contains a Commission-sanctioned **label** that meets the minimum FHSA § 2(p) requirements. 52 Fed. Reg. 34,702 (Sept. 14, 1987). The principal statement of hazard on the label states in part CAUTION: VAPOR HARMFUL. The back panel of the label further states that methylene **chloride** has been shown to cause cancer in certain laboratory **animals**. The statement of hazard impliedly directs consumers to avoid breathing harmful methylene chloride vapors. Likewise the Commission's asbestos label and principal statement of hazard WARNING: BREATHING FIBERS MAY CAUSE CANCER directs consumers to **avoid** inhaling near the product. See 51 Fed. Reg. 33,911.12 (Sept. 24, 1986).

5. Scope of Directions for Use

Clearly, signs that contain brand names and price information are not accompanying literature. However, once the manufacturer provides information concerning the safety of the product it becomes accompanying literature and must be complete. To allow a manufacturer to avoid the accompanying literature requirements simply by omitting express directions for use or by limiting the display information to signal words and statements of principal hazard would undermine the consumer safety purposes of **FHSA** and invite abuse.

It makes no sense that a § 2(p)(I) statement on storage or handling would trigger all the § 2(p) label statements whereas a warning about being harmful if ingested would not. Such a constricted **reading** of "directions for use" is at odds with the provision that they may be "written or otherwise," see **FHSA § 2(n)**, and the Commission's interpretation that **they may** be a "picture" or "design." 16 C.F.R. § 1500.125 It also defeats the very purpose of the accompanying literature requirement which is to ensure that any express or implied direction for use triggers all the § 2(p) label statements. If a manufacturer, for example, can give signal words and statements of principal of hazard without having to give the **remaining 2(p)** statements, he has a license to say what he will about the hazards of a product in literature displayed at point-of-sale irrespective of any contrary precautionary labeling. Clearly, Congress did not intend such a loophole for the manufacturer -- or for the states.

The Commission's regulations on the "Condensation of label information," 16 C.F.R. § 1500.123, acknowledge that a statement of principal hazard itself may contain all the necessary precautionary measures to be followed or avoided and thereby may satisfy **FHSA § 2(p)(l)(E)** label requirements. As "action to be followed or avoided," precautionary measures are undeniably directions for use. If statements of principal hazard may constitute such express directions for use (in the case of certain precautionary measures), they are at least implied directions for use in every other case.

6. Misbranding

Literature accompanying a product is misbranded if it contains only part of the information required under **FHSA § 2(p)**. See 15 U.S.C. § 1261(p). For example, if instructions for handling or for storage are not accompanied by all statements required on the label the product would be misbranded.

Under **FHSA**, precautionary warnings on tags, 'placards, signs, or shelf **labels** cannot be used as a substitute for

cautionary **information** directly on the label. Likewise, precautionary **warnings** that appear on **literature** accompanying a product must be **identical** to precautionary **statements** on the label. **Furthermore**, the accompanying **literature** must convey **all** the **warnings, principal** statements of hazard, precautionary **use** statements and **storage** instructions on the label. The manufacturer cannot be selective among these FHSA requirements and cannot avoid giving them simply by omitting express directions for use such as storage or handling instructions.

For example, a manufacturer of 3-5% ammonia could not state on literature: **"Warning: Irritant Harmful if Swallowed,"** without also providing precautionary use statements like "Avoid contact with eyes or prolonged contact with skin." The manufacturers could not avoid having to give the precautionary use statement simply by giving the foregoing warning and omitting the instruction "Do not mix with chlorine type bleaches or other household chemicals."

7. California Proposition 65 "Directions for Use"

The California Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65") requires persons doing business in California to provide a "clear and reasonable **warning[s]**" to consumers prior to exposing them to certain chemicals "known to cause cancer or reproductive toxicity." Cal. Health and Safety Code § 25249.6. Proposition 65 provides that warnings may be transmitted by various methods such as labeling, posting shelf signs, or placing notices in the news media, as long as the warnings are "clear and reasonable." Cal. Health and Safety Code § 25249.11(f). California's regulations also establish acceptable content and methods of transmitting "clear and reasonable" warnings for each category. 22 C.C.R. § 12601. These minimum standards for warnings are referred to as "safe harbors" since, if complied with, they **are deemed** by the Agency to provide a warning which is clear and reasonable. Revised Final Statement of Reasons accompanying 22 C.C.R. § 12601 at 2, 7 ("Statement of Reasons"). For each type of exposure the warning language must "clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." 22 C.C.R. § 12601(a).

For example, for consumer products that contain a chemical known to the state to cause cancer, the safe harbor warning message must include the following language: **WARNING: This product contains a chemical known to the State of California to cause cancer.*** For consumer products that contain a chemical known to the state to cause reproductive toxicity, the safe harbor warning message must include the following language:

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

A signal word and statement of hazard such as WARNING: "Causes Cancer" or "Causes Reproductive Toxicity," like the FHSA warning "Causes Burns," is an implied direction for use because it warns the user to minimize direct exposure to a product because of these serious effects. For instance, a statement of principal hazard that a product causes "birth defects" unmistakably directs women to avoid direct contact with the product while pregnant. The warning is not necessarily a direction to avoid exposure altogether since its sale and use are permitted if accompanied by the required warning. However, the warning and principal statement of hazard alert the consumer to use the product with care. "The apparent purpose of any warning under the Act [Proposition 65] is to permit the persons exposed to make choices about the exposure." Statement of Reasons at 22.

California's regulations define "consumer products exposure" as an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonable foreseeable use of a consumer good 22 C.C.R. § 12601(b). The term "expose" in Proposition 65 means to cause to "ingest, inhale, contact via body surfaces or otherwise come into contact with a chemical." 22 C.F.R. § 12201(f). Thus, Proposition 65 warnings gives consumers a choice of using a product which will result in exposure through ingestion, breathing and dermal contact and impliedly direct consumers to minimize such direct contact. As such it is a direction for use within the meaning of FHSA § 2(n) which triggers all the label statements of FHSA § 2(p) applicable to accompanying literature.

The California warnings and principal statements of hazard convey inadequate directions for use, yet they do convey significant safety information and therefore impliedly direct consumers to use the product in a way that minimizes dermal and other exposures. Given the comprehensive safety purposes of FHSA, its statutory terms must be given their full effect. Enforcement of FHSA necessarily compels the broadest reasonable construction of its terms. Construing California's warning and principal statement of hazard as within the scope of FHSA "directions for use, written or otherwise" is consistent with this purpose. Any contrary interpretation limits the Commission's enforcement of FHSA accompanying literature requirements and invites abuse by persons seeking to negate FHSA label requirements by placing misleading safety statements like "mild as soap" on displays at the point-of-sale.