IN RE MCLAUGHLIN GORMLEY KING CO.

FIFRA Appeal Nos. 95-2 through 95-7

ORDER ON INTERLOCUTORY REVIEW

Decided March 12, 1996

Syllabus

These appeals are from an interlocutory ruling by the Presiding Officer in six consolidated FIFRA enforcement actions. Respondents in these actions jointly submitted a study to EPA in support of the registration or amended registration of each Respondent's technical grade of a pesticide called Piperonyl Butoxide. Attached to the study was a statement stating that all aspects of the study were conducted in accordance with EPA's Good Laboratory Practice ("GLP") standards at 40 C.F.R. part 160 ("compliance statement"). The Toxics and Pesticides Enforcement Division at EPA Headquarters ("Complainant") filed a complaint against each of the Respondents, alleging that the compliance statement was false because the study had actually deviated from four of the GLP standards listed at part 160. Under section 12(a)(2)(Q) of FIFRA, 7 U.S.C. § 136j(a)(2)(Q), it is unlawful to "falsify all or part of any information relating to the testing of any pesticide * * * submitted to the Administrator * * *." In the complaint against each Respondent, Complainant charged the Respondent with four separate falsifications of the compliance statement resulting in four independently assessable violations of section 12(a)(2)(Q), one violation for each alleged deviation from the GLP standards. Upon a motion to dismiss the complaint submitted by Respondents, the Presiding Officer ruled that submission of the allegedly false compliance statement could result in only one violation of section 12(a)(2)(Q), not four independently assessable violations. At the request of the parties, the Presiding Officer certified this ruling for interlocutory appeal to the Environmental Appeals Board.

Held: The compliance statement in question, which covered a single study only, can give rise to no more than a single violation of section 12(a)(2)(Q), even if, as alleged, the compliance statement may be false for four independent reasons.

Before Environmental Appeals Judges Ronald L. McCallum and Edward E. Reich.

Opinion of the Board by Judge McCallum:

These appeals are from an interlocutory ruling by Senior Administrative Law Judge Gerald Harwood ("Presiding Officer") in six consolidated FIFRA enforcement actions. The Respondents in these actions are registrants of a pesticide called Piperonyl Butoxide and are members of an organization called the Piperonyl Butoxide Task Force II (the "Task Force"). The Task Force submitted a study to EPA in support of the registration or amended registration of each Respondent's

technical grade of Piperonyl Butoxide (the "Study"). Attached to the Study was a statement, signed by the chairman of the Task Force, stating that all aspects of the Study were conducted in accordance with EPA's Good Laboratory Practice ("GLP") standards at 40 C.F.R. part 160 ("compliance statement"). The Toxics and Pesticides Enforcement Division at EPA Headquarters ("Complainant") filed a complaint against each of the Respondents, alleging that the compliance statement was false because the Study had actually deviated from four of the GLP standards listed at part 160.[1] Under section 12(a)(2)(Q) of FIFRA, 7 U.S.C. § 136j(a)(2)(Q), it is unlawful to "falsify all or part of any information relating to the testing of any pesticide * * * submitted to the Administrator * * *." In the complaint against each Respondent, Complainant charged the Respondent with four separate falsifications of the compliance statement resulting in four violations of section 12(a)(2)(Q), one for each alleged deviation from the GLP standards of part 160. Upon a motion to dismiss the complaint submitted by Respondents, however, the Presiding Officer ruled that submission of the allegedly false compliance statement could only constitute one violation of section 12(a)(2)(Q), not four independently assessable violations. Both EPA and the Respondents requested that the Presiding Officer certify this interlocutory ruling for appeal, and on May 1, 1995, the Presiding Officer did so.[2] On May 23, 1995, the Board accepted the certification and requested further briefing, and on December 13, 1995, the Board heard oral argument on the certified issue.

For the reasons set forth below, we hold that the compliance statement in question, which covered a single study only, can give rise to no more than a single violation of section 12(a)(2)(Q), even

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[1] Complainant alleges that each Respondent failed to comply with the GLP standards at 40 C.F.R. §§ 160.195, 160.185 and 160.35(b). Complainant also alleges that each Respondent failed to comply with the compliance statement requirement at section 160.12, which Complainant sometimes refers to as a GLP standard. *See infra* n.5. While it is not clear to us that the compliance statement requirement is a good laboratory practice *per se*, it need not be distinguished from the other three requirements for purposes of this decision. For ease of reference, therefore, we will generally refer to all four requirements as GLP standards in this decision.

[2] In explaining his reasons for certifying the issue, the Presiding Officer noted that two other Administrative Law Judges had confronted the issue and each had resolved the issue differently than the other. In *In re Bio-Tek Industries, Inc.*, FIFRA-92-H-06 (Order Denying Motion to Dismiss Based on Threshold Legal Issues, April 13, 1993), the Presiding Officer ruled that the submission of a compliance statement representing compliance with all of the GLP standards gave rise to a single assessable violation of section 12(a)(2)(Q), despite multiple deviations from those standards. In *In re Boehringer Inglebeim 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), another Presiding Officer ruled that the submission of a compliance statement representing compliance with all of the GLP standards resulted in as many violations of section 12(a)(2)(Q) as there were deviations from the GLP standards.

if, as alleged, the compliance statement may be false for four independent reasons.[3]

I. *REGULATORY BACKGROUND*

All data provided to the Agency in support of a pesticide registration under FIFRA must be submitted in the form of individual studies. 40 C.F.R. § 158.32(b). A study submitted in support of a registration or re-registration of a pesticide on or after October 16, 1989, such as the one at issue here, is subject to the GLP standards, which are published at 40 C.F.R. part 160. 40 C.F.R. § 160.1.[4] The Agency does not at present have authority to mandate compliance with the GLP standards directly; however, it does have a powerful indirect means of encouraging compliance with the GLP standards. Under section 160.12, it requires any person submitting a study subject to part 160 to submit a compliance statement indicating the extent to which the study was conducted in accordance with the GLP standards. 40 C.F.R. § 160.12. Section 160.12 provides as follows:

> Any person who submits to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

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[3] For purposes of deciding the certified issue, we have assumed that Respondents' study was not conducted in accordance with four GLP standards; however, this decision need not and does not reach the issue of whether Respondents actually did fail to comply with the GLP standards.

[4] Section 160.1 provides as follows:

> (a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 4, 5, 8, 18 and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136a, 136c, 136 f, 136 q and 136v(c)) and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, 348).
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> (b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after October 16, 1989.

> (a) A statement that the study was conducted in accordance with this part; or
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> (b) A statement describing in detail all differences between the practices used in the study and those required by this part; or
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> (c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

If the compliance statement indicates that the study was not conducted in accordance with all of the GLP standards in part 160, then the Agency may deem the study unreliable and refuse to consider it. 40 C.F.R. § 160.17(a). This risk of rejection serves as a strong incentive to comply with the GLP standards, since as a practical matter, studies are ordinarily submitted to obtain necessary approvals from EPA or to keep existing approvals in effect. The loss or denial of an approval would represent a significant setback for an applicant or registrant.

The critical importance of accurate and truthful compliance statements to the proper functioning of this scheme is obvious. EPA needs reliable studies on which to base its decisions on whether to allow potentially dangerous pesticide products in the market. To this end, the Agency has a number of enforcement options at its disposal to discourage registrants from submitting false compliance statements. In the event that a registrant submits a false compliance statement, the Agency may: (1) cancel, suspend, or modify any registration based on the study; (2) deny or disapprove an application for such registration; (3) bring a criminal action against the submitter under 18 U.S.C. §§ 2 or 1001 or section 14 of FIFRA; or (4) bring an action for civil penalties under section 14 of FIFRA. 40 C.F.R. § 160.17(b).

Section 14 of FIFRA, 7 U.S.C. § 136*l*, authorizes the Agency to bring an enforcement action for civil penalties against any person who violates a provision of FIFRA. One such provision, section 12(a)(2)(Q) of FIFRA, makes it unlawful for any person to:

> falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that

> the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;

Because a compliance statement contains "information relating to the testing of any pesticide," the submission of a false compliance statement would constitute a violation of section 12(a)(2)(Q), and the Agency would have authority under section 14 of FIFRA to bring an enforcement action for civil penalties against the submitter.

To comply with section 160.12 in this case, Respondents relied on the following compliance statement signed by the Chairman of Respondents' Task Force:

> To the best of my knowledge, all aspects of this study that were conducted by the Biological Testing Center (BTC) were in accordance with the Environmental Protection Agency Pesticide Program's Good Laboratory Practice Standards (40 C.F.R. Part 160).

Complainant contends that the submission of this compliance statement resulted in four different violations of section 12(a)(2)(Q). Three violations occurred because the Study was not conducted in conformity with the following GLP standards in part 160: (1) section 160.195, which requires the retention of documentation records, raw data, and specimens pertaining to a study; (2) section 160.185, which requires among other things that the final report prepared for each study be signed and dated by the study director and include "[t]he signed and dated reports of each of the individual scientists or other professionals involved in the study * * *;" and (3) section 160.35(b), which requires that the quality assurance unit "[p]repare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director." As for the fourth violation, Complainant asserts that the compliance statement itself did not comply with the requirements of section 160.12 and is therefore false for that reason alone.[5]

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[5] The compliance statement at issue here covers work conducted at the Biological Testing Center. It should be noted, however, that part of the Study was apparently conducted in another laboratory. Respondents submitted a second compliance statement pertaining to the work done by the second laboratory in an addendum to the Study, which reads as follows:

> This work was carried out under the GLP protocol in place at the Center for Advanced Food Technology (CAFT), Cook College, Rutgers University. The work was overseen by you

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II. *DISCUSSION*

As a preliminary matter, we must identify the precise documents that are alleged to contain the falsified "information" in this case. Complainant argues that Respondents falsified information in both the compliance statement and the study itself. Oral Argument Transcript at 9. We note, however, that the complaints that initiated these consolidated actions rely on the false compliance statement as the *sole* basis for the charges against Respondents. The complaints do not allege that the submission of the study itself violated section 12(a)(2)(Q). We will therefore restrict our consideration to the compliance statement as the falsified "information" for purposes of applying section 12(a)(2)(Q). With the focus properly on the compliance statement, the task before us, then, is to determine how many separate violations resulted from the submission of the compliance statement. Is it one or four?

The parties have framed the issue in terms of determining the "unit of violation" under section 12(a)(2)(Q). Congress has authority to treat a single act of proscribed conduct as more than one violation of a statute. *Bell v. United States*, 349 U.S. 81, 82-83 (1955). Determining whether Congress has exercised such authority in enacting a particular statute requires application of traditional principles of statutory construction.[6] Courts have typically framed the issue in the criminal context as determining the "unit of prosecution" under the statute. *See United States v. C.I.T. Credit Corp.*, 344 U.S. 218, 221 (1952).

In Complainant's view, the "unit of violation is not the submission of a false statement, but the act of falsifying information." Complainant's Brief at 15. Complainant contends that because the study does not conform to four separate GLP standards, "Respondents falsi-

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in person (referring to Dr. Paul Lin, the first study director of Study No. P01825).

Complainant takes the position that the first compliance statement, quoted in the text, was deficient because it did not cover the work done by CAFT and that the second supplementary compliance statement, quoted in this note, does not cure the deficiency because it does not indicate the extent to which the work done at CAFT adhered to the GLP standards. Based on these considerations, Complainant alleges that the original compliance statement does not fully adhere to section 160.12.

[6] *See U.S. v. Freisinger*, 937 F.2d 383, 388 (8th Cir. 1991) ("The question of how many convictions can lawfully be obtained under these circumstances is a question of the appropriate unit of prosecution, and that is the question of legislative intent."); *U.S. v. Coiro*, 922 F.2d 1008, 1014 (2nd Cir. 1991) ("The relevant inquiry in determining the unit of prosecution under a criminal statute is what Congress intended."); *U.S. v. Evans*, 854 F.2d 56, 59 (5th Cir. 1988) (same).

fied four independent pieces of information by stating that their PBO study complied with FIFRA GLPs." *Id.* at 16.

Respondents, on the other hand, argue that "Congress has unequivocally defined the unit of violation under FIFRA § 12(a)(2)(Q) as the submission of a false statement in connection with a study or test data submitted to the Agency." Respondent's Brief at 11. Respondents contend further that:

> Nothing in the statutory language or the legislative history suggests that there can be multiple charges for submission of an allegedly false piece of information, i.e., a single compliance statement. Rather, the only logical reading of § 12(a)(2)(Q) is that a single penalty is chargeable per piece of information, irrespective of whether that information is false in one or more respects.

Id. at 12.[7]

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[7] The parties and two Administrative Law Judges have erroneously assumed that the standard for determining how many offenses have been committed in cases such as this one is supplied by the U.S. Supreme Court decision in *Blockburger v. United States*, 284 U.S. 299 (1932). The standard articulated in *Blockburger*, and applied by the parties, is as follows:

> [W]here the same act or transaction constitutes a violation of two distinct statutory provisions, the test to be applied to determine whether there are two offenses or only one, is whether each provision requires proof of an additional fact which the other does not.

Note, however, that the standard quoted above refers to "two distinct statutory provisions," whereas in the case before the Board, multiple offenses are charged under the same statutory provision. In cases such as this one, the *Blockburger* standard has been held to have no application. *See Sanabria v. United States*, 437 U.S. 54, 70 (1978) ("Because only a single violation of a single statute is at issue here, we do not analyze this case under the so-called "same evidence" test, which is frequently used to determine whether a single transaction may give rise to separate prosecutions, convictions, and/or punishments under separate statutes. * * * *Blockburger v. United States*, * * *."); *United States v. Christner*, 66 F.3d 922, 1995 U.S. App. LEXIS 26037 at 21, n.7 (8th Cir. 1995) ("We note that, where the double jeopardy challenge focuses on separate punishments or prosecutions for separate acts allegedly violating the same statutory provision, the 'same elements' test, as enunciated in *Blockburger*, does not apply. In such cases, the issue is one of statutory intent."); *United States v. Woods*, 568 F.2d 509, 513 n.1 (6th Cir. 1978) ("Here we are not concerned with whether a single act violates a multiplicity of statutes as in * * * *Blockburger*. Rather, we face what the Supreme Court has recognized to be a different issue: whether a course of conduct - here possession with intent to distribute - can result in multiple violations of the same statute."). The *Blockburger* standard has no application in such cases because it calls for a comparison of the elements that must be proved under each statutory provision (to establish a crime or prima facie case), and such a comparison is obviously meaningless when violations of the same statutory provision have been alleged.

For purposes of deciding this case, we need not articulate what constitutes the "unit of violation" in every case under section 12(a)(2)(Q). For the reasons set forth below, we hold only that the "unit of violation" under that section, as applied in this case, can be no smaller than a false compliance statement containing a single-sentence assertion that a particular study was conducted in accordance with the GLP standards of part 160. We hold, therefore, that the submission of the compliance statement in question could have resulted in no more than one violation of section 12(a)(2)(Q), even if, as alleged, the study failed to conform to four independent GLP standards in part 160.

The compliance statement in question consists of a simple representation that the study complied with the GLP standards. In other words, the statement purports to be of the type identified in section 160.12(a), that is, "A statement that the study was conducted in accordance with this part [160]." This language therefore marks the contours of the unit of violation, as applied in this case; that is, the violation consists of falsifying "[a] statement that the study was conducted in accordance with [the GLP standards]." The Complainant contends that because several of the GLP standards were not complied with, separate violations are attributable to each instance of noncompliance. We are not persuaded by this argument as explained below.

It is clear that only one compliance statement was allegedly falsified, that being the single "statement that the study was conducted in accordance with [the GLP standards]." The fact that this statement may have been false for as many as four reasons in no way alters the fact that only one compliance statement was the subject of the alleged falsification. The compliance statement is clearly the sole item of allegedly false "information" that was furnished to the Administrator for purposes of section 12(a)(2)(Q).[8] In contrast, the study, which is identified in the compliance statement, is not alleged to contain any false "information;" therefore, whether the study did or did not comply with the GLP standards in a single respect or a dozen, is irrelevant to determining how many items of "information" were falsified. Complainant's approach of focussing on the study and the number of

[8] We note that merely because there is only one compliance statement does not mean that there can be no more than one prosecutable falsehood, or "unit of violation." For example, let us suppose that instead of the compliance statement's reference to a single study, it referred to more than one study, and let us suppose further that each of the several studies did not comply with the GLP standards in multiple respects. Presumably everyone would agree that such a compliance statement would give rise to at least as many violations as there were numbers of studies. Thus, if there were four studies identified, the single false compliance statement would give rise to four separate violations.

instances that it did not comply with the GLP standards effectively elevates the study to a level of importance that is on a par with or exceeds the compliance statement itself. This is not a correct interpretation of section 12(a)(2)(Q), for it confuses the "information" that is falsified (here the compliance statement) with the evidence that the Complainant intends to use to support its claim of falsification. (That evidence consists of the study and the testimony that the Complainant will need to adduce to show that the study did not comply with the GLP standards.) Accordingly, for the foregoing reasons, we conclude that, on the facts alleged in the complaint, where only a single study is the subject of a compliance statement, no more than one violation of the statute can occur by reason of a false assertion that the study was conducted in conformity with the GLP standards.[9] We turn now to Complainant's specific contentions.

With respect to the specific language of section 12(a)(2)(Q), Complainant raises a host of arguments in support of its position that the "unit of violation" under section 12(a)(2)(Q) is smaller than the single falsified compliance statement in question. In general terms, Complainant argues that:

> Congress' choice of the specific terms "all or part of" and "any information" confirm that FIFRA section 12(a)(2)(Q) was meant to have a broad scope to encompass this concern [about inadequate data supporting pesticide registrations]. "[A]ll or part of" demonstrates that Congress understood different pieces of information contained in a single study could be independently true or false.

Complainant's Brief at 16. We have no quarrel with Complainant's observations; however, they have no bearing on the issue before us. As noted earlier, the complaints that initiated these consolidated actions do not allege that information in the *study* was falsified. The complaints allege only that the information in the compliance statement was falsified.

Complainant also relies on the legislative history of section 12(a)(2)(Q), which was added to FIFRA in 1988. Complainant argues that "[w]hen Congress enacted FIFRA section 12(a)(2)(Q), * * * it understood that the integrity of the studies submitted to EPA depended on

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[9] Of course, falsification of information in the study itself would result in an entirely separate violation of section 12(a)(2)(Q).

the level of adherence to FIFRA GLPS." It is unquestionably true that Congress was concerned about the integrity of studies submitted to EPA; however, that observation sheds little light on the issue before us.[10] The application of section 12(a)(2)(Q) is triggered not by the failure of a study to comply with one or more GLP standards, but by a false statement concerning the extent to which the study complies with those standards. Thus, if a submitter honestly represents the extent to which a particular study deviates from the GLP standards, section 12(a)(2)(Q) has no application. *See* 40 C.F.R. § 160.12(b) (the compliance statement may consist of a "statement describing in detail all differences between the practices used in the study and those required by" the FIFRA GLP standards); Oral Argument Transcript at 14-17. Moreover, that a study was not conducted in accordance with the GLP standards does not necessarily impugn its reliability. The regulations clearly contemplate the possibility that the Agency might choose to rely on a study, even if it was not performed in accordance with all of those standards. *See* 40 C.F.R. §§ 160.17(a) ("EPA *may* refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part.") (emphasis added).[11] That Congress was concerned with the integrity of studies submitted to EPA, therefore, does not lead to the conclusion that the purpose of section 12(a)(2)(Q) is to punish each instance of non-compliance with the GLP standards.

Complainant also believes that various statutory and regulatory provisions, including section 6(a)(2) of FIFRA[12] and section 3(c)(2)(A)

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[10] We note that Respondents make a persuasive case that Congress, despite this concern, considered and ultimately rejected legislation that would have given the Agency authority to impose civil penalties for deviations from the GLP standards. Respondents' Reply Brief at 5-13.

[11] This conclusion is implicitly acknowledged in the following statement by counsel for Complainant at the oral argument:

> Had the respondents merely stated that there were some deviations, or that they were unaware of the status of compliance with the GLPS, the Office of Pesticides Programs would have treated the study in a much different manner. Information, perhaps, would have been examined a little more closely, OPP may not have relied upon the study to the extent it did.

Oral Argument Transcript at 17.

[12] Section 6(a)(2), 7 U.S.C. § 136d(a)(2) reads as follows:

> Information.—If at any time after the registration of a pesticide the registrant has additional factual information regard

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of FIFRA,[13] support the proposition that "the term 'information' does not describe an indivisible whole, but instead acknowledges that there are a variety of kinds of information that are relevant to the registration decision." Complainant's Brief at 19. Complainant argues that whether a particular study complies with, or deviates from, a particular GLP standard is an independent piece of information that is relevant to the registration decision. Complainant's Brief at 21. That may be true, but it is beside the point. In this case, we are concerned only with a single assertion concerning the study as a whole. As noted above, Complainants are confusing the false compliance statement with the evidence that shows it is false. We find nothing in the legislative history cited by Complainant that supports the argument that the unit of violation under section 12(a)(2)(Q) is each independent reason why a particular statement is false.

Complainant also points out that the Agency has expressed its position on the issue before the Board in a document entitled, "Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act Good Laboratory Practice (GLP) Regulations," issued by the Office of Compliance Monitoring, Office of Pesticides and Toxic Substances (Sept. 30, 1991) ("GLP ERP"). In the GLP ERP, the Agency has taken the position that each deviation from a requirement of the GLP standards in part 160 represents through the compliance statement an independently assessable violation of section 12(a)(2)(Q).[14] Complainant argues, and one Administrative Law Judge has held, that the position expressed in the GLP ERP is entitled to def-

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> ing unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

[13] Section 3(c)(2)(A) of FIFRA, 7 U.S.C. § 136a(c)(2)(A), requires in pertinent part that:

> The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time.

[14] The GLP ERP provides in pertinent part 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. Each independent requirement of the GLPs which has been violated, but has been represented through the statement as in compliance, may be considered a sepa-

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erence. *See In re Boehringer Ingleheim Animal Health, Inc.*, FIFRA-93-H-11, at 20 (Order Denying Respondent's Motion to Reduce Counts in the Complaint from Four to One, Nov. 17, 1993). We note, however, that the GLP ERP, which has never been put out for notice and comment, is a non-binding Agency policy whose application is open to attack in any particular case. *In re James C. Lin and Lin Cubing, Inc.*, 5 E.A.D. 595, 599 (EAB 1994) (While Agency penalty policies "facilitate application of statutory penalty criteria, they serve as guidelines only and there is no mandate that they be rigidly followed."). *See also In re Allied-Signal, Inc. (Frankford Plant)*, 4 E.A.D. 748, 760 (EAB 1993) (a non-binding Agency policy is open to attack in any particular case). Moreover, it is important to remember that the determination of whether an act of proscribed conduct constitutes multiple offenses under a statutory provision is *not* a matter of enforcement discretion; it is, rather, a matter of statutory interpretation. *See supra* n.6. That the Agency has articulated its statutory interpretation within a document that is otherwise devoted to issues committed to the Agency's enforcement discretion does not alter this conclusion. As a matter of statutory interpretation, the Agency's position is only entitled to as much deference as is normally owed to Agency interpretations of statutes. In this regard, we note that the Presiding Officer in the *Boehringer* case felt compelled to defer to the Agency's statutory interpretation under the *Chevron* standard. The Board, of course, is under no such obligation. *See In re Mobil Oil Corporation*, 5 E.A.D. 490, 509 n.30 (EAB 1994) ("Because the Board is the final decision maker for the Agency, the concepts of *Chevron* and *Skidmore* deference do not apply to its deliberations.").

Finally, Complainant argues that:

> Allowing for the imposition of only one count for any study that fails to meet the GLPS, no matter how many deviations, would result in inequitable enforcement against data submitters. For example, the data submit-

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rate count of FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate, and each count assessed a civil penalty up to the statutory maximum (see July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges). For example, a sponsor could be assessed a civil penalty for up to $15,000 because that sponsor submitted a study with a GLP compliance statement which failed to truthfully state that the pesticide testing facility: (1) failed to maintain personnel records; (2) failed to designate a study director; and (3) failed to record raw data.

GLP ERP at 7

> ter who fails to comply with some minor requirement of the GLPS will be subject to the same penalty as the data submitter who fails to comply with significant portions of the GLPS.

Complainant's Brief at 24. This result, however, does not strike us as so unusual or absurd that Congress could not have intended it under the facts of this case. In this regard we note that section 12(a)(1)(E) of FIFRA makes it unlawful to sell or distribute a pesticide that has been adulterated or misbranded. The Agency has taken the position that one sale of a misbranded pesticide constitutes a single offense even if the pesticide has been misbranded in many different respects. *See* FIFRA Enforcement Response Policy, at 26 (June 2, 1990) ("FIFRA ERP"). Complainant's argument concerning inequitable enforcement could be made with equal force about section 12(a)(1)(E). We also note that under the FIFRA ERP, the Agency has some discretion to reflect the seriousness of the GLP standard violations in its recommended penalty. *Id.* at Appendix A-7.[15]

In conclusion, Complainant has not pointed to anything in the language, legislative history, or statutory context of section 12(a)(2)(Q) that supports its position that the unit of violation, as applied in this case, is smaller than the compliance statement.

III. *CONCLUSION*

For all the foregoing reasons, we conclude that the submission by Respondents of a compliance statement containing a one-sentence representation that the attached study was conducted in accordance with the GLP standards of part 160, could result in no more than one violation of section 12(a)(2)(Q), even if the compliance statement was false for more than one reason, as alleged. Accordingly, we are sustaining the Presiding Officer's ruling that submission of the allegedly false compliance statement could result in only one violation of section 12(a)(2)(Q). The case is remanded to the Presiding Officer for resolution of the issues raised in the underlying enforcement action consistent with this opinion.

So ordered.

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[15] Complainant cites several federal decisions that, in its view, "tend to support a finding that FIFRA sanctions multiple violations for multiple deviations of the FIFRA GLPS." Complainant's Brief at 26. The language of the statutory provisions at issue in those cases, however, is so different from the language of section 12(a)(2)(Q) that we find no useful analogies in the cases cited.