UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	Docket Nos.:
McLAUGLIN GORMELY KING CO.	)	FIFRA 94-H-10
S. C. JOHNSON & SON INCORPORATED	)	FIFRA 94-H-11
TAKASAGO INTERNATIONAL CORPORATION U.S.A.	)	FIFRA 94-H-12
AGREVO ENVIRONMENTAL HEALTH	)	FIFRA 94-H-13
PRENTIS INCORPORATED	)	FIFRA 94-H-14
GOODDEED CHEMICAL CO. (USA) DIVISION OF ENDURA S.P.A.	)	FIFRA 94-H-15
Respondents.	)	

ORDER

The EPA, acting pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), §14(a)(1), 7 U.S.C. 136l(a)(1), has issued the above six complaints alleging in each case that Respondent had violated FIFRA, §12(a)(2)(Q), 7 U.S.C. 136j(a)(2)(Q), by falsely representing that a study on Piperonyl Butoxide of which Respondent was a sponsor was conducted in compliance with the FIFRA Good Laboratory Practice Standards ("GLPS"), 40 C.F.R. Part 160. Each Respondent is a registrant of a technical grade of Piperonyl Butoxide and admits to being a member

of the Piperonyl Butoxide Task Force II.[1]

The charges arise out of a report (hereafter "Study") entitled "Absorption, Distribution,Metabolism and Excretion (ADME) Studies of Piperonyl Butoxide in the Rat", which was submitted to the EPA by the Task Force in support of the registration or amended registration of each Respondent's technical grade of Piperonyl Butoxide. The Study was done for the Task Force by the Biological Test Center, an independent testing facility. Attached to the Study was a compliance statement signed by the Chairman of the Task Force that all aspects of the study were in accordance with the EPA's Good Laboratory Practice Standards (40 CFR Part 160). The Complaint charges that the Study failed to comply with the Good Laboratory Practice Standards in four respects:

1. The testing facility failed to retain all raw data, documentation, records, protocols, specimens and final reports, contrary to the requirements of 40 CFR § 160.195.

2. The signed and dated report of one of the scientists or other professionals involved in the Study was not included in the

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[1] McLauglhin Gormely King Co. (Docket No. FIFRA 94-H-10) is the registrant of "Technical Piperonyl Butoxide", EPA Reg. No. 1021-974; S. C. Johnson & Son, Inc. (Docket No. FIFRA 94-H-11) is the registrant of "Piperonyl Butoxide Technical For Manufacturing Purposes Only", EPA Reg. No. 4822-363; Takasago International Corp. USA (Docket No. FIFRA 94-H-12) is the registrant of "TPC Technical Piperonyl Butoxide", EPA Reg. No. 24061-1; Agrevo Environmental Health (Docket No. FIFRA 94-H-13) is the registrant of "Butacide Technical Piperonyl Butoxide", EPA REg. No. 4816-72; Prentis Inc. (Docket No. 94-H-14) is the registrant of "Prentox Piperonyl Butoxide Technical", EPA Reg. No. 655-113; and Gooddeed Chemical Co. (Docket. No. FIFRA 94-H-15) is the registrant of Pieronyl Butoxide Technical Grade", EPA REg. No. 47932-1.

study and the study was not signed and dated by the study director, contrary to the requirements of 40 CFR § 160.185(12) and (14)(b).

3. The quality assurance unit of the testing facility failed to include in its statement contained in the Study the dates that its findings were reported to management and the study director, contrary to the requirements of 40 CFR § 160.35(b)(7).

4. The compliance statement submitted with the Study did not cover the portion of the study that was conducted at Rutgers University, contrary to the requirements of 40 CFR §160.12.

These four alleged deviations from the EPA Good Laboratory Practices Standards are counted as four separate violations, and a civil penalty of $5,000 (the maximum allowable under 136l(a)) is proposed for the first count, and $4,000, for each of the other three counts. Thus, a total penalty of $17,000, is sought against each of the six members of the Task Force.

Respondents have filed a joint motion to dismiss based on threshold legal issues. They contend that they can only be held jointly liable for a single penalty of $5,000, that the EPA is attempting to assess multiple penalties for a single violation, that Respondents should not be held liable for acts of the laboratory over which they had no control and that the EPA is estopped from from bringing separate complaints because the EPA has dealt only with the Task Force.

Each of the Respondents is Separately Liable for a Penalty

The Task Force is a group of registrants who have agreed to develop jointly or to share in the cost of developing a study that

will be filed in support of the registration of each Respondent's product. Respondents apparently have also designated a Chairman to act as their common agent in developing the study and have appointed counsel to jointly represent them. There is nothing in the regulations or Statute or in the papers before me to indicate that the Task Force is any more than what has been set forth here.[2] FIFRA authorizes such joint efforts, including the appointment of an agent to handle data compensation matters, but does not require them.[3] Unlike the parties in those cases cited by Respondents where two or more parties have been held jointly liable for a single violation, there is nothing in the record to indicate that the Task Force has the capacity to be sued so as to be joined as a party. For all that appears here, the Task Force has no existence except as a group of registrants collectively sponsoring the generation of data and has no assets of its own.

The Statute supports the conclusion that each Registrant is separately liable for a violation. FIFRA § 12(a)(2)(Q), 7 USC 136j(a)(2)(Q), makes it unlawful for "any person" to falsify all or any part of any information relating to a pesticide submitted to the EPA or that the person knows will be furnished to the EPA. [4]

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[2] Although reference is made in Respondents' answers to a Memorandum of Understanding, the agreement itself has not been provided.

[3] See FIFRA, § 3(c)(2)(B), 7 USC § 136a(c)(2)(B).

[4] The Task Force may technically come within the definition of a "person". See FIFRA, § 2(s), 7 USC 136(s). It holds no registration, however, and is really acting on behalf of the Task Force members.

Respondents deny the allegations in the complaints that the Study was submitted by each Respondent in support of its own registration, asserting that the Study was submitted by the Task Force. Yet it would appear that the persons acting on behalf of the Task Force, the Chairman and legal counsel, were really acting as agent for each of the Respondents and it is hornbook law that an agent acts on behalf of its principal.

Under FIFRA each applicant for registration of a pesticide and each registrant seeking to maintain a registration, and not any Task Force, must show that the pesticide is safe and effective.[5] It is more consonant with this statutory scheme if each registrant is held separately liable and subject to a separate penalty for submitting data in support of its own registration which it has really co-sponsored and which does not comply with registration requirements, than watering down the penalty by dividing a single penalty among all sponsors. Nor do I found any merit in Respondents' claim that the fact that the EPA permitted Respondents to jointly develop and submit the data and jointly deal with the EPA on data compensation claims should estop the EPA from assessing a separate penalty against each Respondent for the submission of false information relating to the Study.

The Violation Charged is A Single Violation For Which Only One Penalty Can Be Assessed.

The EPA does not charge that the incorrect statement by the Task Force Chairman is a violation. Instead, it claims that each

[5] See FIFRA § 3(c)(5), 7 U.S.C. 136a(c)(5) (requirements for approval of a registration.)

requirement of the GLPS regulations not complied with constitutes a separate violation subject to the maximum $5,000 penalty. It relies for its position upon the Enforcement Response Policy for FIFRA Good Laboratory Practice Regulations (Sep. 30, 1991) (hereafter "GLP ERP").[6] Yet even the GLP ERP recognizes that the violation really consists of submitting a study stated as having been conducted in accordance with the GLPS regulations, when, in fact, the statement was false because certain requirements had not been complied with.[7] The EPA's interpretation of FIFRA as making the failure to comply with each GLPS requirement in a study submitted to the EPA a submission of false information within the meaning of FIFRA, § 12(a)(2)(Q) may or may not be a reasonable interpretation of the Statute. The omission of information from a study is not a false representation within the normal meaning of the word "false", unless the information was being intentionally withheld.[8]

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[6] See EPA's opposition to Respondents' motion to dismiss at 15-16.

[7] Thus, the GLP ERP states as follows:

> A statement, under 40 CFR 160.12, which certifies that a study complies with the GLPs is a statement that all requirements listed in 40 CFR Part 160 have been met. If requirements of the GLPs have not been met, then the GLP compliance statement is false.
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> EPA's brief in opposition at 15-16.

[8] The EPA argues that the submission of the Study is an implied representation by the sponsors that the Study conforms to GLPS. Given the requirements of the rule that the sponsor either certify that the study was conducted in accordance with GLPS or state wherein the procedures differed from GLPS, a more logical

Normally, the GLP ERP is entitled to weight as an informal agency interpretation. The difficulty is that the EPA's interpretation cannot be reconciled with the position it has taken in the Enforcement Response Policy for the Federal, Insecticide, Fungicide and Rodenticide Act (hereafter "FIFRA ERP").[9] This Policy appears to apply to Fifra enforcement generally.

FIFRA ERP distinguishes between actions that result in independently assessable charges and those that do not.[10] An example of an event or action that does not result in independently assessable charges is multiple misbranding on a single product label.[11] Although the EPA attempts to distinguish between multiple

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interpretation of the rule is that there is an affirmative obligation upon the sponsor to state whether the study did comply with GLPS. If it does not contain such a statement, the EPA can reject the study. I fail to see, however, why it would be reasonable for the EPA to assume that the study is being implicitly represented as conforming to GLPS if the statement is missing.

[9] Enforcement Response Policy for the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), Office of Compliance Monitoring, Office of Pesticides and Toxic Substances, U.S. Environmental protection Agency (July 2, 1990)

[10] The policy of distinguishing between separate independently assessable charges and single events or actions that cannot be assessed multiple penalties is one of long-standing. See 39 Fed. Reg. 27711 (Jul 31, 1974) (former FIFRA Civil Penalty Guidelines now superseded by FIFRA ERP.)

[11] The GLP ERP states:

> If a single product label is misbranded in one way or ten ways, as defined by FIFRA section 2(q), it is still misbranding on a single product label and is considered a single product violation of FIFRA section 12(a)(1)(E). As a single violation of FIFRA, the maximum penalty that may be assessed is $5,000.
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> FIFRA ERP at 26.

misbranding on a single label and multiple deviations from GLPS requirements in a single study, I find the distinction unpersuasive. Misbranding can consist of false or misleading statements on the labelling or the omission of a warning or caution statement.[12] Each is subject to its own proof as much as is the proof that raw laboratory data in a study has not been retained or the signed or dated report of one of the scientists involved in the study has not been included.

Where the EPA has issued two policies that on their face are inconsistent, and the inconsistency has not been reconciled, the reasonableness and, therefore, the weight of its interpretation is called into question. Weighing against the interpretation expressed in the ERP GLP is that making the violation consist of the submission of a false statement that the study was conducted in accordance with GLPS is more consistent with the Statutory language than making each deviation from GLPS a separate act of submitting false information.[13]

Respondents' also argue that their certification was given in good faith and that they should not be held responsible since they had no control over how the study was conducted. I disagree. Respondents surely had the control that rests in every party that

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[12] See FIFRA, § 2(q)(1).

[13] It is clear that I agree with Judge Nissen's decision in Bio-Tek Industries, Inc., FIFRA-92-H-06 (Order denying Motion to Dismiss based on Threshold Legal Issues, Apr 13, 1993) and disagree with Judge Vanderheyden's decision in Boehringer Ingleheim Animal Health, Inc., FIFRA-93-H-11, (Order Denying Respondent's Motion to Reduce Counts in the Complaint From Four to One, Nov 17, 1993).

contracts for services.[14] Respondents should have reviewed the study and the laboratory's procedures before submitting the study. If the deviations were not readily discoverable, this may be considered in mitigation of the penalty but it does not excuse the violation. Respondents have the ultimate responsibility for submitting proper data to the EPA, and they cannot contract that responsibility away.[15]

I find, accordingly, that the charges against each Respondent constitute a single violation with respect to that Respondent subject to a single maximum penalty of $5,000. In all other respects Respondents' motion to dismiss based on threshold legal issues is denied.

Gerald Harwood
Gerald Harwood
Senior Administrative Law Judge

Dated: April 19, 1995

[14] Respondents admitted that the laboratory had made a contractual committment to conduct the study in accordance with GLPS.

[15] Respondents claim that they did comply with two of the requirements they are charged with violating. That, however, would appear to raise factual issues that it would not be proper to decide on this motion.

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing ORDER was filed in re FIFRA Docket Nos. 94-H-10 thru FIFRA 94-H-15 and that copies of said ORDER were sent to the following:

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