

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF)
)
HING MAU, INC.,) Docket No. FIFRA-9-2001-0017
)
Respondent)

Appearance for Complainant:

Brien P. Riedel, Esq.
Assistant Regional Counsel
U.S. EPA, Region 9
San Francisco, California

Appearance for Respondent:

Diana D. Sam, Esq.
Law Offices of Kaplan & Sam
San Francisco, California

Federal Insecticide, Fungicide and Rodenticide Act-Sale of Unregistered Pesticides-Determination of Penalty-Enforcement Response Policy: ERP held to provide appropriate guidance in determining penalty for sales of unregistered pesticides.

INITIAL DECISION

I. Introduction and Procedural Background

This proceeding under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA" or "Act"), 7 U.S.C. § 136 *et seq.*, was commenced on September 24, 2001, by the filing of a complaint by the Senior Associate, Cross Media Division, United States Environmental Protection Agency, Region 10 ("EPA" or "Complainant"), charging Respondent, Hing Mau, Inc., with the distribution and sale of unregistered pesticides in violation of Section 12(a)(1)(A) of the Act. Specifically, the complaint alleges that on November 30, 1999, Respondent distributed or sold the products "Naphthalene No. 108" and "Refined Naphthalene

[Ball]”, that these products are pesticides and that neither product was registered.¹ For these alleged violations, Complainant proposes to assess Respondent a penalty of \$9,900.

Respondent, through counsel, filed an Answer on October 25, 2001, admitting that it was a corporation and thus a person, admitting that it owned, operated, controlled and was otherwise responsible for a facility located at 1040 Maunakea Street, Honolulu, Hawaii. Respondent denied liability and denied that the proposed penalty was appropriate. Specifically, Respondent denies the distribution or sales alleged in the complaint and denies for lack of information sufficient to form a belief the allegations that the products are pesticides and that neither product was registered. As affirmative defenses, Respondent alleged “discriminatory enforcement” in that the Act has not been applied equally against those similarly situated and “improper purpose” in that Complainant seeks to impose civil penalties based on the belief Respondent has not sufficiently cooperated with Complainant. With respect to the proposed penalty, Respondent asserted, *inter alia*, that Complainant has failed to allege any facts regarding the “gravity of the violation”; that Respondent is a grocery retail store with a single location in Honolulu; and that Hawaii has been in a recession for ten years and is one of the states most affected economically by the terrorist attacks. Respondent requested a hearing on all issues raised by the complaint and answer.

Both parties have filed prehearing exchanges. Under date of May 15, 2002, Complainant filed a Motion for Accelerated Decision on Liability and Penalty. Although noting that Respondent has denied most of the allegations of the complaint without substantiation, Complainant asserted that there was no genuine issue that: (1) Respondent “distributed or sold” two Naphthalene products; (2) that these products are pesticides; (3) which were not registered under FIFRA (Memorandum in Support of Complainant’s Motion..., hereinafter Memorandum). Complainant says that Respondent’s affirmative defenses of selective enforcement and improper purpose are wholly unsupported by the record and that Respondent is mistaken as a matter of law in claiming that Complainant must prove through laboratory tests that the Naphthalene products are correctly identified by the labels. Moreover, according to Complainant, there is no dispute that Respondent has gross revenues in excess of \$1,000,000 a year and a good credit rating, placing it in an excellent position to pay a civil penalty of \$9,900. Respondent did not file a response to the motion.

By an order dated August 13, 2002, Complainant’s motion for an accelerated decision as to liability was granted, and its motion for an accelerated decision as to the penalty was denied. Because there was no dispute of material fact that Respondent sold or distributed the unregistered pesticides Naphthalene 108 [225] and Refined Naphthalene Ball as alleged in the complaint, Complainant was granted an accelerated decision finding Respondent liable for two violations of FIFRA § 12(a)(1)(A). Complainant’s request for an accelerated decision as to the penalty was denied because it overlooked the provisions of the Administrative Procedure Act, 5

¹ It appears that the product in Count II should be correctly identified as “Refined Naphthalene Ball” (Inspection Report & Related Documents, C’s Ex. 4).

U.S.C. § 556(d), providing in pertinent part that: “[a] party is entitled to present his case by oral or documentary evidence, to submit rebuttal evidence and to conduct such cross-examination as may be required for a full disclosure of the facts.” EPA’s General Counsel has ruled that FIFRA § 14(a)(3) “[r]equires a hearing in accordance with the Administrative Procedure Act (5 U.S.C. § 556), unless the respondent waives the right and agrees to some sort of an abbreviated hearing.” 1973 WL 21963, at *1 (Feb. 12, 1973, E.P.A.G.C.). Respondent has not waived its right to a hearing, but has clearly expressed its intention to proceed, stating, *inter alia*, that it intends to cross-examine Complainant’s witnesses. (Prehearing Exchange at 6, 7). Accordingly, Complainant’s request for an accelerated decision as to the penalty was denied.

A hearing on this matter was held in San Francisco, California on November 14, 2002.

II. Findings of Fact

1. Hing Mau, Inc. is a corporation incorporated in the State of Hawaii and the owner of a small, family-operated retail grocery business located at 1040 Maunakea Street, sometimes referred to as “Chinatown”, in Honolulu, Hawaii (the “Facility”).
2. On November 30, 1999, Mr. Stephen Ogata, an inspector from the Hawaii Department of Agriculture conducted an inspection of the Facility, because it was suspected of selling Federally unregistered and State un-licensed mothball pesticides (Inspection Report Narrative, signed December 17, 1999, C’s Exh 4). Mr. Ogata found two products, one identified as “Naphthalene 108 225” and the other identified as “Refined Naphthalene Ball” (Id.). In the Receipt for Samples (C’s Exh 4), the former product is identified simply as “Naphthalene 225”.
3. The products referred to in finding 2 consisted of round balls of refined naphthalene in cellophane bags, containing approximately 50 balls per bag of Naphthalene 225 and approximately 38 of the Refined Naphthalene Balls (Testimony of William B. Lee, Tr. 73, 74).. Mr. Ogata proceeded to take photographs of the products which were on the bottom shelf of retail shelving at the Facility (Receipt for Samples, C’s Exh 4; Color Photos, C’s Exh 16). The photos reveal that Naphthalene 225 consisted of multi-color balls and that the Refined Naphthalene Balls were white. Although the cellophane bags containing the balls did not have labels as such, language on the bags was primarily foreign, apparently Chinese. The bags contained the statement “Made in Taiwan.” (Exhs 5 and 6). Additionally, each bag contained, among others, the following statement in English : “This product is made of refined naphthalene , which has resistance function against insect, mildew, and bad smell.” . The quoted language was considered to constitute the making of pesticidal claims and was the primary reason “Naphthalene 225” and “Refined Naphthalene Ball” were determined to be pesticides. See Order Granting Motion for Accelerated Decision on Liability and Denying Accelerated Decision as to Penalty, dated August 13, 2002, which is incorporated herein and made a part hereof by reference.

- 4 Other language in English on the bags of "Naphthalene 225" and "Refined Naphthalene Ball" included the following: **Caution.** This is a product made of refined naphthalene which can not be placed with camphor or para in the same box to prevent chemical change otherwise the clothes will be wrinkly and polluted.
Keep away from children.
Don't be used as a preservative of food.
disposal of waste containers: destroy and be sure not to use for other purpose.²
The package can't be used to wrap food.
How to use:
Tear the outer package and wrap up with cotton on paper.³
5. The record reflects that Respondent received one case of "colored moth balls" (Naphthalene 225) and one case of "moth balls" (Refined Naphthalene Balls) from Family Supermarket, Santana, California in early January 1999 (Inspection Narrative, Invoice, dated December 16, 1998, C's Exh 4). At the time of Mr. Ogata's inspection of Hing Mau on November 30, 1999, Ms. Maria Sam was the manager. According to Ms. Sam, each case contained about 100 bags, and there were 78 bags of Naphthalene 225 and 90 bags of Refined Naphthalene Ball on hand at the time of the inspection (Inspection Narrative; Investigation Summary; Dealer's Statement, dated December 10, 1999, C's Exh 4). By a letter, dated December 23, 1999, the Hawaii Department of Agriculture issued a Stop-Sale and Removal from Sale Order to Hing Mau for Naphthalene 225 and Refined Naphthalene Ball because the products were not licensed by the Hawaii Department of Agriculture (C's Exh 4). By a letter, dated December 27, 1999, the Hawaii Department of Agriculture forwarded the inspection report and related documents to EPA, Region 9 in San Francisco (Id.).
- 6 Mr. William B. Lee, an enforcement officer in the Pesticides Program of EPA Region 9, calculated the proposed penalty (Affidavit of William B. Lee, C's Exh 1). He pointed out that Section 14(a)(4) of FIFRA required that the following factors be considered in determining the amount of a penalty: (1) appropriateness of such penalty to the size of the business of the person charged; (2) effect on the person's ability to continue in business; and (3) the gravity of the violation (Id. 2). Respondent has stipulated that "ability to pay" is not in issue (Tr. 11, 12). For the purpose of calculating the penalty, Mr. Lee used the Enforcement Response policy for FIFRA (ERP) (July 2, 1990) (Tr.53) of which official notice is taken.

². Only on the package of "Naphthalene 225" (Exh 5).

³. Although the "How to Use" directions on the bag of Naphthalene 225" state "Tear the outer package and wrap with CC" on paper", it is concluded that the use directions for "Naphthalene 225" and "Refined Naphthalene Balls" were intended to be identical.

7. Because Hing Mau was selling pesticides, it was considered to be a dealer and subject to Section 14 (a)(1) of FIFRA, which authorizes a penalty of up to \$5,000 for each offense.⁴ Mr. Lee pointed out that Appendix A-1 of the ERP sets out numerical levels for the severity of the violations ranging from one to four, one being the most severe, four being the least severe (Tr.54) He stated that in this instance the ERP reflects that the gravity or severity level for the sale of an unregistered pesticide is two. The next step was to determine the size of business category. Although Hing Mau has stipulated that “ability to pay is not in issue” (Tr. 11, 12), it objects to being placed in Category I (sales or revenue over \$1 million) for penalty calculation purposes (Reply Brief at 1, 2). As support for the Category 1 determination, Mr. Lee referred to an undated Reference USA Document (C’s Exh 3), which reflects that Hing Mau’s estimated sales were \$1 million to \$2.499 million. It is noted, however, that the Document contains a caveat as to the accuracy of the information contained therein.⁵ Mr. Lee testified that because Hing Mau’s gross sales were over \$1 million, it was in Category 1 size of business [for penalty calculation purposes] (Tr. 56). He indicated that information in the Reference USA Document was confirmed by a Dun & Bradstreet Report. The D & B Report (C’s Exh 14) actually states that Hing Mau’s [annual] sales volume is \$1,000,000.
8. Mr. Lee testified that the next step was to refer to the penalty matrices in the ERP at Appendix C-1, also at page 19-A, which reflect that the maximum or base penalty for a Category 1 size of business, Level 2 gravity, is \$5,500 per violation (Tr.57). Thereafter, gravity adjustment factors are applied, considering gravity of the harm:: (1) pesticide toxicity; (2) human harm; (3) environmental harm; and gravity of the misconduct, i.e., (4) compliance history; and (5) culpability (ERP at 21; Affidavit of William B. Lee at 4). Numerical values for these adjustments ranging from one to five are set forth in Gravity Adjustment Criteria , ERP, Appendix B. Unlike the FIFRA Charges and Gravity Levels, Appendix A, the lower numerical values here represent the least serious violation, i.e., risk of harm or potential for harm. Mr. Lee stated that he had access to labels of EPA

⁴The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. § 3701), requires EPA to periodically adjust penalties to account for inflation. The Agency has done so and for violations of FIFRA occurring after January 30, 1997, by persons subject to § 14(a)(1) of the Act , the maximum penalty is \$5500 for each offense. See 40 C.F.R. Part 19 (2001).It is noted that for violations occurring after August 19, 2002, the maximum penalty per offense is \$6200 (67 FR 41343, June 18, 2002; 40 CFR Part 19, 2002).

⁵A note in the Reference USA Document provides in part: Our Credit Rating Codes are indicators of probable ability to pay. They are based on business demographic factors such as number of employees, years in business, industry stability, bill paying history, barriers to entry and government data. We recommend that these ratings be used primarily as a starting point and should not be the sole factor used in making a credit decision.....

registered products containing identical active ingredients as the products at issue here (Tr. 58). He determined that the [missing] signal word from the labels here was “warning” based on the Toxicity Category..⁶ He, therefore assigned the lowest value of one to pesticide toxicity (Id.; Penalty Calculation Worksheet, C’s Exh 2). The next gravity adjustment factor is ‘human harm’ and Mr Lee considered that there was a potential for serious or widespread harm to human health for which he assigned a value of 3 (Tr.59; Affidavit at 5). He based this determination on the fact that the products were not registered, the labels had not been reviewed or approved by EPA, the inherent toxicity of naphthalene, deficiencies in the labels in that labels of registered products would inform users of product ingredients, physical and chemical hazards, and use, storage and disposal instructions (Tr. 60; Affidavit). Additionally, he pointed out that the color of the products made them look like candy which together with their location on the bottom shelf of the display at Hing Mau created what he referred to as an “attractive nuisance “ to children (Tr.61, 65).

9. The next gravity adjustment is environmental harm for which there are four circumstance levels to be considered (Tr.65; ERP, Appendix B-1). Mr. Lee explained that actual serious or widespread harm to the environment would receive a level of 5, while potential serious or widespread harm to the environment would receive a value of 3.⁷ A minor potential or actual harm to the environment, neither widespread nor substantial, is assigned a value of 1. Mr. Lee assigned a value of 1 to environmental harm, because he determined that the potential for actual harm to the environment was minor and neither widespread nor substantial (Tr. 66). Turning to the gravity of the misconduct, Mr Lee assigned a value of zero to compliance history because Hing Mau had no prior FIFRA violations. The final gravity adjustment was for culpability and Mr. Lee pointed out that a value of 4 would be assigned if the violation were knowing and willful and [the violator] had general knowledge of the hazardousness of the action (Tr.66; ERP, Appendix B-2). He stated that they were directed [by the ERP] to assign a value of 2, if culpability were unknown or resulted from negligence. If the violation were neither knowing or willful and did not result from negligence and, if upon discovery of the violation, the violator took immediate action to correct the violation, a value of zero would be assigned (Tr. 66, 67). In this instance, a value of 2 was assigned because he determined that the violation

⁶. Signal words are required on the labels of registered pesticides based on the toxicity of the pesticide (40 CFR § 156.64). Four toxicity categories are established ranging from I to IV with Category I representing the highest toxicity (40 CFR § 156.62). A Category I pesticide requires the signal word “Danger”and, depending on the reason for the assignment of Toxicity Category I, the word “poison” in red on a contrasting background with the “skull and crossbones” in immediate proximity. A Category II pesticide requires the signal word “Warning”.The word “Caution” is required on the labels of Category III pesticides and, if a signal word is used, on Category IV pesticides.

⁷. There is no Level 4 in Appendix B-1.

resulted from negligence. He reached this conclusion because he considered that a prudent dealer or store [owner or operator], selling pesticides and in business for 15 years would review the products offered for sale to determine [assure] that the products were in compliance with all rules and regulations (Tr.67). He relied upon the Reference USA Document for information that Hing Mau had been in business for at least 15 years. He emphasized that determining whether a pesticide product was registered was a simple matter of reviewing the label for an EPA registration number (Tr. 68, 69, 70, 71). This, of course, assumes that a person knows or has reason to believe that the product is, or may be, a pesticide.

10. The next step in the penalty calculation was to add the values assigned for toxicity, human harm, environmental harm, compliance history and culpability (Tr. 72; Penalty Calculation Worksheet, C's Exh 2). Mr. Lee noted that this resulted in a total of seven for which the ERP provides for a reduction of 10% of the matrix value (Id. 22). Ten percent of the matrix value equals \$550, which deducted from \$5,500 equals \$4,950., which times two for the two violations equals \$9,900, the penalty sought by Complainant (Tr.72, 73). On cross-examination, Mr. Lee acknowledged that he had no information to contradict the assertion that Hing Mau immediately removed the products at issue from its shelves when it was notified that the products were or might be in violation of the law (Tr. 77, 78).
11. Although it is common for grocery stores and supermarkets to sell pesticides such as ant and roach killers, Mr. Lee testified that he had no information that Hing Mau was selling pesticides other than the Naphthalene products at issue here (Tr.102-03, 125). He further testified that his determination that Hing Mau was negligent was based on its failure to police its shelves and the sale of unregistered pesticides (Tr.106-07). In other testimony, he explained that the concern a small child might place a Naphthalene ball in his or her mouth extended beyond the placement of the bags on the shelves at the Hing Mau facility to the time the purchasers brought the products to their homes where the lack of proper use instructions increased the potential danger (Tr.112). Regarding the signal words "danger, warning and caution", he explained that they were related to the toxicity of the product (Tr.121). See supra note 6.
12. Dr. Linnea Hansen was accepted as an expert in pesticide toxicology (Tr.136). Dr. Hansen's affidavit is in evidence as Exhibit 17. She states that the purpose of her affidavit is to provide information as to the toxicity of Naphthalene and why the unregistered Naphthalene moth ball products at issue pose an increased risk to consumers (Id.1). She states her understanding that the two unregistered mothball products at issue were packaged in clear cellophane bags having labeling in Chinese and a small set of use and hazard directions in English on the back of the bag.. She addresses only the portion in English and points out that the bag, particularly the multicolored pastel (green, pink and yellow) balls, have an appearance very similar to candy.(Affidavit at 2). Referring to the importance of labeling, she asserts that labels of pesticides are the sole source of use and hazard information to consumers. She says that label language and use directions are based on an evaluation of toxicity and exposure data for active ingredients. She opines

that, if insufficient information is provided on the label, the risk of misuse or accidental poisoning is increased. First Aid treatment information is provided [on the labels of registered pesticides] in the event of accidental exposure. On cross-examination, she acknowledged that the Agency had no information linking [proper] labeling to fewer exposures and injuries to children or improper labeling to increased exposures (Tr.166-67).

13. Describing the toxicity of Naphthalene, Dr. Hansen opined that Naphthalene has the potential to cause serious human health effects (Tr.142). Relying, inter alia, on an EPA Integrated Risk Information System (IRIS) Summary (Exh 11) she explains that, in humans, exposure to Naphthalene may result in symptoms such as nausea, vomiting, headache, lethargy, confusion and in cases of severe poisoning, death (Affidavit at 2). She asserts that clinical findings of poisoning from exposure to Naphthalene reported in humans are quite-well documented. She testified Naphthalene may cause irritation to the skin and eye upon contact and that a potential life threatening effect of Naphthalene is induction of hemolytic anemia which may result from exposure by any route.⁸ She explained that glucose-6-phosphate dehydrogenase (G6PD) is an enzyme in the red blood cells that helps protect from certain types of injury and that affected individuals may show increased sensitivity to certain compounds, including Naphthalene. Pointing to a recent National Toxicology Program (NTP) study on rats, Dr. Hansen testified that an increase in the incidence of two different kinds of nasal cell tumors was observed and, although she indicated that these types of tumors were considered to be rare, she opined that when the Agency reconsiders Naphthalene for possible carcinogenicity, it would be classified as a possible human carcinogen.
14. Table 2 in Dr. Hanen's affidavit is a Summary of Published Reports of Naphthalene Poisoning, divided as to "Oral exposure or a combination oral/inhalation exposure" and "Inhalation exposure or combination inhalation/dermal exposure" the earliest of which is 1951 and the latest of which is 2000 (Tr. 167-68). Reported poisoning incidents are not confined to the United States, but included incidents occurring in Greece, Germany, and Japan. The 1951 incident reported under the combination "inhalation/dermal exposure" concerned the death of an infant due to exposure to Naphthalene from diapers stored in Naphthalene. An incident in 1963, which apparently occurred in Greece, states that acute hemolytic anemia developed in 21 infants also exposed to Naphthalene from diapers stored in Naphthalene of which two died. Other poisoning incidents, reported under the "combination oral/inhalation" exposure, resulting in death were of a six-year old child who consumed about 2 g of Naphthalene over two days and of a child, age not provided,

⁸.Tr. 144-45; Affidavit at 2. Although Naphthalene-induced hemolytic anemia can occur in any population, Dr. Hansen states, that in practice, it is most commonly observed in persons lacking the enzyme glucose-6-phosphate dehydrogenase (G6PD) in their red blood cells. She points out that this inherited condition is observed primarily in males of African, Mediterranean or Asian descent (Tr.152).

who consumed 5 g of Naphthalene, reported in 1960 and 1987, respectively. While this a limited number of deaths over a 49-year period, Dr. Hansen emphasized that the sample was limited and that not all deaths from chemicals are reported (Tr.170). Other poisoning incidents resulting from Naphthalene exposure, reported in Table 2, include hemolytic anemia in infants, children and adults.

15. Referring to a Toxic Exposure Surveillance System database maintained by the American Association of Poison Control Centers, Dr. Hansen testified that Naphthalene poisoning or exposure was reported on a fairly high basis and that Naphthalene exposure might constitute 0.1% of all reported poisoning exposure categories (Tr. 149-50). In 1999, there were 1,767 reported exposure incidents to Naphthalene of which 1,744 were unintentional (Affidavit at 4). She pointed out that approximately 77% of these exposures involved young children under the age of six. Most of these exposures had no significant outcome or only minor clinical effects and no mortality was reported. She stated, however, that there were 22 cases of moderate severity and four of major severity. Although the majority of exposures did not result in serious illness, she emphasized that the data nonetheless indicate that Naphthalene has the potential to cause significant toxicity in humans (Id).
16. Dr. Hansen testified that Naphthalene is in Toxicity Category II which means that the signal word required on the label is “Warning” (Tr.156). She explained that a user of Naphthalene should be aware that Naphthalene can be harmful or even fatal, if ingested or inhaled; that avoiding inhalation during use can be accomplished by keeping the product in a closed container; because the product is orally toxic, you should wash your hands after touching the product; clothing exposed to Naphthalene should not be worn without being thoroughly aired and cleaned; that there should be a prominent warning on the label to keep away from children; and, in the event of accidental exposure, users should know some immediate or First Aid that could be undertaken until professional medical assistance was obtained (Tr. 156-57). She also noted that users should know how much to use so as not to risk overexposure and not to re-use the packaging.
17. Attachment B to Dr. Hansen’s affidavit sets forth Key Points as to the inadequacy of the labels and packaging of Naphthalene No . 108 [225] and Refined Naphthalene Ball She notes that in the Precautionary Statements, the signal word should be “Warning” instead of “Caution”; that there are no statements of potential hazards from use; that there are no First Aid or physician directions information; and that the warning to keep the product away from children is not prominent. Concerning Instructions for Use and Disposal, she points out that there are no instructions on how much product to use; that there are no use restrictions (storage in airtight containers); no post application directions (airing and cleaning stored items) and that storage and disposal instructions are inadequate. Concerning packaging of the product, she states that the products look like candy; that the clear cellophane bags provide easy viewing and access to children; and that label visibility is reduced by printing directly on the bag. She opined that the packaging of the products at issue here was an attractive hazard to children (Tr. 157).

18. On cross-examination, Dr. Hansen acknowledged that she could not say whether any of the 1,767 reported cases of Naphthalene exposure in 1999 resulted in hemolytic anemia, jaundice, kidney failure, or any other clinical condition, because accumulating such data was beyond the scope of the article or report (Tr.158-59). She pointed out, however, that because hemolytic anemia is a well documented result of Naphthalene poisoning, she would presume that some of the symptoms reported in the 22 outcomes of moderate severity and the four cases of major severity were of hemolytic anemia. Additionally, she acknowledged that out of the 1,767 reported cases of Naphthalene exposure in 1999, there were no mortalities and less than 0.1 of one percent had outcomes of moderate severity (Tr. 161). Although she could not describe with specificity outcomes [clinical symptoms] of moderate severity, she explained that major severity would be hospitalization and/or a life-threatening illness. She agreed that a very small percentage of reported actual Naphthalene exposures in 1999 resulted in any degree of severity whatsoever. However, she emphasized that the majority of [Naphthalene] products used in this Country were registered with the Agency, and hence, would have proper labeling (Tr.162). Asked whether there was any data reflecting how many of the reported instances of Naphthalene exposure in 1999 involved unregistered or improperly labeled products, she replied in the negative, stating that such information is not recorded by the Poison Control Centers or otherwise available to the Agency (Tr.165-66, 167). Asked whether a deficiently labeled or packaged product would pose an [increased] risk of Naphthalene exposure, she opined that it was not reasonable to assume that most people know what Naphthalene is and that without [appropriate labeling] the consumer would have no way of knowing [proper handling and use] (Tr.185-86). She pointed out that the Office of Pesticide Programs has developed labeling and where it is not sufficient to protect an individual from bad effects, the label must be modified with a use pattern.
19. Mr. Daniel Peacock is a biologist in the Registration Division of the Office of Pesticide Programs of the U.S. EPA (Tr. 187). His affidavit is in evidence as Exhibit 18. Mr. Peacock has been employed by EPA in the Registration Division since 1973 and his primary duties involve [review of applications] for registration of pesticides under FIFRA. In addition to his extensive experience in reviewing applications for pesticide registration, he estimated that he had conducted 6,000 label reviews and testified that had been extensively involved in developing format labels for products such as the pesticides at issue here (Tr.188-89). He explained that the purpose of pesticide registration was to assure that pesticides are effective and would not pose unreasonable adverse effects upon man or the environment (Tr. 190). He stated the requirements for pesticide registration included an application describing packaging and other basic information, a confidential statement of formula which would indicate active and inert ingredients, data supporting the registration, [proposed] labeling, and assurance that the product was properly packaged (Tr. 191). He pointed out that products for residential use and meeting toxicity criteria required "child-resistant packaging" (Tr.191-92). He had reviewed the color photographs of Naphthalene 108 and Refined Naphthalene Ball (Exh

16) and concluded that the requirement for child-resistant packaging was triggered, because the product was historically used in and around the home and because one of the toxicity criteria is packaging and the clear cellophane wrapper would likely attract children (Tr. 192-93). He opined that the deficiencies in packaging of the products at issue here were very serious, that the labels here clearly differed from the labels on registered products and that he knew of no registered products which were packaged in cellophane (Tr.196). He considered that it was irresponsible to market a [Naphthalene] product which looked like candy[in a cellophane package].

20. Describing the requirements of a legal pesticide label, Mr Peacock testified that this would include a clear ingredient statement on the front label, the proper signal word based on data on the front panel, correct precautionary statements which are based on data, First Aid or practical treatment statement, a note to physician, information on proper use, a misuse statement⁹, use directions, i.e., airtight containers, statements such as “avoid inhalation exposure” which this product did not have, how to properly store the product and avoid unnecessary exposure of your child and, finally, how to dispose of the product (Tr.197). He also mentioned that the EPA Registration Number and the Establishment Number were required to be on the label. Mr. Peacock stated that about four years ago he developed a format label for Naphthalene End-Use Products (Tr.199). This label is in evidence as Exhibit 8 and also as an attachment to his affidavit (Exh 13). He explained that when an application for a Naphthalene based product came across his desk he compared the proposed label with the format label to determine any deficiencies (Tr. 200). Comparing the format label with the labels on the products at issue here, he pointed out that the instant labels used the wrong signal word, “caution” instead of “warning”; that the signal word should have been on the front panel where it would draw attention to the relative hazards of the product., that the labels here lacked basic warning statements. e.g. “May be fatal if inhaled”, “Harmful if swallowed”, wash [contaminated] clothing prior to use or re-use; and that the labels contained only a partial ingredient statement (Tr.203-05). Mr. Peacock’s second affidavit, executed on October 29, 2002, is in evidence as Exhibit 18, and has as an attachment, a document entitled “Deficiencies in Labels of Unregistered Products Naphthalene No. 108 and Refined Naphthalene Ball and Their Significance”. This document prepared by Mr. Peacock lists the deficiencies in the labels of the products at issue here as compared with the format label in accordance with his testimony cited above, includes additional deficiencies and his opinion as to the significance of the deficiencies.
21. Respondent’s sole witness was Ms. Maria Sam, who described Hing Mau, Inc as a “mom and pop” grocery store and herself as office manager on November 30, 1999 (Tr.225-26). Hing Mau, Inc is a Hawaiian corporation owned by her parents. She testified that her primary duties related to dealing with what she referred to as the

⁹. It is a violation of Federal law to use this product in a manner inconsistent with its labeling (40 C.F.R. § 156.10(i)(2)(ii)).

“English-speaking situation” as her parents, who had come to Hawaii from Viet Nam in 1975, were unable to communicate in English well. She estimated that 99% or more of the clientele or customers of Hing Mau spoke Chinese rather than English (Tr. 227). She was not involved in stocking shelves or examining incoming merchandise. She estimated that Hing Mau stocked five thousand to six thousand different items for sale in its store and stated that it maintained a warehouse about seven miles from the store (Tr.227-28).

22. Describing events on November 30, 1999, Ms. Sam referred to a visit from an official (Steven Ogata) of the Hawaii Department of Agriculture (Tr. 228-29). She testified that he told her that he was there to inspect a mothball product about which he had received some sort of report [complaint] and that these product(s) were not registered with EPA (Tr. 233). This was her first indication that this particular product was being sold (Tr.229). Examining enlargements (Exhs 19 and 20) of color photos of Naphthalene 108 [225] and Refined Naphthalene Ball (Exh 16), she testified that she was able to read some of the Chinese characters on the labels which meant “stink ball” (Tr. 229-31) She affirmed that these were the products called to her attention by Mr. Ogata and that the products were removed from the shelves immediately (Tr.232-33). She indicated that the products removed from the shelves were still in the storage area awaiting instructions from EPA. She emphatically denied ever offering the products for sale from November 30, 1999, to the date of the hearing and pointed out that Mr. Ogata did not find any of these products on the shelves at Hing Mau in inspections subsequent to November 30, 1999 (Tr.234).
23. Ms. Sam testified that she had difficulty locating the EPA regulations Hing Mau was alleged to have violated on the EPA website (Tr.235-36). She further testified that she did not know that these products were considered to be pesticides and did not know whether anyone else at Hing Mau was aware of that fact. Asked on cross-examination, whether other Hing Mau employees examined merchandise at the warehouse to determine whether it was registered with EPA, and whether they were aware of what a pesticide was, she replied that in general they knew what pesticides are (Tr. 239).

Conclusions

1. “Naphthalene 108 [225]” and “Refined Naphthalene Ball” are pesticides, because their purpose is pesticidal and pesticidal claims were made on the packaging and labeling of the products
2. The products referred to in the preceding paragraph were on the shelves at the Hing Mau retail store in Honolulu, Hawaii on November 30, 1999, and thus sold or offered for sale on that date. These products were not registered with EPA. Hing Mau, Inc. violated FIFRA § 12(a)(1)(A), which provides that it is unlawful for any person in any State to distribute or sell any pesticide which is not registered.. The sale or offering for sale of two unregistered pesticides constitutes separate violations (offenses) for which separate penalties may be assessed in

accordance with FIFRA § 14(a)(1).

3. The Enforcement Response Policy (ERP) provides an appropriate method of determining the penalty. The penalty proposed by Complainant is based upon the contention that Hing Mau is a Category I size of business, that is sales in excess of \$1 million. The evidence, however, reflects and we have found that Hing Mau is a Category II size of business, that is sales from \$300,000 to \$1 million, but not in excess of \$1 million. An appropriate penalty is thus \$4,400 per violation less 10%, because the products were immediately removed from the shelves when the violation was discovered, resulting in a total penalty of \$7,920.

Discussion

I. Naphthalene 108 (225) and Refined Naphthalene Ball are Pesticides.

Cellophane packaging or bags containing Naphthalene 108 [225] and Refined Naphthalene Ball contained printing or labeling stating: "This product is made of refined naphthalene which has resistance function against insect, mildew and bad smell." FIFRA § 2(u) defines a "pesticide" in part as meaning any "(1) substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest;...."; FIFRA § 2(t) defines "pest" as including "insects and fungi"(mildew is a form of fungi); and, in common usage "resist" or "resistance function" means "to strive against, oppose, repel or ward off". Webster's Third New International Dictionary (1981) It is, therefore, concluded that Naphthalene 108 (225) and Refined Naphthalene Ball are pesticides. Moreover, it should be noted that the regulation (40 C.F.R. § 152. 15), entitled "Pesticide products required to be registered", provides in pertinent part that:

"A substance is considered to be for a pesticidal purpose, and thus to be a pesticide requiring registration, if (a) the person who distributes or sells the pesticide claims, states, or implies by labeling or otherwise (1) that the substance (either by itself or in combination with any other substance) can or should be used as a pesticide."

II. The Pesticides Naphthalene 108 (225) and Refined Naphthalene Ball Were Not Registered with EPA and Were Sold or Offered for Sale by Hing Mau

There is no allegation and no evidence that the pesticides referred to above were registered with EPA and thus, no issue that the pesticides were not so registered. The only evidence of actual sales of the pesticides is an inference rising from the fact that the pesticides were received in cartons containing 100 bags of each product and that only 78 bags of Refined Naphthalene 108 and 90 Bags of Refined Naphthane Ball were on hand at the time of the inspection of the Hing Mau retail establishment on November 30, 1999. Nevertheless, the evidence is clear that the pesticides were on shelving available to the public at the Hing Mau

retail establishment on November 30, 1999, and thus offered for sale. FIFRA § 2(g)(g) defines the term “distribute or sell” as meaning to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. It is therefore clear that selling or offering to sell an unregistered pesticide constitutes the “sale or distribution” of such a pesticide and thus, a violation of FIFRA § 12(a)(1)(A). Because there were two pesticidal products offered for sale, there were two violations of the Act.

III Determination of Penalty

In determining the proposed penalty, Complainant followed the ERP (findings 7 and 8). The ERP states at 18 that: computation of the penalty amount is a five stage process: (1) determination of the gravity or “level” of the violation using Appendix A of this ERP; (2) determination of the size of business category for the violator, found in Table 2; (3) use of the FIFRA civil penalty matrices found in Table 1 to determine the dollar amount associated with the gravity level of violation and the size of business category of the violator; (4) further gravity adjustments of the base penalty in consideration of the specific characteristics of the pesticide involved, the actual or potential harm to human health and/or the environment, the compliance history of the violator, and the culpability of the violator, using the “Gravity Adjustment Criteria” found in Appendix B; and (5) consideration of the effect that payment of the total civil penalty will have on the violator’s ability to continue in business, in accordance with the criteria established in this ERP.

Appendix A-1 of the ERP reflects that the gravity or severity level for the sale of an unregistered pesticide is two. . The next step is to apply this gravity level to the matrix at 19-A of the ERP, which indicates that the maximum or base penalty for a Category I size of business, Level 2 gravity is \$5,500 per violation. A Category I size of business, however, applies only to businesses having gross revenues in excess of \$1 million and here the D & B report reflects that Hing Mau’s annual sales volume is \$1 million, but not more (finding 7). Hing Mau maintains that it should be placed in Category II for purposes of the ERP, sales of \$300,001 to \$1,000,000 (Brief at 3, 4; Reply Brief at 1, 2). The Reference USA Document, upon which Complainant relies, indicates that Hing Mau’s estimated sales are \$1 million to \$2.499 million (finding 7). Sales in excess of \$1 million are on the face of the Document merely an estimate. Moreover, the Document contains a caveat as to its accuracy (supra note 5) and, while Complainant asserts that it has made a prima facie case that the relief sought is appropriate, the burden of proving that assertion is on Complainant (Consolidated Rule 22.24). Complainant hasn’t shown that the accuracy of the Reference USA Document is to be preferred over that of the more well-known D & B.¹⁰ Therefore, Hing Mau is placed in Category II size of business, sales or revenues of

¹⁰ The Reference USA Document also refers to a second Hing Mau, Inc store at 2312 Kamehamheha Highway, Honolulu, Hawaii, which has estimated sales of \$500,000 to \$999,999. The only other evidence of a second establishment maintained by Hing Mau, Inc is Ms. Sam’s

(continued...)

\$300,001 to \$ 1,000,000, for penalty calculation purposes, which results in a base penalty of \$4,400 per violation (ERP at 19-A).

The next step in the penalty determination is to apply adjustment factors which are given numerical values and totaled. These factors are: (1) pesticide toxicity; (2) human harm; (3) environmental harm; (4) compliance history; and (5) culpability (finding 8). Mr. Lee, who calculated the proposed penalty, assigned the lowest value of 1 to pesticide toxicity, that is Toxicity Categories II through IV, signal word “Warning” and “Caution”, no known chronic effects.¹¹ Notwithstanding this assessment of the toxicity of Naphthalene, he considered that there was a potential for serious or widespread harm to human health, based in part on the inherent toxicity of Naphthalene, deficiencies in the labels in that labels of registered products would inform users of product ingredients, physical and chemical hazards and use, storage, and disposal instructions (finding 8) He assigned a value of 3 to the harm to human health factor.¹² . He considered that the actual or potential for harm to the environment was minor and neither widespread nor substantial, and he assigned the lowest value of 1 to that factor. Because Hing Mau had no prior FIFRA violations, a value of 0 was assigned to compliance history; and because he considered that Hing Mau was negligent, Mr. Lee assigned a value of 2 to culpability (findings 8 and 9). As indicated (finding 10), these values total 7, which under the ERP call for a 10% reduction in the matrix value.

Hing Mau contends that the total gravity adjustment value should be three rather than seven as proposed by Complainant (Brief at 5; Reply Brief at 2 et seq.). Accepting Complainant’s characterization of a value of 1 for pesticide toxicity, 1 for environmental harm,

¹⁰(...continued)

testimony that it maintained a warehouse approximately seven miles from the Maunakea Street store (finding 21). Moreover, the relationship, if any, of this alleged store on Kamehamheha Street with the Hing Mau, Inc. store on Maunakea Street at issue here has not been shown and the Dun & Brad report describes Hing Mau, Inc as a “single location type”. The existence of a second retail store owned or operated by Hing Mau, Inc has not been established and will not be considered in determining its size of business category.

¹¹ ERP, Appendix B-1; 40 C.F.R. § 156.62. This is based on an LD₅₀ for Naphthalene at a dose of >50 thru 500 mg/kg, which in turn requires precautionary statements: May be fatal if swallowed , [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing, and a First Aid statement. 40 C.F.R. § 156.76.

¹² .Footnotes to Appendix B of the ERP at B-3 define “serious or widespread harm” and “ minor harm” as follows:

2. For purposes of this ERP, serious or widespread harm refers to actual or potential harm which does not meet the parameters of minor harm, as described. below.

3. For the purposes of this ERP, minor harm refers to actual or potential harm, which is, or would be of short duration, no lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss.

and zero for compliance history, Hing Mau reaches the total of 3 by assigning to “harm to human health” a value of 1, that is “minor potential or actual harm to human health, neither serious nor widespread” and a value of zero to “culpability” (Brief at 15; Reply Brief at 2 et seq.). Hing Mau asserts that Complainant has failed to meet its burden that Naphthalene poses serious and widespread harm to human health (Id.) Specifically, Hing Mau says that harm to human health from Naphthalene is not widespread, that hemolytic anemia is not a widespread risk of Naphthalene, and that the notion that Naphthalene is carcinogenic is pure speculation (Reply Brief at 2, 6 et seq.). Under the ERP, a total gravity value of 3 or below, calls for no action, a Notice of Warning, or a 50% reduction of matrix value (Id. 22, Table 3). The 50% reduction in matrix value option is recommended where there are multiple violations.

The Appendix B criteria for a toxicity value of 1 are Toxicity Categories II through IV, Signal Word “Warning” and “Caution,” “no known chronic effects”¹³. The fact that Naphthalene is in Toxicity Category II, requiring the signal word “Warning” in accordance with 40 C.F.R. § 156.64, does not in and of itself preclude a finding of “minor harm” harm to human health and a gravity value of 1 for the purpose of the ERP. “Serious or widespread harm” in the Appendix B Footnotes is any actual or potential harm which does not meet the parameters of “minor harm” which, in turn, requires that the harm be of short duration, no lasting effects or permanent damage, effects are easily reversible, and harm does not, or would not result in significant monetary loss (supra note 12). The same definitions of “serious or widespread harm” and “minor harm” apply to environmental harm and, while Complainant apparently had little difficulty in determining that both toxicity and environmental harm warranted adjustment values of 1, there is no requirement that the gravity adjustment values for environmental harm and harm to human health be identical. In fact, given the normal household use of Naphthalene in moth balls, it is at least logical that the potential for environmental harm and harm to human health would differ. Less readily explainable is the fact that, although the value of 3 assigned to human harm was based in part on label deficiencies (finding 8), the same deficiencies did not preclude a value of 1 for environmental harm.¹⁴ Nevertheless, it is concluded that, on this record, Naphthalene cannot be said to have no lasting effects or permanent damage. Consequently, it does not meet the parameters of “minor harm” and will be placed in the category of “serious or widespread harm” to human health in accordance with the Appendix B footnotes.

¹³ “Chronic” is defined as “marked by long duration or frequent recurrence”.. Webster’s Third New International Dictionary (1981)

¹⁴ . Hing Mau attacks as “at best speculative” , Complainant’s assertion that deficient labeling of the pesticides creates or may create serious risks to human health (Reply Brief at 8). This argument is contrary to the central premise of FIFRA, which is that users, handlers, and others coming into contact with a pesticide will read and comply with the label. Accordingly, evidence and arguments that properly labeled pesticides do not serve to protect the public or conversely, that improperly labeled pesticides do not increase risks to the public from use of pesticides, will not be considered in an enforcement proceeding.

As noted above, Hing Mau contends that harm to human health from Naphthalene is not widespread and that hemolytic anemia is not a widespread risk of Naphthalene. The record reflects, however, that hemolytic anemia is a well documented result of Naphthalene poisoning and can occur in any population (finding 13). While in practice the condition is most commonly observed in males of African, Mediterranean, and Asian descent, the condition is nevertheless within the definition of "widespread" as "widely extended or spread out",¹⁵ however thinly it may be spread. Moreover, the fact that as many as .1% of all poisonings reported to American Poison Control Centers may result from exposure to Naphthalene (finding 15), is evidence that exposures to Naphthalene and resulting poisonings, are not uncommon. It is true that of 1,767 instances of Naphthalene exposure reported to Poison Control Centers in 1999, most had no significant outcome or only minor clinical effects and no mortality was reported (finding 15). Additionally, most of these exposures (77%) involved young children under the age of six, the majority of reported exposures did not result in serious illness, and there were only 22 instances of moderate severity and only four cases of major severity were reported. While these data would arguably support a finding of "minor potential or actual harm to human health, neither serious nor widespread", it has already been determined that Naphthalene does not on this record meet the Appendix B definition of minor harm, and thus by definition must be within "potential serious and widespread harm"

Lastly, Hing Mau asserts that the violation was neither knowing or willful, and did not result from negligence, and that Respondent took steps to correct the violation as soon as the violation was called to its attention, Thus, in accordance with Appendix B-2 of the ERP, Hing Mau says the "culpability" level should be zero rather than 2 assigned by Complainant (Brief at 5). As indicated (finding 11), the determination that Hing Mau was negligent was based upon the sales of an unregistered pesticides and its failure to police its shelves.

"Negligence" or "negligent" is not defined in the ERP and it may be assumed that the term is used in its ordinary sense, which is that "negligent" is characterized by a person's failure to exercise the degree of care that someone of ordinary prudence would exercise under the same circumstances. Black's Law Dictionary 1058(7th ed. 1999).

Here, Ms. Sam, and by extension Hing Mau, did not know that the Naphthalene based products at issue here were considered to be pesticides (finding 23). Hing Mau concludes from this testimony that lay business people have no idea that a moth ball is a pesticide (Brief at 14). Assuming that Ms. Sam is typical or representative of "lay business people", and there is no reason to believe otherwise, this tends to support Hing Mau's contention that it was not negligent in failing to realize that Naphthalene No. 108 [225] and Refined Naphthalene Ball were pesticides..¹⁶ Aquarium Products (supra note 16) is not controlling here, because Naphthalene is

¹⁵. Webster's Third New International Dictionary (1981).

¹⁶. Cf. Aquarium Products Inc, IF & R Docket No. III-439-C, 1995 EPA LEXIS 87
(continued...)

more toxic than the oxygenator at issue there and the primary purpose of moth balls is clearly pesticidal, i.e., to “ prevent, destroy, repel, or mitigate”moths. It is concluded that in failing to realize that the Naphthalene balls at issue here were pesticides Hing Mau’s conduct fell below that of a reasonably prudent person under the circumstances and thus, that Hing Mau was negligent. Moreover, the labeling which did not contain adequate use, storage and disposal instructions and the fact that Naphthalene balls in cellophane bags, some of which looked like candy, were placed on the lowest shelving at the Hing Mau store and thus, available to small children, may not be ignored in determining whether Hing Mau’s conduct was that of a reasonable and prudent person. Hing Mau’s argument that there are no FIFRA regulations on the appearance or display of Naphthalene and that nothing establishes that it violated FIFRA by placing Naphthalene on the bottom shelf at its store or by selling Naphthalene that looked like candy (Reply Brief at 11), thus misses the point, because the issue for the purpose of applying the ERP is whether Hing Mau’s conduct met that of a reasonable and prudent person under the circumstances. It is concluded that it did not.

ERP gravity adjustment values are thus as follows:

Toxicity	1
Harm to Human Health	3
Environmental Harm	1
Compliance History	0
Culpability	<u>2</u>
	7

In accordance with Table 3 of the ERP, a gravity value of 7 results in a 10% reduction in the matrix penalty value. The total penalty is thus \$4,400 - 10%=\$3960 x 2 (violations)=\$7,920.

Hing Mau has stipulated that its “ability to pay”, or, in the language of the statute “ the effect of the penalty on the person’s [Hing Mau’s] ability to continue in business”, is not at issue (Tr.11, 12; Reply Brief at 2).

¹⁶(...continued)

(ALJ, June 30, 1995)(an ERP culpability value of zero was assigned where the evidence established that respondent had no reason to believe that an oxygenator, designed to promote a desirable environment for fish and plant life in an aquarium, the pesticidal effects of which were incidental, would be regarded by EPA as a pesticide).

IV. Order

The violations alleged in the complaint having been established, Hing Mau, Inc. is assessed a civil penalty of \$3,960 for each violation for a total of \$7,920, pursuant to Section 14 of FIFRA, 7 U.S.C. § 1361.¹⁷ Payment of the full amount of the penalty shall be made by sending or delivering a cashier's or certified check payable to the Treasurer of the United States to the following address within 60 days of the date of this order:

Mellon National Bank
EPA Region 9 (Regional Hearing Clerk)
P.O. Box 360863M
Pittsburgh, PA, 15251

Dated this 25th day of August, 2003.

/s/ _____
Spencer T. Nissen
Administrative Law Judge

¹⁷. Unless appealed to the Environmental Appeals Board (EAB) in accordance with Rule 22.30 (40 C.F.R. Part 22), or unless the EAB elects to review this decision sua sponte as therein provided, this decision will become the final order of the EAB and of the Agency in accordance with Rule 22.27(c).