

US EPA ARCHIVE DOCUMENT

“Animal Testing” Factual Statements

{ Kristie Sullivan

PCRM

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- & Recap issue
- & Current (personal care) labeling programs
- & Subgroup work history
- & Two potential proposals for pilot program

Summary

- ⌘ Identify acceptable label language and criteria demonstrating the extent to which animal testing was avoided in the registration of the product.
- ⌘ In vitro tests are available and at various stages of regulatory acceptance for eye irritation, skin sensitization, and dermal irritation.
- ⌘ By combining in vitro tests with weight-of-evidence analyses, waivers, and other strategies, obtaining a registration without conducting animal tests is possible.

Introduction

- ⌘ Encourage a global approach, on the part of registrants and EPA, to minimize the use of animal tests for EPA registration purposes
- ⌘ Encourage the development, use, and acceptance of “alternative” methods and approaches
- ⌘ Help consumers make purchasing decisions based on documented preferences for products not tested on animals

Pilot Aims

- ⌘ “Me Too” registrations
- ⌘ Connotation of Safety?
- ⌘ Inerts should be included--is this a burden on EPA?
- ⌘ Multi-national products
- ⌘ Balancing correctness and feasibility of language

Issues for Consideration

- & The Accord Group: Patrick Quinn
- & EPA: ~~Jeff Kempter~~, Mark Hartman, Jeaneanne Gettle, Greg Akerman, Tim McMahon
- & CleanWell Company: Larry Weiss
- & Clorox: Bill McCormick, Patrick Elias
- & Steptoe and Johnson: Seth Goldberg, Sue Crescenzi, Erik Janus
- & SC Johnson: Steve Smith, Chris Pierce
- & PCRM: Kristie Sullivan

Small Group

Coalition for Consumer Information on Cosmetics

- ⌘ “The Leaping Bunny Program provides the best assurance that no animal testing is used in any phase of product development by the company, its laboratories, or suppliers.”
- ⌘ Companies sign pledge that they [or their suppliers] do not currently test using animals and will not do so in the future
- ⌘ Fixed cutoff date



Current Standard I: Leaping Bunny

People for the Ethical Treatment of Animals

⌘ Companies listed either have signed PETA's statement of assurance or provided a statement verifying that they do not conduct or commission any animal tests on ingredients, formulations, or finished products and that they pledge not to do so in the future

⌘ 5-year “rolling” cutoff



Current Standard II: Caring Consumer

- ⌘ Review of proposed language and criteria
- ⌘ Survey of registered products
- ⌘ Discussion with stakeholder groups
- ⌘ Additional proposal created

Steps Taken

‡ Level 1: Never tested on animals

‡ Level 2: Not tested on animals

‡ Level 3: Minimized animal testing

Proposal #2

Level 1: Never tested on animals

- ⌘ Criteria: The product and its ingredients were produced entirely without any animal testing, or reliance on animal data from other registrants.
- ⌘ Example: A product manufacturer was able to obtain registration for the product using a combination of waivers, in vitro test methods, in silico models, or read-across from structurally-similar substances.

Proposal #2

Level 2: Not tested on animals

- ⌘ Criteria: The product and its ingredients were not tested in animal tests by the registrant, but other entities may have conducted animal tests on the product or its ingredients, currently or at some point in the past.
- ⌘ Example: A product manufacturer was able to obtain registration for the product without conducting any testing, but the AI was tested for sensitization and dermal irritation in the past by another company.

Proposal #2

Level 3: Minimized animal testing

- ⌘ Criteria: The registrant and EPA have worked together to minimize animal testing to the greatest extent possible under the conditions of that particular product registration.
- ⌘ Example: A product manufacturer was required to do some testing to register the product but also worked together with EPA to design a read-across approach from a structurally-similar substance, and did an in vitro test, for other endpoints.

Proposal #2

& Simpler label language

& Provides levels of entry to encourage participation

& Accommodates concerns related to past testing or testing by other entities

& However: multinational requirements need to be discussed

Proposal #2: Advantages