5/27/94

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Ignatios Hadjiloukas,	)	**Docket No. I.F.& R.-III-358-C**
d/b/a Tradig Company	)	
and	)	
J. L. Hoffman Co.,	)	
Inc.,	)	
	)	
Respondents	)	

Federal Insecticide, Fungicide and Rodenticide Act - Penalties - Gravity of Violations -

Where evidence established that violations resulted from Respondent's good faith understanding that his actions were in accordance with the law and the violations did not materially increase the risks of handling the pesticide at issue, the FIFRA penalty guideline was disregarded and a substantial reduction in the penalty proposed by Complainant was held to be warranted.

Appearance for Complainant:

Daniel E. Boehmcke, Esq.
Assistant Regional Counsel
U.S. EPA, Region III
Philadelphia, Pennsylvania

Appearance for Respondents:

Ignatios Hadjiloukas
Pro Se
Bethlehem, Pennsylvania

INITIAL DECISION

This proceeding under § 14(a)(1) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. § 136l(a)) was commenced by the filing of a complaint on December 21, 1988, charging Respondent, Ignatios Hadjiloukas, d/b/a Tradig Company with violations of the Act. Specifically, Respondent was charged in Counts I and II with the sale of an unregistered pesticide on February 26, 1987, and April 10, 1987, respectively; in Counts III and IV with the distribution of a misbranded pesticide on February 26 and April 10, 1987, respectively; and in Count V with the production of a pesticide in an unregistered establishment or facility. For these alleged violations, it was proposed to assess Respondent a penalty totaling $20,600.

Respondent answered, denying that Tradig Company manufactured or produced an unregistered pesticide and denying that it sold any material described in its literature, shipping documents or invoices as a pesticide. Respondent alleged that any repacking or transferring of product was performed at an EPA registered facility owned by J. L. Hoffman Co., Inc. Respondent requested a hearing.

By an order, dated June 20, 1989, Complainant's motion for leave to file an amended complaint was granted. The amended complaint added J. L. Hoffman Co., Inc. as a party respondent, included Count VI alleging the filing of a false pesticide product report and increased the proposed penalty from $20,600 to $24,850. At the hearing, however, counsel for Complainant adopted the position that Tradig Company was solely liable for the violations alleged in Counts I through V of the complaint (Tr. 11, 12). Complainant agreed to drop claims against J. L. Hoffman Co.,, Inc., including Count VI, which alleges the submission of a false pesticide production report.

A hearing on this matter was held in Philadelphia, Pennsylvania on August 18, 1992.

Based on the entire record, including the Stipulations of Fact filed by the parties,[1/] and proposed findings and brief filed by Complainant,[2/] I make the following:

[1/] Findings 1 through 8 are based on the Stipulations of Fact, Joint Exh A.

[2/] Respondent failed to submit a post-hearing brief and Complainant filed a motion for a default order on May 27, 1993. The law is, however, that actions should be decided on their merits, if possible, and entry of a default order for failure to file a post-hearing brief would seldom, if ever, be warranted. Complainant's motion for a default order is denied.

FINDINGS OF FACT

1. Respondent, Ignatios Hadjiloukas, is an individual, who at all time relevant to this action, conducted business in the Commonwealth of Pennsylvania as the "Tradig Company."

2. Respondent, J. L. Hoffman Co., Inc. is a Pennsylvania Corporation, which at all times relevant to this action conducted business in the Commonwealth of Pennsylvania. Ignatios Hadjiloukas is the president, treasurer and one of two directors of J. L. Hoffman Co., Inc.

3. On or about February 26, 1987, Tradig shipped to U.S. Chlorine, Inc., Miami, Florida, 12,000 pounds of trichloroisocyanuric acid--7 ounce tablets packed in 250-pound drums. The drums were labeled "Oniachlor 90." This trichloroisocyanuric acid had previously been purchased by Tradig from PetroKem Corporation, Patterson, New Jersey, under the label "Super Concentrated Stabilized Slow Dissolving Swimming Pool Chlorinating Giant 3" 10 Day Tablets."

4. The tablets described in the previous finding were at the time of the shipment an EPA-registered pesticide (EPA Reg. No. 2292-89). Tradig intended to sell this material, contained in drums labeled "Oniachlor 90," for a pesticidal purpose, specifically, use following repackaging by U.S.

Chlorine into the pesticide product "Sta Clear Tablets" (EPA Registration No. 2292-89-51540) as an agent for chlorination of swimming pool water, i.e., for bactericidal, fungicidal and algicidal purposes.

5. On April 10, 1987, Tradig shipped 25 250-pound drums of trichloroisocyanuric acid to U.S. Chlorine, Inc., Miami, Florida. As in the case of the February shipment referred to in previous findings, the trichloroisocyanuric acid in this shipment was made in drums labeled "Oniachlor 90." Also as in the case of the February shipment, this material was purchased by Tradig from PetroKem Corporation, Patterson, New Jersey, under the product name referred to in finding 3.

6. The product "Oniachlor 90" was not registered with EPA at any time prior to April 10, 1987, nor had Tradig submitted an application to EPA for the registration of "Oniachlor 90" prior to the mentioned date.

7. The labeling on the product "Oniachlor 90" as shipped by Tradig to U.S. Chlorine, Inc. on February 26 and April 10, 1987, did not bear the registration number of the producing establishment, did not bear any Human Hazard Signal Word, did not bear directions for use as required of pesticides, did not bear any of warnings and precautionary statements required of pesticides, did not bear an ingredient and net

weight statement, did not bear a statement of the use classification as required of pesticides, did not bear the name and address of the producer, registrant or person for whom produced and did not bear a product registration number as required of pesticides.

8. The site, 1414 North Fulton Street, Allentown, Pennsylvania, where employees of Tradig repackaged trichloroisocyanuric acid received from PetroKem into drums labeled "Oniachlor 90," which was subsequently shipped to U.S. Chlorine as detailed above, was owned and operated by J. L. Hoffman Co., Inc. as a pesticide-producing establishment, EPA Establishment No. 2136-PA-01. At no time during the calendar year 1987 was the mentioned site registered with EPA by Tradig for purposes of Tradig's product activities.

9. Photos of drums, bearing the identification "Oniachlor 90," observed during an inspection of U.S. Chlorine, Inc. on March 16, 1987, are in evidence (C's Exh 2). The drums bear the symbol for "flammable" followed by the word "oxidizer" in large letters. The photos include labels which, although difficult to read, are identical to labels on drums of trichloroisocyanuric acid as imported from France (R's Exh B), which read as follows:

Trichloroisocyanuric Acid

RISK

Contact with combustible material may cause fire.
Harmful by inhalation and if swallowed.
Irritating to eyes and skin.
Contact with water liberates chlorine and gives oxidizing and corrosive conditions.

SAFETY PRECAUTIONS

Keep container tightly closed and dry.
In case of contact with skin and eyes wash immediately with plenty of water.
In case of fire use large volume of water and avoid breathing fumes.
Keep in a cool, well ventilated place.
Clean contaminated clothing before re-wearing.
Do not leave the product within children's reach.
Do not reuse empty container.

10. Mr. Donald J. Lott, Chief of the Pesticides Management Section, EPA, Region III, testified as to the calculation of the proposed penalties. For this purpose, he used the Guidelines for Civil Penalties Under FIFRA (39 Fed. Reg. 27711, July 31, 1974) (C's Exh 11). With respect to Counts I and II, alleging the sale of an unregistered pesticide, he determined that Charge Code E1, for a non-registered product, was applicable (Tr. 47-49; Civil Penalty Assessment Worksheet, C's Exh 10). He also concluded that this was a case where Respondent had knowledge of the requirement for registration, but nevertheless, did not submit an application for registration. Because Respondent's annual gross sales were in excess of one million dollars, Respondent was placed in Category V of the

penalty schedule and a penalty of $3,200 proposed for Count I and a like amount was proposed for Count II.

11. For Count III, involving the distribution of a misbranded pesticide on February 26, 1987, Mr. Lott proposed to assess Tradig the maximum penalty for a single violation of $5,000. For Count IV, involving the distribution of a misbranded pesticide on April 10, 1987, he also proposed to assess the maximum penalty of $5,000 (Tr. 76; Civil Penalty Assessment Worksheet). He reached these conclusions by referring to the various charge codes in the penalty guideline, e.g., E2, E3, E16, E4, E5, E9 and E12. Codes E2, E3 and E16 are under the heading "Labeling Violations" and concern deficient precautionary statements, e.g., E2, lacks "Signal Word" and/or "Caution: Keep Out Of Reach Of Children." The severity of the latter violation is based on the toxicity of the material and in this instance Mr. Lott determined that the toxicity level was Line A of the penalty matrix and that missing signal word was "Danger" (Tr. 95, 96). This conclusion was based on the fact that "Danger" was the signal word on the PetroKem registration (C's Exh 7). Because Tradig was in Category V for sales purposes, this resulted in a proposed penalty of $2,800 (Tr. 98).

12. Charge Codes E3 and E16, respectively, refer to the failure of the label to bear a warning or caution statement which is necessary and, if complied with, adequate to protect

health and the environment and to the product containing a substance in quantities highly toxic to man and the label fails to bear required symbols or statements (Tr. 99, 114-15). As to Charge Code E3, Mr. Lott determined that Line A of the penalty matrix, "adverse effects highly probable," was applicable, which at sales Category V resulted in the maximum penalty of $5,000 (Tr. 100, 114). He considered that "adverse effects [were] highly probable" based on the EPA accepted label for the PetroKem product, which, inter alia, indicated that the product was toxic to fish, that it was highly corrosive, caused skin and eye damage and may be fatal, if swallowed (Tr. 103-04). He pointed out that the lack of these warnings and precautionary statements represented a significant risk to anyone handling the product whether an end-user, some one doing further packaging or transporting the product, because they would have no knowledge of steps needed to prevent unnecessary risks (Tr. 100-01). As to Charge Code E16, Mr. Lott testified that the product had already been determined to be highly toxic to man and that, in addition to the signal word "Danger," the label should have included the word "corrosive" (Tr. 109-10, 114-15). Although these failures would normally have called for a $5,000 penalty, Mr. Lott testified that he basically disregarded a penalty assessment in this instance, because the product was not

acutely toxic as to oral exposure or intake, i.e., its LD_{50} did not place it in Toxicity Category 1.

13. Charge Code E4 represents the failure of the label to contain directions for use which are necessary and, if complied with, adequate to protect health and the environment. Because the "Oniachlor 90" label did not contain any directions for use, Mr. Lott considered that this failure was likely to result in mishandling or misuse (Tr. 116-20). He determined that Line A of the penalty matrix was applicable and because Tradig was in Sales Category V, that a $5,000 penalty for each of the counts or shipments was appropriate (Tr. 121). Charge Code E5 concerns "Defective Ingredient Statements." Mr. Lott pointed out that the ingredient statement on the approved PetroKem label identified the active ingredient as "trichloro-s-triazinetrione" 99 percent and specified inert ingredients as 1 percent and available chlorine as 89 percent, while the "Oniachlor 90" label simply states "trichloroisocyanuric acid" (Tr. 122-23). He testified that ingredient statements were related to the safe handling and use of the product and that lack of proper information increased the likelihood of mishandling or misuse and some sort of injury occurring, especially when dealing with a "Tox 1" compound (Tr. 124-25). Based on the penalty matrix, he concluded that a penalty of $5,000 for each of the counts would be appropriate (Tr. 126).

14. Although, as indicated (findings 11 - 13), there were multiple misbranding violations, which would result in penalties several times the statutory maximum of $5,000, if independently assessed, only $5,000 was assessed for Count III and $5,000 for Count IV, because the FIFRA Compliance Enforcement Guidance Manual (1983) (C's Exh 16) provides that, where there are shipments of a single pesticide, multiple misbrandings are not independently assessable.[3/]

[3/] Tr. 82, 83, 128-29. The cited Guidance Manual provides at 7-50 - 7-51:

> Multiple Misbranding
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> Multiple instances of pesticide and device misbranding, however, are not independently assessable when there is a shipment of a single pesticide product. Multiple misbrandings must appear either:
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> - As lesser included charges to accompany a count of misbranding; or
> - As allegations in a single count.
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> In either case, only a single civil penalty should be assessed. The gravity of the single violation involving several label deficiencies, however, may be determined to be greater than that of a violation involving only one misbranding. Thus it may support a higher penalty than that proposed for a single misbranding. A proposed penalty may be derived by locating on the penalty matrix a figure for one of the misbranding violations and increasing that figure up to as much as $5,000. The increase would depend on the number and/or seriousness of the additional misbrandings, as well as whether they are cited as primary or lesser included charges.

15. Count V alleges that Respondent produced a pesticide in an establishment not registered with EPA and Mr. Lott determined that Charge Code E33, for which the base penalty was $4,200, applied (Tr. 129-30, 137). He reached this conclusion, because Tradig was in Category V for sales purposes and he considered that Mr. Hadjiloukas had knowledge of the registration requirement. As indicated previously (finding 8), the establishment where chlorinated tablets received from PetroKem were repackaged by employees of Tradig into drums labeled "Oniachlor 90" is owned and operated by J. L. Hoffman Co., Inc. and is an EPA registered establishment. After considering the factors listed in the first full paragraph of the second page of the penalty guidelines (39 Fed. Reg. 27712), Mr. Lott determined that no adjustments in the proposed penalty were appropriate.[4/]

[4/] Tr. 138-39. The cited para. of the guideline provides:

> (1) Factors considered in determining the proposed civil penalty. (a) Gravity of violations. One determinant of the amount of a proposed civil penalty is the gravity of the violation. The gravity of any violation is a function of (1) the potential that the act committed has to injure man or the environment; (2) the severity of such potential injury; (3) the scale and type of use anticipated; (4) the identity of the persons exposed to a risk of injury; (5) the extent to which the applicable provisions of the Act were in fact violated; (6) the particular person's history of compliance and actual knowledge of the Act; and (7) evidence of good faith in the instant circumstance.

16. In determining Respondent's gross annual sales, Mr. Lott relied on Dun & Bradstreet reports, dated May 17, 1988, April 6, 1990, and August 14, 1992 (C's Exhs 9 and 17). These reports show Tradig's gross sales were over two million dollars in each of the fiscal years 1984, 1985 and for the period January 1, 1986, to June 30, 1987. For the fiscal year ending December 31, 1988, gross sales exceeded nine million dollars. These reports indicate that information therein was provided by Ignatios Hadjiloukas. Gross sales for the fiscal years 1989 and 1990 were reported to exceed six million dollars. Called as an adverse witness by Complainant, Mr. Hadjiloukas affirmed the accuracy of these reports (Tr. 179, 181).

17. As support for his opinion that Respondent was fully aware of pesticide registration requirements, Mr. Lott pointed out that Mr. Hadjiloukas was directly associated with Tradig Company and J. L. Hoffman Co., Inc. (Tr. 50, 130-31, 136). He testified that J. L. Hoffman was a registered EPA establishment in the business of producing and packaging pesticide products and that Mr. Hadjiloukas had been involved in numerous inspections of that company by EPA or its agents. Mr. Hadjiloukas has stipulated that J. L. Hoffman Co., Inc. held an EPA establishment registration number at the time of the violations alleged in the complaint (Tr. 135). Mr. Lott referred in particular to a report of an inspection of J. L. Hoffman, conducted on

October 13, 1983, wherein Mr. Hadjiloukas was identified as representing the company (C's Exh 13). Attached to the report are copies of labels of more than a dozen pesticide products produced or formerly produced by J. L. Hoffman. A report of another inspection of J. L. Hoffman Co., Inc. conducted on February 17, 1987, is also in the record (C's Exh 15). Mr. Hadjiloukas is identified as the individual representing Hoffman.

18. A copy of an EPA approved label for a product identified as "Nissan T.C.C.A. Granular," EPA Reg. No. 33906-6, is in evidence (R's Exh C). The ingredient statement describes the product as follows:

Active Ingredient
Trichloro S Triazinetrione 96.2%
(Trichloroisocyanuric Acid)
Available Chlorine 88%

The label contains the Signal Word "Warning" and "Keep Out Of Reach Of Children." The label indicates that the product is an "oxidizing agent," contains the word "Caution" followed by "For Manufacturing, Repackaging or Reformulating disinfectants, Sanitizers and Algicides." Mr. Lott attributed the fact that there was considerably less detail as to warnings or precautionary statements on

the Nissan label[5/] than on the PetroKem label to the fact the PetroKem product was marketed to the end-user, while the Nissan product was for the purpose of manufacturing, repackaging or reformulating.[6/] Regarding the risks faced by employees of U.S. Chlorine upon receipt of a drum labeled "Oniachlor 90" as contrasted with a drum bearing the "abbreviated" Nissan label, he maintained that, even though the active ingredient may be the same, the products

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[5/] The label on the Nissan product provides:

Storage:

Oxidizing material; avoid contact with combustible materials. In the event of fire, accidental contact or spillage, flood promptly with large amounts of water and wash to sewer. Store in cool, dry, well-ventilated area. Avoid moisture contamination.

Thermal Decomposition:

Keep away from all sources of heat, flames or sparks. At elevated temperatures (above about 325°F) a self-propagating thermal decomposition may occur with resultant irritating and toxic gases. In the event of thermal decomposition, flood with large quantities of water.

Personal Safety:

Not for personal use, internally or externally. In case of contact, remove material and flood skin or eyes with cold water for at least 15 minutes. For eyes, call physician. Harmful if swallowed. Avoid contact with skin, eyes, or clothing.
Do not breathe fumes, dust, or spray mist. Wear gloves and goggles when handling.

[6/] Tr. 148. There is evidence that product received by U.S. Chlorine directly from PetroKem is packaged in containers appropriate for end-users (Inspection Report, C's Exh 2).

were completely different (Tr. 149-50). He pointed out that the percentage of active and inert ingredients were not the same and stated that the data submitted in support of the Nissan registration apparently differed from that submitted as part of the PetroKem label. He concluded that, for whatever reason, EPA's review required more strict label language and expanded precautions than on the Nissan label.

19. Mr. Lott characterized Tradig as a broker in the sale of the PetroKem product to U.S. Chlorine and, because there was no evidence that Tradig had an agreement with PetroKem to perform repackaging, he concluded that Tradig was not acting as an agent for PetroKem in this regard.[1/] He testified that, if PetroKem were selling a product to U.S. Chlorine, through Tradig or some other broker, which was specifically intended for the purpose of manufacturing, repackaging, relabeling or reformulating, he would assume that an abbreviated label [such as the Nissan label] would

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[1/] Tr. 148-49. There is reason to question the characterization of Tradig as a broker, because brokers by definition are agents who arrange or facilitate sales, but do not ordinarily acquire title to property which is the subject of the sale. Here, the evidence is that Tradig purchased the tablets from PetroKem (finding 3), which supports the conclusion that Tradig was not operating as an agent for PetroKem in repackaging the product. An affidavit by Mr. Steven Sidelko, President of U.S. Chlorine states, however, that U.S. Chlorine repackages tablets received in drums labeled "Oniachlor 90" into different size containers to meet customer demand (C's Exh 2 at 24). The affidavit further states that raw material is received through Tradig who represents PetroKem.

be appropriate (Tr. 151). He explained, however, that the product manufactured [repackaged] by U.S. Chlorine was produced under a supplemental registration from PetroKem and that, with few exceptions, the label on a supplementally registered product was required to be identical to that on the base registration of the product.[8/] He concluded that the full label as originally on the PetroKem containers was the appropriate label [for the product shipped to U.S. Chlorine by Tradig].[9/]

20. Mr. Lott opined that it would be illegal for PetroKem to ship to U.S. Chlorine product under the Nissan label, because the Nissan label was not, to his knowledge, identified as a source of the active ingredient used for the product registered as 2296-89 (Tr. 156). He explained that in order for U.S. Chlorine to obtain a supplemental registration, the product had to be Registration No. 2292-89 or it had to be a PetroKem manufacturing label which had

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[8/] Tr. 151-52. The exceptions are that the EPA establishment number will be different, the registration number will include the supplemental distributor indicator, the net weight statement may change and the brand name of the product may change.

[9/] Although the parties have stipulated that Tradig purchased the product from PetroKem under the label "Super Concentrated Stabilized Slow Dissolving Swimming Pool Chlorinating Giant 3^{11} 10 Day Tablets" (finding 3), Mr. Hadjiloukas denied that the PetroKem label as approved by EPA (C's Exh 2 at 15-19) was on product Tradig received from PetroKem (Tr. 189). In the course of cross-examining Mr. Lott, Mr. Hadjiloukas indicated that the drums received from PetroKem contained a Nissan label (Tr. 161).

been identified as a source of the active ingredient for the product 2292-89 (Tr. 159). According to Mr. Hadjiloukas, there are five or six producers of trichloroisocyanuric acid in the world. He referred to an ad hoc committee of manufacturers and to an agreement whereby product of any of the producers may be used interchangeably in support of a basic registration (Tr. 156-57). Mr. Lott testified that this would be legal as long as these producers were identified as alternative sources in the confidential statement submitted in support of the registration.

21. Mr. Lott pointed out that the label on the product as it arrived at the Tradig facility was different than the label as it left Tradig's facility and that there was repackaging involved. Because the repackaging was not authorized by PetroKem, it was a distinct independent activity of Tradig, which required registration, if the product is sold for use as a pesticide (Tr. 159-60, 168-70). Mr. Lott asserted that in this instance the product was being sold for the development of a pesticide, which is a pesticidal purpose.

22. Mr. Hadjiloukas acknowledged discussing with inspectors during the various inspections of J. L. Hoffman Co., Inc. the requirements of FIFRA that pesticides be registered (Tr. 183). He denied, however, that these discussions extended to "how to go about" FIFRA registration. Mr. Hadjiloukas also acknowledged that certain of the

pesticides referred to in the report of inspection of J. L. Hoffman Co., Inc. conducted on October 13, 1983 (finding 17), were supplementally registered products, e.g., concentrated Pool Chlorinating tablets and Dry Pool Chlorinator (Tr. 184). A copy of the label of "concentrated Pool Chlorinating tablets," EPA Reg. No. 2292-89-2136, is attached to the report of inspection of J. L. Hoffman Co., Inc. conducted on February 17, 1987 (C's Exh 15 at 7). Mr. Hadjiloukas testified that the base registration for that product was held by PetroKem and that he made the arrangements for and obtained the supplemental registration (Tr. 185-87). He recalled that this registration was in effect from 1986 until 1988. His understanding of the law prior to February 1987 was that, if a facility were manufacturing a pesticide for sale to the public with an end-use label, the facility was required to be registered.[10/]

[10/] Tr. 191. FIFRA § 3(b) permitted the transfer of unregistered pesticides between registered establishments owned or operated by the same producer for packaging or formulating purposes. It should be noted that the Agency implemented an amendment to FIFRA § 7, P.L. 95-396 (September 30, 1978), in 1988, which for the first time required that producers of active ingredients register their establishments. See 53 Fed. Reg. 35056 (September 8, 1988). The preamble to the rule specified that producers of active ingredients would have six months after the effective date of the rule to comply. The rule was not effective until August 9, 1989 (54 Fed. Reg. 32638, August 9, 1989).

23. A memorandum, dated March 24, 1987, from Pennsylvania Department of Agriculture inspector, John C. R. Tacelosky, attached to a report of inspection of J. L. Hoffman Co., Inc. (C's Exh 15) describes the procedure by which the "concentrated Pool Chlorinating tablets," referred to in finding 22, were produced and distributed. PetroKem Corp. is the registrant and J. L. Hoffman Co., Inc. holds a supplemental registration for the mentioned product. Tradig obtains EPA registered raw material (trichloroisocyanuric acid) from importers and has the acid delivered to Pro Industries, a division or subsidiary of PetroKem, which presses the material into tablets. The finished tablets are shipped to J. L. Hoffman Co., Inc., but as to the property of Tradig, are sold to J. L. Hoffman Co., Inc. J. L. Hoffman Co. Inc. affixes its approved supplemental labels and distributes the product.

24. Mr. Hadjiloukas testified that to his knowledge the practice was that registered material would be delivered to the presser and then the tablets would be returned to the ultimate distributor in the same drums (Tr. 195). He acknowledged that regrettably, we have been unknowingly--totally unknowingly--in violation of federal law. In further testimony, he asserted that the typical practice was to use these drums and his understanding was that until such time as the tablets were offered for sale to the swimming pool using public, they were, in essence, in an

intermediate form, because the repackager was authorized by EPA to repackage the product, i.e., take the material out of a drum and place it in a package of his own with a particular label (Tr. 199).

25. Mr. Hadjiloukas testified that in the course of shipment from New Jersey to Allentown some of the drums were damaged (Tr. 199). He explained that DOT did not allow these materials to be shipped in plastic drums containing more than 50 pounds. Consequently, he made certain that his employees understood that only DOT approved drums with proper toxicity statements were used for the transferred product (Tr. 200). He asserted that the paperwork [invoices and shipping documents] at all times clearly identified the product and that the large and very noticeable, flammable "oxidizer signs" on the "Oniachlor 90" drums would be of more benefit to HAZMAT teams in case of an accident than the fine print on a finished product label (Tr. 200-01). He pointed out that U.S. Chlorine was an EPA-registered facility and that the repacking operation consisted of taking X number of tablets from a big drum and putting the tablets into a little package with a label. He contended that under these circumstances the absence of some of the precautionary statements, which are on the finished product label, would not materially increase the risk (Tr. 202).

CONCLUSIONS

1. Material in the drums labeled "Oniachlor 90" shipped by Tradig to U.S. Chlorine, Inc. on February 26 and April 10, 1987, was a pesticide as defined in FIFRA and applicable regulations.

2. Inasmuch as the drums in which the mentioned shipments of "Oniachlor 90" were made did not bear labeling as required by the Act, the shipments were misbranded.

3. Tradig's action in repackaging the chlorinating tablets received from PetroKem into drums labeled "Oniachlor 90" constituted the production of a pesticide.

4. Although the site, 1414 North Fulton Street, Allentown, Pennsylvania, where the repackaging referred to above was accomplished, was owned and operated by J. L. Hoffman Co., Inc. and was an EPA registered establishment, the repackaging was accomplished by employees of Tradig and each organization or entity using a facility for the production of pesticides requires an EPA establishment registration. At no time during the calendar year 1987 was the mentioned site registered with EPA for purposes of Tradig's product activities.

5. For the listed violations, an appropriate penalty is the sum of $10,000.

D I S C U S S I O N

A. Product Shipped By Tradig Was A Pesticide

Section 2(u) of FIFRA (7 U.S.C. § 136(u)) defines a pesticide as follows:

> (u) Pesticide.--The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w) of Title 21, that has been determined by the Secretary of Health and Human Services not be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) of Title 21 bearing or containing a new animal drug.[11/]

This definition is repeated in the regulation effective at the time of the shipments at issue herein, 40 CFR § 162.3(ff) (1986). Additionally, 40 CFR § 162.4 made it clear that whether a product is a pesticide is largely a function of its intended use. Section 162.4(a) provided:

[11/] Under the regulation as rewritten and redesignated, the knowledge, actual or constructive, of a person selling or distributing a product, that the product will be used, or is intended to be used, for a pesticidal purpose, will suffice to make the product a pesticide for the purpose of the Act and regulation. See 40 CFR § 152.15 (1993).

> (a) Determination of intent of use. A substance or mixture of substances is a pesticide under the Act if it is intended for preventing, destroying, repelling or mitigating any pest. (See section 2(u) of the Act and § 162.3(ff)). Such intent may be either expressed or implied. If a product is represented in any manner that results in its being used as pesticide, it shall be deemed to be a pesticide for the purposes of the Act and these regulations.

The tablets as shipped by PetroKem to Tradig were intended for chlorinating swimming pool water, which is accomplished for bactericidal, fungicidal and algicidal purposes and thus for a pesticidal purpose. Moreover, Mr. Hadjiloukas has stipulated that Tradig intended to sell the tablets, repacked into drums labeled "Oniachlor 90" for a pesticidal purpose, i.e., use following repackaging by U.S. Chlorine into an EPA registered product "Sta Clear Tablets" (finding 4). The product as shipped by Tradig was unquestionably a pesticide.

B. Product As Shipped By Tradig Was Misbranded

Section 2(q) of FIFRA (7 U.S.C. § 136(q)), specifies the manner in which pesticides may be misbranded (Attachment A). Also, Mr. Lott testified in some detail as to the manner in which the shipments by Tradig at issue here were misbranded (findings 11 - 13). This testimony conforms to the statute and is accepted as accurate. Nevertheless, an explanation of

required labeling on permissible transfers of unregistered pesticides will enable a better understanding of Mr. Lott's testimony and will be helpful in assessing the risks of such misbranding.

The regulation, 40 CFR § 162.5 (1986), is entitled "Pesticides required to be registered" and para. (b) of that section provided an exemption from the registration requirement as follows:

> (b) Exemption from Registration Requirement. The following pesticides are exempt from the registration requirements of the Act and this part:
>
> (1) Pesticides transferred between establishments. A pesticide which is transferred from one registered establishment to another registered establishment, operated by the same producer, solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment. However, pesticides transferred in accordance with this subsection shall be subject to the following misbranding provisions under section 2(q) of the Act: 2(q)(1) (A), (B), (D), (E), (G), (F) in accordance with § 162.10(i)(1)(iii)(C), 2(q)(2)(A), (C)(i) and (iii)), (D);
>
> * * * *.

"Operated by the same producer" was defined to include another registered establishment operated under contract with

the registrant of the pesticide either for packaging or for use as a constituent of another pesticide product.[12/]

For the misbranding provisions of the Act to which unregistered transfers of pesticides were subjected by the quoted provision of the regulation, see Attachment A. The foregoing requirements were imposed pursuant to 40 CFR § 162.10(i)(1)(iii)(C), currently § 156.10(i)(1)(iii), which provided that, under specified conditions, directions for use may be omitted from labeling of pesticides intended for use only by formulators in preparing pesticides for sale to the general

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[12/] Section 162.3(dd) (1986) provided:

> (dd) The term "operated by the same producer" means (1) another registered establishment owned by the registrant of the pesticide product or (2) another registered establishment operated under contract with the registrant of the pesticide either to package the pesticide product or to use the pesticide as a constituent part of another pesticide product, provided that the final pesticide product is registered by the transferor establishment.

public.[13/] For the requirements of §§ 2(q)(2)(A), 2(q)(2)(C) and 2(q)(2)(D) of the Act, see Attachment A.

C. Repackaging A Pesticide Constitutes Production Of A Pesticide

The regulation, 40 CFR § 167.1(c) (1986), defines produce as follows:

[13/] This was the regulatory basis for the "abbreviated" Nissan label. Section 162.10(i)(1)(iii)(C)(1) provided:

> (C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:
>
> (1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;
>
> (2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;
>
> (3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and
>
> (4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

> (c) Produce. The term "produce" means to manufacture, prepare, propagate, compound, or process any pesticide, including any pesticide produced pursuant to Section 5, or device, or to repackage or otherwise change the container of any pesticide or device.[14/]

Accordingly, Tradig's action in repackaging or repacking tablets received from PetroKem into drums labeled "Oniachlor 90" constituted production of a pesticide.

D. The Facility Where Repackaging Was Accomplished Was Not An EPA Registered Establishment

The regulation (40 CFR § 167.1(b)) defined Establishment as follows:

> (b) Establishment. The term "establishment," for purposes of this part, means each site where a pesticide, as defined by this Act, or a device is produced, regardless of whether such site is independently owned or operated and regardless of whether such site is domestic and producing any pesticide or device for export only or whether the site is foreign and producing any pesticide or device for import into the United States.

The stipulated facts are that the repackaging was accomplished by employees of Tradig (finding 8). Because the regulation, by the phrase "regardless of whether such site is independently owned or operated," requires that each entity or

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[14/] The definition of "produce" was clarified to specifically include "labeling and relabeling" (§ 167.3(d), 53 Fed. Reg. 35058, September 8, 1988), effective August 9, 1989 (54 Fed. Reg. 32638, August 9, 1989).

organization producing pesticides at a particular establishment register that establishment, the fact that 1414 North Fulton Street, Allentown, Pennsylvania, was an EPA registered establishment for the activities of J. L. Hoffman Co., Inc., does not make it a registered establishment for pesticide product activities of Tradig.

E. Amount Of Penalty

Complainant has proposed to assess Tradig the maximum penalty permitted by the FIFRA penalty guideline upon the theory that Tradig had knowledge of the pesticide and establishment registration requirements, but failed to obtain or apply for such registration. Mr. Hadjiloukas has maintained his good faith in the matter, asserting in his opening statement, which is accepted as argument in lieu of a brief, that "at no time did we feel that a transfer of material from one drum to another enroute to a subsequent facility for final packaging for distribution to the trade was a sale to the public" (Tr. 17). He also asserted that common industry practice, if pressing of trichloroisocyanuric acid into tablets was done on a contract basis, which he claimed the evidence demonstrated PetroKem was doing in this case, and then giving us (Tradig) authorization to sell these tablets under its basic registration, was to place the tablets in the very same drums the trichloroisocyanuric was delivered in and return the drums to the establishment where a

final end-use label was applied.[15/] Mr. Hadjiloukas' testimony at the hearing was substantially to the same effect (finding 23). Evaluation of these arguments, which concerns the gravity of the violations,[16/] requires further explanation of the Agency's regulation.

It should be emphasized that manufacturing or packaging a pesticide under contract and distributing a pesticide under a supplemental registration are different activities. As we have seen (ante note 12 and accompanying text), the Agency defined "operated by the same producer" as including another registered establishment operated under a contract with the registrant either for packaging or to use the pesticide as a constituent of

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[15/] Tr. 19. This appears to more accurately describe the activities of J. L. Hoffman Co., Inc. in the distribution and sale of "concentrated Pool Chlorinating tablets," (finding 23), rather than the activities of Tradig at issue here. Moreover, PetroKem's contract for pressing was with Pro Industries rather than Tradig.

[16/] Evaluation of the gravity of the violation requires, inter alia, consideration of the perpetrator's good faith and knowledge of the Act (supra note 4). FIFRA § 14(a)(4) (7 U.S.C. § 136l(a)(4)) provides:

> (4) Determination of penalty.--In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

another pesticide product, provided the final pesticide product was registered by the transferor establishment. Accordingly, the repackaging performed by Tradig would be legal only if its establishment were registered and only if accomplished under contract with the registrant, PetroKem.[17/] The same restrictions would apply to the packaging or repackaging performed or contemplated by U.S. Chlorine in order that it be regarded as an agent of PetroKem for such activities.

[17/] PR Notice 87-7, June 3, 1987, explained the effect of the contract policy as follows:

> The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) generally provides that all pesticides must be registered with the Agency before being shipped or distributed in commerce. An exemption in section 3(b)(1), however, allows an unregistered pesticide to be shipped between producing establishments operated by the same producer for the purposes of formulation or packaging into a pesticide product that is registered.
>
> In implementing this provision of FIFRA, EPA defined the phrase "operated by the same producer" to include not only establishments owned by a single company, but also, under certain conditions, establishments owned by different companies under contract to each other. Current regulations in 40 CFR 162.3(dd) permit unregistered pesticides to be shipped between establishments owned by different companies only if the transferor is the registrant of the final product produced.
>
> The exemption thus created permits a registrant who produces a pesticide himself to transfer it to any other establishment operated by him or under contract to him for formulation into his registered product, or to transfer a finished pesticide formulation to a second establishment for packaging or labeling. The transferor of the pesticide is the registrant of the final product, so the second establishment is considered to be "operated by the same producer" by virtue of the contractual arrangement between them.

Supplemental registration or distribution, on the other hand, was governed by § 162.6(b)(4)) (Attachment B).

Absent a contract for repackaging with the registrant, the requirement that the supplementally distributed product remain in the producer's unopened container (§ 162.6(b)(4)(D)) prohibits the repackaging performed by U.S. Chlorine on the material received from Tradig in the "Oniachlor 90" drums. Relabeling is, however, permissible.

By PR Notice 87-7 (supra note 17), the Agency notified producers, formulators and registrants of pesticides of a change in policy with regard to the registration of pesticides supplied under contract. The notice provided in pertinent part:

> The Environmental Protection Agency is revising its policy with respect to the required registration of pesticides supplied under contract. Generally, pesticides supplied under contract (even to a single formulator) must be registered with the Agency before being transferred. A 60-day grace period for applying for registration is provided for producers having existing contracts as of July 31, 1987.
>
> As of August 1, 1987, any pesticide transferred between establishments not operated by the same producer will be considered to be in violation of FIFRA sec. 12 unless it is:
>
> 1. Registered with the Agency;
>
> 2. The subject of a pending application for registration;
>
> 3. Transferred under a contract entered into before August 1, 1987; or
>
> 4. Eligible for an exemption from registration because:

a. Its pesticide constituents are derived from registered products; or

b. Its producer is also the registrant of the final product for which the transfer is accomplished, in accordance with 40 CFR 162.5(b)(1).

Although the transfer at issue here occurred well before August 1, 1987, Tradig did not have a contract with PetroKem for repackaging. With regard to the exception in para. 4.a. of the Notice, there would appear to be no doubt that, if the product received by Tradig from PetroKem bore the PetroKem label described in finding 3, then the pesticide produced by Tradig was derived from a registered product. Because the Nissan product was registered, the same would be true if product received by Tradig from PetroKem were in drums bearing the Nissan label in accordance with Mr. Hadjiloukas' version of the facts (supra note 9). The evidence is, however, that trichloroisocyanuric acid imported from France in drums labeled "Oniachlor 90" was not registered and, accordingly, pesticide constituents in that product were not derived from registered pesticides.

On May 4, 1988, the Agency published a final rule which narrowed the definition of "operated by the same producer" to the language of the statute, specifically excluding from the definition establishments owned or operated by different persons regardless of the contractual arrangement between such

persons.[18/] In explaining the revised rule, the Agency stated that it would not preclude contract manufacturing, but would limit the use of unregistered pesticides in contract manufacturing.[19/] At the same time as it promulgated the mentioned rule, the Agency issued an exemption which allowed the transfer of unregistered pesticides between registered establishments not operated by the same producer under specified circumstances. The regulation, 40 CFR § 152.30, provides in pertinent part:

> (b) A pesticide transferred between registered establishments not operated by the same producer. An unregistered pesticide may be transferred between registered establishments not operated by the same producer if:
>
> (1) The transfer is solely for the purpose of further formulation, packaging, or labeling into a product that is registered;

[18/] Section 152.3(q). 53 Fed. Reg. 15952, et seq. (May 4, 1988), effective August 12, 1988, 53 Fed. Reg. 30431 (August 12, 1988).

[19/] The preamble provides in pertinent part at 53 Fed. Reg. 15955:

> The commenters are correct in their analysis of the effect of the proposed change; as stated in the preamble to the proposal, "[t]he practical effect would be that a product would have to be registered prior to any transfer representing a sale or change in ownership." It was the Agency's intention to require that pesticides be registered before they are sold or transferred from one person to another, even for further formulation under contract. The final rule will not preclude contract manufacturing, but will limit the use of unregistered pesticides in contract manufacturing.

> (2) Each active ingredient in the pesticide, at the time of transfer, is present as a result of incorporation into the pesticide of either:
>
> (i) A registered product; or
>
> (ii) A pesticide that is produced by the registrant of the final product; and
>
> (3) The product as transferred is labeled in accordance with part 156 of this chapter.

In view of the regulatory definition of "operated by the same producer" and the quoted provisions of the PR Notice, Mr. Hadjiloukas' understanding, at the time of the shipments at issue here, that shipments of unregistered pesticides in the intermediate stage, i.e., before a final label was affixed and the pesticide was offered for sale to the general public, were permissible, clearly had a basis in fact. Moreover, as indicated (supra note 10), producers of active pesticide ingredients were not required to register their establishments for more than two years after the shipments involved here were made. The foregoing facts plus the fact that the facility where the repackaging was performed was registered for the pesticide production activities of J. L. Hoffman Co., Inc. support Mr. Hadjiloukas' contention that the violations here occurred

because he misunderstood the law.[20/] Although conditions under which the shipments would have been legal, i.e., transfers between registered establishments owned or operated or under contract to the registrant plus required labeling, did not exist,[21/] Mr. Hadjiloukas was a credible and forthright witness and I find that he acted with the utmost of good faith.

Remaining for consideration is the risk of the violations which, as Mr. Lott recognized (findings 11 - 13), relates primarily to lack of required labeling on the drums. Mr. Lott's assessment that "adverse effects" from the labeling violations were highly probable was based primarily on a comparison between the approved PetroKem label, which, inter alia, contained the signal word "Danger," indicated that it was toxic to fish and highly corrosive and the lack of such warnings and precautionary statements on the "Oniachlor 90" label. Mr. Lott, however, did

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[20/] It appears that J. L. Hoffman Co., Inc. was owned "lock, stock and barrel" by Mr. Hadjiloukas.

[21/] Because transfers of unregistered pesticides by the registrant to registered establishments for, inter alia, labeling purposes were permissible at the time of the shipments at issue here and are legal at the present time, it seems nonsensical that such shipments be made with end-use labels. Nevertheless, the only exception to that requirement, § 162.5(b)(1) (1986) and § 152.30(b) (1993), is that detailed directions for use may be omitted from products intended only for manufacturing, formulating, mixing or repacking (§ 162.10(i)(1)(C) (1986) and § 156.10(i)(1)(iii) (1993)).

not accept the characterization of the product as "highly toxic to man" for as to Charge Code E16, the product is highly toxic to man and the label fails to bear required symbols or statements, he basically disregarded a penalty assessment in that instance, because the product was not acutely toxic as to oral exposure or intake.[22/] Moreover, the approved Nissan label contained the signal word "Warning," which is specified for pesticides in "Toxicity Category II" (§ 162.10(i)(B)). It should be noted that the Nissan label was approved without many of the precautionary statements on the PetroKem label, notwithstanding the fact that the only omission specifically authorized by the regulation for product specified to be for manufacturing, repackaging or reformulating purposes appears to be "directions for use" (supra note 13).

At the time trichloroisocyanuric acid in drums labeled "Oniachlor 90" was imported, there was no requirement that either the acid or the facility in which the acid was produced be registered. In view thereof, and because, for all that appears, the only operation required for producing a pesticide for chlorinating swimming pools from the acid was to press the

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[22/] Finding 12. It should be noted that, if the product contained any substance or substances in quantities "highly toxic to man," the label would be required to contain the "skull and crossbones" in addition to the word "poison" (FIFRA § 2(q)(2)(D)). The approved PetroKem label did not contain such a symbol or word.

acid into tablets, producing a pesticide from the acid did not increase the risk of handling vis-a-vis registrants, formulators, packagers or repackagers. Under all the circumstances, I have no difficulty in accepting Mr. Hadjikoukas' contention that shipping the tablets to U.S. Chlorine, Inc., an EPA-registered facility, in drums lacking all required precautionary statements, did not materially increase the risk of such handling.

Because Mr. Hadjiloukas' good faith in the matter is clear and because the FIFRA penalty guideline overstates the risks of the violations at issue under the circumstances present here, it is my determination to disregard the guideline as I am permitted to do by Rule 22.27(b) (40 CFR Part 22) and to assess Respondent a penalty of $10,000.[23/]

O R D E R

Ignatios Hadjiloukas, d/b/a Tradig Company, having violated the Federal Insecticide, Fungicide and Rodenticide Act as alleged in the complaint, a penalty of $10,000 is assessed against him in accordance with § 14(a)(1) of the Act (7 U.S.C. § 1(a)). Payment of the penalty shall be made by submitting a cashier's or certified check in the amount of $10,000 payable to

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[23/] Although considered not to be strictly applicable here, the guideline permits a reduction of 40% where extraordinary circumstances are determined to exist (§§ 1(D)(1) and (3) of the penalty guideline, 39 Fed. Reg. 27712).

the Treasurer of the United States to the following address within 60 days of the date of this order:[24/]

Regional Hearing Clerk
U.S. EPA, Region III
P.O. Box 360515M
Pittsburgh, PA 15251

Dated this 27th day of May 1994.

Spencer T. Nissen
Administrative Law Judge

ATTACHMENTS A & B

[24/] Unless this decision is appealed to the Environmental Appeals Board (EAB) in accordance with Rule 22.30 (40 CFR Part 22) or unless the EAB elects sua sponte to review the same as therein provided, this decision will become the final order of the EAB in accordance with Rule 22.27(c).

FIFRA § 2(q) provides:

(q) Misbranded.--

(1) A pesticide is misbranded if--

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America."

(2) A pesticides is misbranded if--

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions or purchase, except that a pesticide is not misbranded under this subparagraph if--

(i) The size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing--

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter--

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

40 CFR § 162.6(b)(4) provided:

> (4) Notification of supplementally distributed product. (i) A distributor may sell or distribute a registered product bearing his own name and address and brand name if:
>
> (A) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product;
>
> (B) The composition of the supplementally distributed product is identical to that of the registered product;
>
> (C) The supplementally distributed product is manufactured, packaged and labeled in a registered establishment operated by the same producer who manufactures, packages, and labels the registered product;
>
> (D) The supplementally distributed product remains in the producer's unopened container (is not repackaged);
>
> (E) The label of the supplementally distributed product bears the name and address of the distributor and the registration number, and the label or immediate container bears the establishment number of the final establishment at which the product was produced;
>
> (F) Except as provided by paragraph (b)(4)(i)(E) of this section, the labeling of the supplementally distributed product is the same as that of the registered product; provided, however, that: specific claims may be deleted if by so doing no other changes are necessary; the brand name of the distributor product may be different; and the name and address of the supplemental distributor may be substituted for that of the registrant;
>
> (G) The distributor product name is not misleading, as defined in § 162.10.

(ii) If a registrant has a potential distributor to whom a company number has not been assigned, he should have the distributor apply, by letterhead, to the Agency for a company number.

(iii) The distributor is deemed to be an agent of the registrant for all intents and purposes under the Act.

Certificate of Service

I hereby certify that on this 31st day of May 1994, copies of the initial decision in the matter of Ignatios Hadjiloukas, d/b/a /Tradig Company and J.L. Hoffman Co., Inc. Docket No., I.F.&R.-III-358-C, were distributed as follows:

Certified Mail To:

Ignatios Hadjiloukas
Tradig Group
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Bethlehem, PA 18016

First Class Mail To:

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Headquarters Hearing Clerk
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401 M Street, S.W.
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Hand Delivered To:

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Assistant Regional Counsel
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Philadelphia, PA 19107

DATE: MAY 31 1994

Lydia A. Guy
Regional Hearing Clerk