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Label Review Manual

Chapter 12: Labeling Claims

National Garden Bureau



I. Introduction

This chapter provides guidance for reviewing claims made on proposed labels. A label claim is a statement of something as a fact or an assertion on the label open to challenge. For purposes of this chapter there are three types of claims: 1) general claims, 2) claims associated with the product name, and 3) efficacy related claims. This chapter also provides guidance on Warranty and Disclaimer statements on labels and claims made in advertising.

II. General claims

Every pesticide must have labeling which is accepted by EPA before the pesticide can be sold or distributed. Labeling is defined in the *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(p)(2)* as meaning labels and all other written, printed, or graphic material accompanying a pesticide or device at any time or to which reference is made on the label or in accompanying literature. As defined in *FIFRA Section 2(q)(1)(A)* a pesticide is misbranded if its labeling bears any statement, design or graphic representation which is false or misleading. *FIFRA Section 12(a)(1)(E)* provides that it is unlawful for any person to distribute or sell any pesticide which is misbranded. EPA's regulation, at *40 CFR 156.10(a)(5)* provides examples of statements that are considered to be misbranded; such as:

- ▶ A false or misleading statement concerning the composition of the product;
- ▶ A false or misleading statement concerning the effectiveness of the product as a pesticide or device (EPA may review and approve or disapprove non-pesticidal claims appearing on a pesticide label);
- ▶ A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- ▶ A false or misleading comparison with other pesticides or devices;
- ▶ Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by an agency of the Federal Government;
- ▶ The name of a product if the name suggests some but not all the active ingredients in the product, even though the names of the other ingredients are stated elsewhere in the labeling;
- ▶ A true statement used in such a way to give a false or misleading impression to the purchaser;
- ▶ Label disclaimers or warranty statements which negate or detract from labeling statements required under FIFRA and EPA's regulations;

- ▶ Safety claims of the pesticide, or its ingredients, including statements such as trusted, safe, nonpoisonous, noninjurious, harmless or nontoxic to humans and pets with or without such a qualifying phrase as when used as directed.
- ▶ Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
 - “Contains all natural ingredients”
 - “Among the least toxic chemicals known”
 - “Pollution approved”

For certain aquatic use products, claims to reduce sludge and unpleasant odors in water or to clean, clarify or deodorize ponds and lakes are not considered pesticidal claims; nor are claims regarding the reduction of nutrients and organic matter in water, provided no claim is directly made or implied that the reductions will result in reduced pest populations. The claims “Reduces critical nutrients for cleaner, clearer ponds”, “Ponds with algae need to reduce nutrients”, and “Bacterial Product to Control Excess Nutrients for Clear, Clean Ponds” imply pesticidal use and therefore require registration.

Slime and odor control agents and other products expressly claiming control of microorganisms of economic or aesthetic significance are **not** considered to be public health related, but should bear accurate pesticide labeling claims. Registrants are still responsible for ensuring that these products perform as intended by developing efficacy data, which must be kept on file by the registrant.

EPA’s policy does *not* permit the use of the terms “natural”, or “naturally” in the labeling of any registered product, including biopesticide products, both microbials and biochemicals. These terms cannot be well defined, and may possibly be misconstrued by consumers as a safety claim.

The claim “new” may be used on the labeling of a product of new composition for a period of 6 months following approval of the labeling; however, the word “new” may not be a part of the product name of record. If a label reviewer is in doubt as to whether a claim or statement is false or misleading, he or she should consult their division’s Ombudsperson or OGC representative before allowing the claim. *PR Notices 98-10* and *93-6* also provide guidance on claims, however, the statute and applicable regulations take precedence.

III. Some examples of unacceptable claims

- ▶ Statements that imply or suggest that the product can or will prevent or control disease or offer health protection, such as an insecticide that claims control of Lyme disease.

- ▶ “Commercial Line,” “Commercial Size,” “Institutional Size,” “Garden Center Size”: The use of these terms for products clearly intended for consumer household use is misleading.
- ▶ “Kills Numerous Insects,” “Kills Many Insects,” “Kills All Insects”: These claims imply a greater range of effectiveness than labeled. If however, these claims are limited to those pests listed on the label, i.e., “Kills many insects as listed below (or as listed on the label)”, it may be acceptable.
- ▶ Claims about the *Absence* of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by [40 CFR 156.10 \(a\)\(5\)](#). These claims are examples of a true statement used in such a way as to give a false or misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained or was not likely to contain in the first place.
- ▶ “Child Resistant Package” or Other CRP Related Claims: If a pesticide product requires child-resistant packaging (CRP), and has complied with the CRP regulations in [40 CFR 157](#) then the claim to that effect on the label is acceptable. Whether CRP is mandatory or voluntary the label may indicate the use of CRP and the proper use instructions for the CRP. However, in no circumstances may any safety claims beyond the statement “in Child Resistant Packaging” be made due to the use of CRP.
- ▶ “Organic”, “For Organic Lawns”, “Organic Disease Control”, “An Organic Alternative to _____”, and “Your Organic Solution” are all examples of misleading label claims as to safety. Under the National Organic Program (NOP), the phrase, “*For Organic Production*”, and “*For Organic Gardening*” located on the front panel of the label in close proximity to the product name are examples of acceptable labeling statements relating to the term “organic”. The phrase should not appear above the product name (in the location normally reserved for a Restricted Use Statement). See the next section for more information on organic claims.
- ▶ Biodegradable: The term “biodegradable” is generally unacceptable for any pesticide product. Except the term may be used only in reference to the package or packaging and then only if the registrant certifies that the package breaks down and they provide information to support it. Otherwise “biodegradable” may not be used on a pesticide label in any context.
- ▶ Claims Such as “Prevents Infection”, “Controls Infection”, or “Prevents Cross Infection” or that the product will control or mitigate any disease, infection or pathological conditions constitute public health claims and are not acceptable.

- ▶ The term “steri-” implies sterilant activity and is not acceptable as a product name or on a product label unless it is a sterilant.
- ▶ Statements that imply indefinite or all encompassing protection against bacteria, fungi or algae such as “germ-free”, or “algae-free” are not acceptable.

IV. Pesticides Eligible for USDA’s National Organic Program

Certain information on the pesticide label assists organic growers in knowing which products meet the requirements of the National Organic Program (NOP) Rule. If the criteria described in *Pesticide Registration (PR) Notice 2003-1*, and the clarification attached to it, http://www.epa.gov/PR_Notices/pr2003-1-clarification.html are met, a pesticide product may bear the following phrases

“For Organic Production”,

“For Organic Gardening”,

“For Organic Lawn Care”, and

“For Use in Organic Production”.

Label language and/or logos from other groups that review materials proposed for organic agriculture may also be considered (E.g. OMRI). The reviewer needs to determine if this information is false or misleading. Label reviewers should consult with the National Organic Program Liaison in the Biopesticides and Pollution Prevention Division for an evaluation of the product’s proposed labeling before approving any organic claims, regardless of whether BPPD is the registering division.

V. Claims made about the active ingredient

A product label may include the statement “contains [name of active ingredient], the active ingredient used in [Brand Name (™ or ®)]”, if the following criteria are met:

A. Placement

The claim may be placed anywhere on the label, however the preferred location is in close proximity to the Ingredient Statement.

B. Presentation

The claim should not be presented in an overly large font, such that the claim is set in a font type no larger than that of the Signal Word on the label. Furthermore, the claim should not be presented with heavily bolded or highlighted type or use coloring to cause the claim to

excessively stand out over the rest of the labeling text. The format of the claim should not be in such a way that it causes greater attention than other required precautionary labeling on the label.

C. Appropriate Comparison

If the subject product is a single active ingredient product, the claim should only refer to another similar single ingredient product. If the subject product is a multiple active ingredient product, the claim should only refer to another similar multi-ingredient product with the same active ingredients. Appropriate disclaimers stating that the generic product is not manufactured or distributed by the maker or marketer of the brand-name product as well as the trademark of the brand may be cross-referenced by use of a footnote.

VI. Product names

The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label. See [40 CFR 156.10\(b\)](#). No name, brand, or trademark may appear on the label which is false or misleading, or has not been approved by the Administrator through registration, or that the Agency has been notified of a name via supplemental registration, as an additional name pursuant to [40 CFR 152.132](#), or by notification as allowed by [PR Notice 98-10](#).

Product names cannot constitute false and misleading claims. Although a company has the discretion to name its product, the company is still governed by the false and misleading standard. An example of a misleading product name is, “*Fresh Squeezed Disinfectant*”. The phrase “Fresh Squeezed” in the name is misleading because it could convey that the product is meant to be consumed. Following is the Agency’s current guidance on false or misleading product names:

1. Product names, claims or statements that express or imply a higher-level of efficacy than demonstrated by testing are not acceptable.
2. General superlative terms such as “super”, “superior”, and “ultra” no longer need to be qualified by the term “brand” in a product name. However, this determination still does not allow terms or claims like those which clearly imply heightened efficacy (e.g., “hospital strength”, “professional strength”, etc.) (see PR Notice 93-6).
3. The Office of Pesticide Programs is under no obligation to ensure registrants use the correct trademark TM or ® and copyright © symbols on labels. Registrants are encouraged to use the correct symbols.
4. If a product falls within the scope of the Worker Protection Standard and contains an organophosphate (i.e., an N-organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the

label shall indicate the term directly under the Product Name or in the first aid statement.
40 CFR 156.206(c)(1).

The exact same name cannot be used for different products registered by any registrant.
40 CFR 156.10(b)(2)(ii). The product name must be sufficiently different to clearly distinguish one product from another. However, a supplemental distributor may use the same product name as the parent product. See *40 CFR 152.132(d).*

VII. Efficacy-related claims

Even though registrants/applicants must conduct efficacy studies, the Agency only routinely requires the submission of these studies for certain types of products. Nevertheless, each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration. EPA routinely reviews efficacy data (also referred to as product performance data) when a pesticide product bears a claim to control pest organisms that pose a threat to human health. Such pests include, but are not limited to, (a) microorganisms which are infectious to man in any area of the inanimate environment, (b) vertebrates (e.g., rodents, birds, bats, dogs, and skunks) that may directly or indirectly transmit diseases to or injure humans, and (c) insects that carry human diseases (e.g., mosquitoes, ticks, etc.). *40 CFR 158.400.* EPA also requires submission of efficacy data to support claims for the control of termites. On a case-by-case basis, the Agency may require substantiation of an efficacy claim. The following points should be kept in mind when reviewing labels bearing public health efficacy claims:

1. The terms “microbiocide”, “microbicide”, and “microbiostat” generally are not acceptable on a public health product. If used on a non-public-health product, the claim must be qualified to indicate that the product does not provide public health protection.
2. The term “biocide” generally is unacceptable on a public health product because it implies that the product can kill all living organisms. It may be used on a non-public-health product provided it is qualified by directions for use or other statements that make clear the types of organisms to be controlled.
3. True, non-misleading claims regarding the effectiveness of a product against target pests, e.g., “kills roaches”, “controls target pests”, and “kills pests on contact” are acceptable. However, such claims may not be exaggerated or used in a way that would make them misleading. EPA may require additional efficacy data to substantiate claims that go beyond mere control of claimed pests. *PR Notice 93-6.*

4. Terms which describe a specific level of efficacy and which are standard EPA-accepted claims such as “bacteriostatic”, “sanitizer”, “disinfectant” and “sterilant” are acceptable when data supports their use. *PR Notice 93-6*.
5. Implied claims (e.g., any statement, design, graphic representation or brand name) of heightened efficacy of a pesticide product by itself or as compared with another product or device are false and misleading. Examples of such claims include, but are not limited to: “professional strength”, “extermination strength,” “hospital strength”, “industrial strength”, “institutional strength”, “super strength”, “ultra strength”, “maximum strength”, “maximum efficacy”, “extra strength”, “double-strength”, “triple-strength”, “hospital grade”, “high potency”, and “high-powered” *PR Notice 93-6*.
6. Terms which function only to define a use site and which are not themselves claims of heightened efficacy, provided that such terms are not used in a manner that is misleading, are acceptable. For example, “hospital use” may be acceptable as long as it doesn’t imply “hospital strength”, is not used in the product name and is not highlighted on the label to the exclusion of other acceptable use sites. *PR Notice 93-6*.
7. Words or phrases that imply a product possesses unique characteristics because of its composition are not acceptable. See *40 CFR 156.10(a)(5)(i)*. Examples of such terminology are, “unique formula”, or “strongest on the market”. Other statements not supported by efficacy data that has been reviewed and accepted by the Agency are not allowed.
8. Claims that are inconsistent with efficacy established by testing are unacceptable. For example, a claim of 30-second efficacy is not acceptable if testing and/or use directions require two-minute contact time for efficacy.
9. Claims of efficacy based on an unsubstantiated, or improbable site/pest relationship are unacceptable. For example, a claim for control of Legionnaire’s disease in cooling tower water is unacceptable.

VIII. Instructions to label reviewers for efficacy issues

Check with the efficacy reviewers if the label makes unusual claims, deviates from a standard use pattern, or if the formulation changes. For example, formulation changes in an antimicrobial product can alter the efficacy of the product. Also, alternate formulations are not acceptable for rodenticides. Request a formal efficacy review for all claims that differ significantly from existing claims.

As mentioned earlier, do not allow any claim that would render the product misbranded under FIFRA or false and misleading under *40 CFR part 156.10(a)(5)*.

IX. Warranty and disclaimer statements

Most, if not all, pesticide labels contain some type of warranty disclaimer language. It is important, as always, that the Agency be consistent in reviewing such language when it is first submitted or subsequently amended. Warranty and Disclaimer statements containing language intended to limit liability of the registrant or act as disclaimers or warranties for the product are generally covered by state law or may fall under the jurisdiction of the Federal Trade Commission. The Agency will evaluate these statements to assess the extent to which the statements impact FIFRA label standards or the Agency's implementing regulations. An EPA guidance document on warranty statements was developed in 2006 and the examples it offers may be consulted at this site: <http://www.epa.gov/pesticides/regulating/labels/pdf/warranty.pdf>. Also see Chapter 3, Section IV. C. (page 8) for information on what is allowable for warranty statements on distributor product labels.

There are four types of label language associated with disclaimers, warranties and limitations of liability that the Agency has found to be unacceptable under statutory and regulatory standards. It is important to recognize that these statements must be assessed on a case-by-case basis. They are as follows:

1. Overly broad statements negating or detracting from the Directions for Use or other label language (including precautionary statements and directions for use). For instance, a warranty statement that the product may not work would undermine Directions for Use that explain how the product is to be used.
2. Label language asserting that the buyer has accepted the manufacturer's statement of his/her respective rights. (e.g., manufacturer states buyer's rights are extremely limited; "all of these conditions are beyond the control of registrant X"). Because these statements are almost always incomplete (in terms of fully explaining a buyer's rights in the jurisdiction (state) of purchaser and because they can mislead buyers into thinking that they have no legal remedy, they may constitute "misbranding" under FIFRA.
3. Overly broad language implying buyer has no legal right to recover damages from manufacturer (e.g., "all such risks shall be assumed by the buyer").
4. Because EUP labels must be used in strict accordance with the EUP program, the warranty on EUP labels may not disclaim control over use. As with No. 2 above, these statements can be considered to be misleading.

The reviewer should check the proposed label for warranty/disclaimer/liability language statements (like those above) that appear to negate or detract from Directions for Use or other language. The label reviewer should make sure that the disclaimer statement makes it clear that it is the **registrant's** or **manufacturer's** warranty disclaimer, by using such statements like “To the fullest extent permitted by law, the manufacturer shall not be liable...” or “It is the manufacturer's intention that...”. This way it is clear that the language is coming from the registrant (and not EPA).

The following are examples of problematic warranty statements. The problematic portions of the label statements are stricken, and necessary language is added in red.

EXAMPLE 1

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The directions for use of this product are believed to be adequate and ~~should~~ **must** be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of XXXX. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: **To the extent consistent with applicable law**, XXX makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of XXX is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. **To the extent consistent with applicable law**, XXX disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: **To the extent consistent with applicable law**, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at XXX's election, the replacement of product.

Reasons for Corrections

The phrase “should follow directions” could mislead users to believe that the directions for use are only suggestions and not enforceable restrictions on how the product may be used; therefore, all statements relating to using the product in accordance with its labeling will be required to be mandatory (i.e., “must”).

The phrase, “to the extent consistent with applicable law” has been added to the disclaimers of liability and damages to avoid the statements being false or misleading. Some states or localities may not allow certain disclaimers of liability or damages; therefore, the user/buyer may have a remedy under other law governing warranties.

EXAMPLE 2

Warranty and Disclaimer Notice

Warranty

The directions for use of this product are believed to be adequate and ~~should~~**must** be followed carefully, it is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result due to such factors as weather conditions, presence or absence of other materials, or the manner of use or application, all of which are beyond the control of XXX, the manufacturer, or the seller.

To the extent consistent with applicable law, the products sold to you are furnished “as is” by XXX. The manufacturer and the seller are subject only to the manufacturer’s warranties, if any, which appear on the label of the product sold to you. Except as **warranted by this label** ~~expressly provided herein~~, XXX, the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability, fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. ~~Except as expressly stated herein, XXX, the manufacturer, or the seller makes no warranty of results to be obtained by use of the product.~~ **To the extent consistent with applicable law**, Buyer’s or user’s exclusive remedy, and XXX, the manufacturer’s or the seller’s total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of XXX, or the seller is authorized to amend the terms of this warranty disclaimer or the product’s label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, XXX, the manufacturer, or the seller shall not be liable for consequential, special, or indirect damages resulting from the use,

handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may have to such damages.

Reasons for Corrections

Prior to legal use of a pesticide product it must be registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA). Registration of a pesticide requires, in part, that the product be effective in controlling the pest(s) for which it is registered. In registering the product under FIFRA, the product must perform as purported when used in accordance with its labeling. The phrase, “Except as expressly stated herein, XXX., the manufacturer, or the seller makes no warranty of results to be obtained by use of the product”, is overly broad and could be misleading to the consumer. Overly broad statements, which negate or detract from the Directions for Use, must be qualified by a phrase such as “Except as warranted in this label”. Statements such as those used in the example above (“Except as expressly provided herein” and “Except as expressly stated herein”) are not adequate qualifiers because they are misleading in that they do not clearly incorporate the warranty offered through the act of registration.

State and local laws may not allow the manufacturer to limit its liability by offering its product “as is”. In addition, the same laws may not allow certain limitations of liability or remedy. Therefore “to the extent consistent with applicable law” has been added in appropriate places.

More examples of Warranty and Disclaimer Statements can be found on EPA’s [Labeling Committee Projects](#) Web site. If, after reviewing the examples, a label reviewer is still in doubt as to the acceptability of any warranty or disclaimer statement, the statement should be referred to the Office of General Counsel.

X. Claims made in advertising

Advertising and collateral literature or verbal claims for the product must not substantially differ from any claims made on the label or labeling. See *FIFRA § 12(a)(1)(B)*. In other words, if a claim is not on the label or substantially differs from what appears on the label (or any part of its distribution or sale which for example appears on a brochure), it cannot be made in advertising. Although OPP does not routinely review advertising in connection with the registration, the Agency may require advertising used in the marketing of the product to be submitted upon request and be reviewed to see that it is in compliance with *FIFRA section 12(a)(1)(B)*. If reviewers come across any advertising inconsistencies, refer them to the following address for further investigation:

Branch Chief
Agriculture Branch
Agriculture Division
Office of Compliance (2225A)