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ENVIRONMENTAL PROTECTION
AGENCY-REGION VII
REGIONAL HEARING CLERK

Position Statement
Reference Article Number: 7005 1160 0004 4818 9482
Docket No. FIFRA-07-2006-0284

Following are Cornhusker State Industries' (CSI's) comments and positions referencing specific complaints noted in Docket No. FIFRA-07-2006-0284, which we feel require review and consideration.

Count 1

¶ 38 *A copy of the label on the container of Sample Number 041505 F3234 0102, EPA Reg. No. 106-79-47359, displayed the following misbranded items:*

- a. ***The text regarding the Statement of Practical Treatment on the front panel is incorrect:***
CSI regards this issue as somewhat semantical. The label states "See Right Panel" as opposed to the approved label per Brulin that states, "See Side Panel". Per Label Review Manual (current as of August 2003, page 7-12, paragraph 3), provided to CSI by Brulin, the text regarding the Statement of Practical Treatment on the front panel is technically correct. (Attachment A).
- b. ***Incorrect EPA Establishment Number:***
This error that has a logical explanation. All USPS Federal designations for the state of Nebraska are "NE". The approved EPA designation was "NB" but the CSI label was printed with "NE". The original printing dates back a number of years and no previous inspections noted the error.
- c. ***Incorrect statement under the Hazards to Humans and Domestic Animals:***
The root cause of the incorrect statement was the result of the lack of, or miscommunication between CSI and Brulin. In recent conversations, Brulin stated to CSI that the EPA approved a label change in 2002. Brulin cannot provide any documentation showing that they directed CSI to make a corresponding label change nor does CSI have documentation to support that label changes were required. Therefore, no change occurred. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.

- d. ***First Aid Statement and required text is missing:***
While a "First Aid Statement", which would have been included in the 2002 label change, was not officially on the label, there was a "STATEMENT OF PRACTICAL TREATMENT" on the label. While this may not have been the latest language, there was treatment information on the label. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.
- e. ***Veterinary Clinics site listed without specific Veterinary Clinic directions for use stated on the label:***
The notification to separate "Veterinary Clinic" was in the missing 2002 notification letter. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.
- f. ***Under Storage and Disposal-the word, "Prohibitions" and the text following should be deleted; a Pesticide Storage heading is not on the label and should be; a heading titled "General" and the statement immediately following should be deleted; a heading titled "Container Disposal-Plastic Container" is incorrect:***
These requirements were cited in the missing 2002 letter therefore, no change was made. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.
- g. ***Instructions for cleaning personal protective equipment are not listed on label:***
This particular product would not be used for cleaning personal protective equipment nor are there any CSI claims to that effect. In fact, Brulin has advised us that they would not allow us to put that information on the label.

¶ 39 The label referenced in paragraph 38 was not the label accepted by EPA on January 31, 2002, for EPA Reg. No. 106-79:

CSI agrees that the label on the product was not the latest EPA approved version. However, CSI does not have any correspondence or documentation from Brulin that directed us to change to the approved EPA label. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.

¶ 40 Respondent violated Section 12(a) (1) (E) of FIFRA, 7 U.S.C. §§ 136j (a) (1) (E), by distributing and holding for distribution a misbranded pesticide:

CSI did not willfully violate any laws. The possible miscommunication and subsequent inadequate follow up created this labeling error.

¶41 Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136l, and based on the facts stated in paragraphs 34 through 40, it is proposed that a civil penalty of \$6,500 be assessed against Respondent:

Since this violation was neither intentional nor willful, coupled with the very low volume of product sold, and sold only to state agencies, CSI requests that the civil penalty be set aside. CSI is an inmate worker program in which profits are deposited in a Revolving Fund that supports and expands the program. Benefits from this program include training inmates on job skills, ultimately reducing recidivism.

Count 2

¶47 Respondent repackaged the pesticide referenced in paragraphs 43 through 46 without authorization from the registrant, Lonza, Inc., and the repackaged containers did not bear the accepted label dated March 31, 2003:

Again, the results of this violation appear to be possible miscommunication and subsequent inadequate follow up between CSI and Brulin. A “Repackaging Agreement” between CSI and Brulin did not exist. In 2001, CSI ordered labels from Brulin’s Customer Service Department for repackaging. Unfortunately Brulin’s Customer Service Department and Brulin’s Environmental Department did not have an internal communication channel that alerted Environmental to CSI’s repackaging. Since a large number of labels were ordered in 2001, CSI was not aware there were any label changes. Brulin sales representatives were aware that CSI was repackaging but did not realize that proper agreements were not in place.

¶48 The repackaged pesticide described in paragraphs 43 through 46 was not encompassed within the terms of the basic registration under EPA Reg. No. 6836-108, and required separate product registration with EPA under provisions of Section 3 of FIFRA:

It is CSI’s understanding from Brulin that CSI does not need a separate product registration. What should have been in place was a “Repackaging Agreement”. Prior to any violation notification, CSI discontinued this product from CSI’s product line.

¶49 40 C.F.R. § 152.44 states that any modification in the composition, labeling, or packaging of a registered product must be submitted by application to and approved by the EPA before the product as modified may be distributed or sold:

It is our understanding from Brulin that CSI does not need a separate product registration. What should have been in place was a “Repackaging Agreement”.

¶50 Respondent violated Section 12 (a) (1) (A) and Section 12 (a) (1) (E) of FIFRA, 7 U.S.C. §§ 136j (a) (1) (A) and (E), in that it failed to comply with the provisions of FIFRA by producing and distributing a misbranded and unregistered pesticide:

CSI did not willfully violate any laws. The possible miscommunication and subsequent inadequate follow up created this labeling error.

¶51 Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136l, and based on the facts stated in paragraphs 42 through 50, it is proposed that a civil penalty of \$6,500 be assessed against Respondent:

Since this violation was neither intentional nor willful, coupled with the very low volume of product sold, and sold only to state agencies, CSI requests that the civil penalty be set aside. CSI is an inmate worker program in which profits are deposited in a Revolving Fund that supports and expands the program. Benefits from this program include training inmates on job skills, ultimately reducing recidivism.

Count 3

¶54 The pesticides referenced in paragraph 53 were adulterated in that the strength or purity fell below the professed standard of quality expressed on the labeling:

CSI agrees that the label was not accurate. The CSI label reflected the undiluted ingredients.

¶55 Respondent violated Section 12 (a) (1) (E) of FIFRA, 7 U.S.C. §136j (a) (1) (E), in that it sold or distributed or held for distribution the misbranded and adulterated pesticides described above:

CSI did not willfully violate any laws. The possible miscommunication and subsequent inadequate follow up created this labeling error. CSI has developed and submitted a label to Brulin for approval with the appropriate changes.

¶56 Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136l, and based on the facts stated in paragraphs 52 through 55, it is proposed that a civil penalty of \$4,550 be assessed against Respondent:

Since this violation was neither intentional nor willful, coupled with the very low volume of product sold, and sold only to state agencies, CSI requests that the civil penalty be set aside. CSI is an inmate worker program in which profits are deposited in a Revolving Fund that supports and expands the program. Benefits from this program include training inmates on job skills, ultimately reducing recidivism.

Count 4

¶58 Respondent repackaged the pesticides identified as Sample No. 041505 F3234 0105 from Lot Number/Batch Code 260 03 05, and Sample No. 041505 F 3234 0107 from Lot Number/Batch Code 250 11 04 without authorization from the registrant, Sunshine Makers, Inc.:

Appropriate "Repackaging Agreements" were not in place.

¶59 The repackaged products described in paragraph 58 were not encompassed within the terms of the basic registration under EPA Reg. No. 56782-1, and therefore required separate product registration under provisions of Section 3 of FIFRA:

It is CSI's understanding from Brulin that CSI did not need a separate product registration. What should have been in place was a "Repackaging Agreement".

¶60 40 C.F.R. § 152.44 states that any modification in the composition, labeling, or packaging of a registered product must be submitted by application to and approved by the EPA before the product as modified may be distributed or sold:

CSI agrees that a label error existed.

¶61 Respondent violated Sections 12 (a) (1) (A) of FIFRA, 7 U.S.C. § 136j (a) (1) (A), in that it failed to comply with the provisions of FIFRA by producing and holding for distribution an unregistered pesticide:

CSI did not willfully violate any laws. The possible miscommunication and subsequent inadequate follow up created this labeling error.

¶62 Pursuant to Section 14 of FIFRA, 7 U.S.C. § 136l, and based on the facts stated in paragraphs 57 through 61, it is proposed that a civil penalty of \$4,550 be assessed against Respondent:

Since this violation was neither intentional nor willful, coupled with the very low volume of product sold, and sold only to state agencies, CSI requests that the civil penalty be set aside. CSI is an inmate worker program in which profits are deposited in a Revolving Fund that supports and expands the program. Benefits from this program include training inmates on job skills, ultimately reducing recidivism.

Label Review Manual

Current as of August 2003

3. **Location and Prominence.** First Aid statements shall appear on the front panel of the label for all products classified as toxicity category I [40 CFR 156.68]. The Agency may, however, permit reasonable variations in the placement of the statement of First Aid as long as the reference statement "See First Aid (or Statement of Practical Treatment) on [identify appropriate panel]" appears on the front panel, preferably near "Poison" and the skull and crossbones. First Aid statements for toxicity categories II and III classification may appear on any panel of the label. However, any time First Aid statements appear other than on the front panel, a referral statement such as "see side/back panel for first aid" should appear on the front panel in close proximity to the Signal Word. Furthermore, First Aid statements on the side or back panel should be grouped near the other precautionary labeling text, yet set apart or distinguishable from the other label text, for example placed in a box below the Hazards to Humans and Domestic Animals section. First Aid statements should be organized so that the most severe routes of exposure, as demonstrated by the toxicity classification, are listed first.

4. **Determining the First Aid Statements for Fumigant Products:** Refer to PR Notice 84-5 and Registration Standards/REDs.

5. **Determining the First Aid Statements for Non-Fumigant Products.** Review Table 9 to determine the preferred First Aid statements for each route of exposure. Registrants should support alternative First Aid statements with medical evaluations of the product. Approval of alternative First Aid statements is guided by considerations such as those set out in the "Content and Clarity" section below. The Agency has not approved the use of salt water for emesis as a first aid technique. (See PR Notice 80-2).

a. **Content and Clarity.** First Aid statements must be brief, clear, simple and in straightforward language so that the average person can easily and quickly understand the instructions. First Aid statements should apply to all ages or when necessary, should include distinctions between the treatments for different ages (e.g., children vs. adults). Any reasonably competent individual should be able to perform the First Aid statements. These statements should not include procedures which must be performed by medical personnel or require specialized equipment. Such procedures belong under the Note to Physician heading (see section G below).

b. **Acute Dermal and Primary Skin Irritation.** Because both of these studies focus on the dermal route of exposure, any first aid statements required by the results of these two studies can be combined. Use the first aid statement required for the acute dermal toxicity study if the results of both studies place the product in the same acute toxicity category. Use the statements for the more severe acute toxicity category if the results of the studies would place the product in different acute toxicity categories.

c. **Eye and Skin Irritation.** If the product is corrosive and is in toxicity category I or II for eye or dermal irritation, then a first aid statement for ingestion may also be included.