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TOXIC SUBSTANCES

ENDOCRINE DISRUPTORS

Now that EPA has published its list of the first chemicals to be screened under the Endocrine Disruptor Screening Program, the authors of this article say all technical registrants of listed active ingredients, and all manufacturers and importers of listed inert ingredients, must begin to prepare for how they will address joint data development, cost sharing, data compensation, and data protection. The authors compare the program and its policies with the long-established data compensation provisions of the Federal Insecticide, Fungicide, and Rodenticide Act. They say it is none too soon to start thinking about legal, business, and communication strategies that best address applicable legal obligations, while protecting commercial and business interests.

Endocrine Disruptor Screening Program: Data Sharing, Compensation, Protection

BY LYNN L. BERGESON, LISA M. CAMPBELL, AND LISA R. BURCHI

The Environmental Protection Agency issued three important *Federal Register* notices April 15, 2009, laying the foundation for the Endocrine Disruptor Screening Program (EDSP), EPA's next major data development initiative. This article focuses on those aspects of EPA's *Federal Register* notices concerning how EPA will address joint data development, cost sharing, data compensation, and data protection under the EDSP (EDSP Policy Notice).

Pesticide registrants may be familiar with many of EPA's stated policies, as EPA has indicated that EDSP data submitted by pesticide registrants will be subject to policies and procedures similar to those in place for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Sections 3(c)(1)(F) and 3(c)(2)(B). These policies and procedures, and the compensability of data generated by chemical manufacturers and importers of inert ingredients, particularly data generated by chemical manufacturers and importers of inert ingredients that have neither a tolerance nor tolerance exemption, can be expected to be less familiar to pesticide registrants, however.

Now that EPA has published its list of the first chemicals to be screened under the EDSP, all technical registrants of listed active ingredients, and all manufacturers and importers of listed inert ingredients, must begin to prepare for how they will address joint data development, cost sharing, data compensation, and data protection for EDSP data. It is none too soon to start thinking about developing legal, business, and communication strategies that best address applicable legal obligations, while protecting commercial and business interests.

We provide below background on the EDSP; discuss EPA's policies regarding data development, cost sharing, data compensation, and data protection; and analyze the similarities and differences of these policies and long-established FIFRA data compensation provisions.

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The opinions expressed here do not represent those of BNA, which welcomes other points of view.

Background

On April 15, 2009, EPA issued a suite of notices. One announced a list of the 67 pesticide active ingredients and high production volume (HPV) chemicals that are

used as pesticide inert ingredients which will be the first chemicals screened under the EDSP.[1] A second described the policies and procedures EPA generally intends to adopt for the initial screening of chemicals under the EDSP (EDSP Policy Notice).[2] The last announced an Information Collection Request (ICR) EPA forwarded to the Office of Management and Budget (OMB) focusing on the information collection activities associated with the Tier 1 screening of the first group of chemicals selected for initial screening under the EDSP.[3] As is well known, EPA created the EDSP in 1998 to implement Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires EPA ''to develop a screening program . . . to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.''[4]

The EDSP Policy Notice has been the subject of significant concern and comment on a number of issues. Addressed here are the joint data development, cost sharing, data compensation, and data protection issues addressed by the EDSP Policy Notice. To understand these issues in the context of how they will be implemented under the EDSP, below is a brief explanation of the EDSP's parameters:

- **Screening Program:** FFDCA Section 408(p)(1) requires EPA to ''develop a screening program, using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.'' In response, EPA has developed a two-tier screening and testing program — Tier I, which would include short-term assays intended to identify chemicals that have the potential to interact with the endocrine system and Tier II, which would involve longer-term assays intended to identify the specific impact caused by each endocrine disruptor and establish a dose at which the effect is believed to occur.
- **Substances at Issue:** Under FFDCA Section 408(p)(3), EPA ''shall provide for the testing of all pesticide chemicals.'' EPA also has discretionary authority under FFDCA Section 408(p)(3) to ''provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance.'' In addition, Section 1457 of the Safe Drinking Water Act (SDWA) authorizes EPA to screen substances that may be found in sources of drinking water and to which a substantial population may be exposed, for endocrine disruption potential. On April 15, 2009, EPA released a list of the 67 pesticide active ingredients and HPV chemicals that are used as pesticide inert ingredients that will be the first chemicals screened under the EDSP.[5]
- **Testing Orders:** FFDCA Section 408(p)(5)(A) provides that EPA ''shall issue an order to a registrant of a substance for which testing is required [under FFDCA Section 408(p)] or to a person who manufactures or imports a substance for which testing is required [under FFDCA Section 408(p)] to conduct testing in accordance with the screening program.'' According to EPA's EDSP Policy Notice, EPA generally intends to issue Tier 1 test orders to pesticide technical registrants and chemical companies identified as the manufacturer or importer of a pesticide inert ingredient.[6] Each test order recipient would be required to inform EPA, within 90 days of the issuance of the order, whether it will: generate new data; submit or cite existing data (including other scientifically relevant information); form a task force or offer to join a task force; claim the recipient is not subject to the order; voluntarily cancel the pesticide registration(s); reformulate the product(s) to exclude this chemical from the formulation; claim on formulators' exemption; or offer another response option, such as asking EPA to reconsider some or all of the testing specified in the order if certain conditions are met.[7] To ensure that data conducted under the EDSP are considered compensable and that recipients of test orders comply with the procedures EPA has established for joint data development and the availability of data compensation and data protection, EPA intends to issue the testing orders for pesticide active ingredients jointly under FFDCA Section 408(p)(5) and FIFRA Section 3(c)(2)(B).
- **Minimizing Duplicative Testing:** FFDCA Section 408(p)(5)(B) states that ''[t]o the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.'' EPA's EDSP Policy Notice states EPA's intent to minimize duplicative testing by promoting the formation of cost sharing consortia. For example, EPA states that its decision to issue Tier 1 test orders only to pesticide registrants and chemical companies identified as the manufacturer or importer of a pesticide inert ingredient is, in part, an effort by EPA to reduce the number of companies that receive test orders, thus keeping costs to organize testing consortia lower and promoting cost sharing.[8]

Key Differences Between EDSP and FIFRA Data Sharing, Compensation Policies

EPA states that its approach in its policy notice is ''intended to achieve . . . essentially the same outcome for

[1] 74 Fed. Reg. 17579 (Apr. 15, 2009) (33 CRR 430, 5/4/09).
[2] 74 Fed. Reg. 17560 (Apr. 15, 2009). *See also* 72 Fed. Reg. 70842 (Dec. 13, 2007) (proposed EDSP Policy Notice); EPA, *Response to Comments on the Draft Endocrine Disruptor Screening Program (EDSP): Policies & Procedures for Initial Screening and Testing* (Mar. 26, 2009) (Response to Comments), available at http://www.epa.gov/endo/pubs/pandp_r2c_041509.pdf.
[3] 74 Fed. Reg. 17477 (Apr. 15, 2009). The comment period on the ICR closed on May 15, 2009. As of the date of this memorandum, OMB has not publicly announced whether it has approved the ICR.
[4] 74 Fed. Reg. at 17561.
[5] 74 Fed. Reg. at 17579.
[6] *Id.* at 17570.
[7] *Id.* at 17571-17574.
[8] *Id.* at 17565.

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all inert ingredients as the outcome the procedures under FIFRA section 3(c)(2)(B) and section 3(c)(1)(F) produce for active ingredients.''[9] EPA also acknowledges, however, that it is ''only able to use existing statutory authorities, and these do not provide EPA the ability to establish identical procedures to provide confidentiality protections and data use protections for all affected respondents.''[10] The differences between the data compensation procedures set forth under the EDSP and the policies and procedures set forth under FIFRA, particularly with regard to pesticide inert ingredients, are discussed below.

- **No Requirement for Binding Arbitration or Joint Data Development:** Under FIFRA Section 3(c)(1)(F)(iii), ''follow-on'' or ''me-too'' pesticide applicants are required to pay ''compensation'' to original data submitter(s) for use of their test data for a period of 15 years from the date the data were originally submitted to EPA.[11] Pursuant to FIFRA Section 3(c)(2)(B), if EPA determines that additional data are required to maintain in effect an existing registration of a pesticide, EPA will issue a Data-Call-In (DCI) to all existing registrants of the pesticide, and those registrants can then enter into one of two types of agreements: (1) an agreement to develop data jointly; or (2) an agreement by which the follow-on registrant shares in the cost of the data being developed by the original registrant.[12]

  In the case of data developed under the EDSP, EPA has ''concluded that FFDCA section 408(p)(5) does not provide the authority to create requirements for joint data development, including a requirement to use binding arbitration to resolve disputes, as does FIFRA section 3.''[13] Instead, EPA states that its authority under FFDCA Section 408(p) allows it only to develop procedures that would ''facilitate joint data generation.''[14] EPA thus is instituting a policy that it states parallels the policies under FIFRA Section 3(c)(2)(B), whereby each recipient of a Tier 1 test order will have fulfilled its obligation to provide data when the recipient: (1) submits the required data; (2) obtains permission to rely on data submitted by another person; or (3) relies on data submitted by another person and makes an offer to commence negotiations regarding the amount and terms of paying a reasonable share of the testing costs, including an offer to ''resolve any dispute over the recipients' shares of the test costs by submitting the dispute to a neutral third party with authority to bind the parties (e.g., through binding arbitration).''[15] Thus, although EPA does not believe it has the authority to require parties to enter into binding arbitration to settle any data compensation disputes, it will not consider a company to have satisfied its Tier 1 test order obligations when it cites to another's data if that company has not offered to settle any disputes though binding arbitration or something similar.
- **Different Enforcement Procedures for EDSP Data on Pesticide Inerts:** Under FIFRA Sections 3(c)(1)(F) and 3(c)(2)(B), EPA has the authority to enforce an offer to pay compensation by suspending the registration of the company that has not complied with the offer to pay requirements. For pesticide active ingredients, EPA has a similar authority under FFDCA Section 408(p)(5)(C)(i) to issue a notice of intent to suspend for any registrant that is believed to fail to comply with a test order. Prior to the suspension, a registrant may request a hearing, but EPA states that ''the statute restricts the issues in the hearing solely to whether the registrant has complied with the test order.''[16] EPA states these procedures are ''wholly consistent with the procedures applicable to FIFRA section 3(c)(2)(B), which similarly limits the issues for resolution in any suspension hearing held for failure to comply with the order.''[17] EPA states that FFDCA Section 408(p) does not confer the same authority in the context of endocrine data on pesticide inerts, however.[18] Instead, EPA has determined that FFDCA Section 408(p)(5)(D) provides it with the authority to apply penalties and sanctions under TSCA Section 16 for ''any person (other than a registrant) who fails to comply with a [FFDCA section 408(p)] order.''[19] Despite this difference, EPA has stated that it will interpret FFDCA Section 408(p) and TSCA Section 16 similarly to the extent that it will treat test orders as final agency actions and allow limited pre-enforcement judicial review of any test order. Specifically, EPA states:

> Although neither FFDCA section 408(p) nor TSCA Section 16 expressly imposes the same restriction on the issues that a non-registrant may raise in the penalty hearing, EPA's interpretation of the statutes and existing regulations is to impose a similar restriction. In large measure this interpretation turns on the fact that, at least for pesticide registrants, FFDCA section 408(p) test orders constitute final agency action, and consequently, would be subject to review in the appropriate district court. Logically, it makes sense to interpret the test order to be final for all parties, as the provisions of FFDCA section 408(p)(5)(A) that describe the test order do not distinguish between registrants and other test order recipients. Accordingly, pre-enforcement judicial review of the test order will be available, and would be the means by which any test order recipient would challenge the validity of the test order. As a consequence of that interpretation, EPA interprets TSCA section 16 to restrict the issues that may be raised in any enforcement hearing to whether the test order recipient had violated the test order, as well as the appropriate amount of any penalty.[20]

- **Limited Data Use Protection for Pesticide Inert Ingredients Data:** Under FIFRA, a follow-on registrant who relies on data submitted by other registrants has two main choices (although variations exist) under EPA's regulations for citing those

[9] 74 Fed. Reg. at 17565 (''To the extent permitted by FFDCA, EPA's intended policies and procedures for EDSP resembles the policies and procedures used for Data-Call-Ins under FIFRA'').
[10] Response to Comments at 6.
[11] 7 U.S.C. § 136a(c)(1)(F)(iii).
[12] 7 U.S.C. § 136a(c)(2)(B).
[13] 74 Fed. Reg. at 17566.
[14] *Id.*
[15] *Id.*
[16] *Id.* at 17576.
[17] *Id.*
[18] *Id.* at 17575-17576.
[19] *Id.* at 17576.
[20] *Id.*

data. One is the selective cite method, where the follow-on applicant may ''selectively [identify] one or more studies to satisfy each individual data requirement.''[21] The other is the cite-all method, where the follow-on applicant cites to all relevant data in EPA's files previously submitted by other registrants.[22] The right to cite all data is established by certifying to EPA that the applicant has obtained permission to cite to particular studies or has notified each affected company on EPA's Pesticide Data Submitters List (PDSL) that it intends to apply for registration and offered to pay compensation to each data submitter to the extent required by FIFRA Section 3(c)(1)(F)(ii) and to commence negotiations with each data submitter to determine amount and terms of compensation.[23] EPA maintains the PDSL, which is a compilation of names and addresses of registrants that wish to be notified and offered compensation for use of their data, to assist pesticide applicants in fulfilling their obligation as required by FIFRA Sections 3(c)(1)(F) and 3(c)(2)(D).[24]

EPA intends to manage submissions of EDSP data on active ingredients in the same matter used under FIFRA. This means that the name of the EDSP data submitter would be added to the PDSL and all future applicants would be required to cite and offer to pay compensation for those data for 15 years following the submission of the data.[25] EPA has stated that it does not have the ability to establish identical procedures to provide data use protections for generators of endocrine data on pesticide inert ingredients than what is now in place for pesticide active ingredients under FIFRA.[26] Procedures that EPA has put in place for pesticide inert ingredients to ''ensure effective enforcement of data use protections as well as maintaining a 'level playing field' ''[27] include:

- **Establishment of a Pesticide Inert Ingredients Data Submitters and Suppliers List (PIIDSSL):** To ensure that pesticide registrants are not obtaining inert ingredients from companies that have not complied with EDSP testing requirements, EPA intends to develop a PIIDSSL that will identify any person who has submitted compensable data on pesticide inert ingredients in response to a FFDCA Section 408(p) test order.[28] When a pesticide applicant's product contains a pesticide inert ingredient listed in the PIIDSSL, EPA will require the applicant to identify the source of that inert. If the applicant's source does not appear on the PIIDSSL, EPA will require the applicant to switch to a source on the PIIDSSL, offer to pay compensation to those company(ies) on the PIIDSSL for that active, or generate its own data to support its application.[29] Thus, EPA is creating a list for pesticide inert ingredients similar to the PDSL EPA currently maintains for pesticide active ingredients.
- **Catch-Up Orders:** EPA intends to issue ''catch-up'' test orders to any manufacturer or importer of a pesticide inert ingredient that enters the market after EPA receives data in response to a test order. EPA states that it will be relying on industry to self-police and report to EPA competitors that should receive these catch-up orders.[30] EPA will send catch-up orders to those new market entrants within 15 years after the initial test order was issued, so that the timing for compensability matches the timeframe for compensable data under FIFRA Section 3(c)(1)(F).
- **Amending Registrations:** EPA states that it will revise Pesticide Registration Notice 98-10 to provide that a registrant cannot change its source of pesticide inert ingredient by notification if that inert ingredient is listed on the PIIDSSL.[31] By requiring such registrants to submit an application for an amended registration, EPA can review that application and issue a catch-up order to that registrant if necessary.

- **Limited Data Compensation for EDSP Data on Non-Food Use Pesticide Inerts:** EPA states that some chemical manufacturers and importers that generate data on pesticide inert ingredients that do not have a tolerance or tolerance exemption are entitled to compensation only when ''submitted jointly by an applicant or registrant to support initial or continued registration of a pesticide product containing that inert ingredient.''[32] EPA states that there are no compensation rights for EDSP data for non-food use inerts under FFDCA Section 408(i) because ''such EDSP data could not be considered 'data submitted in support of a tolerance or exemption.' ''[33] Moreover, EPA states that ''since FIFRA Section 3(c)(1)(F) establishes compensation rights only for data submitted by an applicant or a registrant and inert ingredients do not have separate or technical registrations, data submitted to EPA in response to a FFDCA section 408(p) order by a person who is neither a registrant nor an applicant are not compensable under FIFRA.''[34] Despite comments asserting that manufacturers and importers of non-food use pesticide inerts may have legitimate business reasons not to submit jointly with a pesticide registrant, a joint submission remains the only avenue available under the EDSP Policy Notice if such a manufacturer or importers seeks compensation for its data.[35]
- **Limited Formulator's Exemption Protection for Non-Food Use Pesticide Inert Ingredients Data:**

[21] 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984).
[22] 40 C.F.R. § 152.86.
[23] 7 U.S.C. § 136a(c)(1)(F); 40 C.F.R. § 152.86.
[24] 74 Fed. Reg. at 17568. *See also* Pesticide Data Submitters List, available at http://www.epa.gov/opppmsd1/DataSubmittersList/ (last updated March 31, 2009).
[25] 74 Fed. Reg. at 17577.
[26] Response to Comments at 6.
[27] 74 Fed. Reg. at 17564.
[28] 74 Fed. Reg. at 17569; Response to Comments at 13 (taking measures to ''ensure that pesticide registrants are not obtaining the pesticide inert ingredient from an 'unapproved' source'').
[29] 74 Fed. Reg. at 17564, 17569.
[30] *Id.* at 17568.
[31] *Id.* at 17569.
[32] *Id.* at 17568.
[33] *Id.* at 17567-17568.
[34] *Id.* at 17568.
[35] Response to Comments at 8-9.

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Under FIFRA, a registrant can be exempt from data citation and compensation requirements if the company purchases a registered pesticide (*i.e.*, active ingredient) from another producer to formulate it into the registrant's product.[36] EPA states that the policy underlying this exemption, known as the formulator's exemption, is ''equally applicable'' to non-food use pesticide inert ingredients.[37] EPA also states that the exemption would only be applicable to customers who purchase pesticide inert ingredients for use in formulating registered pesticides if the manufacturers or importers who sell to such customers jointly submit data generated on non-food use pesticide inert ingredients ''jointly by a registrant or applicant for registration.''[38]

- **Limited Confidentiality Protections for Non-Food Use Pesticide Inert Ingredients Data:** EPA states: ''As with the directives to develop procedures for sharing test costs and minimizing duplicative testing, EPA does not think that FFDCA section 408(p)(5)(B) provides the authority for the Agency to either create new rights or to modify existing rights to confidentiality.''[39] Instead, EPA believes it can only ''create procedures that operate within the existing confines of FFDCA section 408(i), FIFRA section 10, the Freedom of Information Act (FOIA), and the Trade Secrets Act.''[40] Thus, confidential information submitted to support a tolerance or tolerance exemption and confidential information submitted by pesticide registrants will be ''entitled to confidential treatment to the same extent as under FIFRA section 10, pursuant to FFDCA section 408(i).''[41] In addition, ''CBI submitted by pesticide registrants in response to a FFDCA section 408(p) test order is considered as part of the registration process, and is therefore considered to be submitted in support of a registration[;] [a]s such, that information is directly subject to FIFRA section 10.''[42] EPA notes that ''[h]owever covered, information subject to FIFRA section 10 is provided certain protections that go beyond those authorized by FOIA.''[43] EPA notes as an example the protections afforded under FIFRA Section 10(g) which ''prohibits EPA from releasing information submitted by a registrant under FIFRA to a foreign or multinational pesticide producer, and requires the Agency to obtain an affirmation from all persons seeking access to such information that they will not disclose the information to a foreign or multinational producer.''[44] All other confidential information ''submitted in response to a FFDCA section 408(p) test order (i.e., data not in support of a registration or tolerance/tolerance exemption) is only protected by the provisions of the Trade Secrets Act which incorporates the confidentiality standard in FOIA Exemption 4'' unless that confidential information is submitted jointly with a registrant or as part of a consortium in which pesticide registrants participate.[45] As with data compensation and formulator's exemption rights discussed above, non-food use pesticide inert ingredients manufacturers and importers will receive only the same protections as technical registrants or food use pesticide inert ingredient manufacturers and importers by jointly submitting data with pesticide registrants. Specifically, EPA states:

> As with EPA's approach for data compensation, EPA considers that data submitted jointly with a registrant, or as part of a consortium in which pesticide registrants participate, to be data submitted in support of a tolerance/tolerance exemption or registration, and therefore entitled to protection under FIFRA section 10. However, if a non-registrant chooses not to partner with a registrant, such data is only subject to the protections available under FOIA and the Trade Secrets Act.[46]

Next Steps

EPA has issued its list of the pesticide active ingredients and pesticide inerts that will be subject to the initial Tier 1 test orders. While it is unclear when testing orders will be issued, they could be as early as July 2009. In its notice, EPA states that it intends for the test orders to include a final submission due date of 24 months after the issuance of the order.[47] Any technical registrant of a listed pesticide active ingredient, and any manufacturer or importer of a listed pesticide inert ingredient, thus must begin to prepare for how it will address joint data development, cost sharing, data compensation, and data protection.

How this initial testing proceeds, and how the policies and procedures set forth are implemented, should also be of interest to any other company that may be subject to EDSP testing requirements, as EPA subjects more chemicals to EDSP testing. EPA states: ''If chemicals identified for future screening and testing under the EDSP are not used in pesticides, the Agency intends to consider whether the policies and procedures identified . . . would be appropriate for other categories of substances.''[48] Pesticide registrants and interested others may wish to monitor the forthcoming EDSP testing to determine whether EPA's EDSP policies and procedures are effective in promoting joint data development and cost sharing and providing substantive data compensation and data protection rights. Interested parties should begin now to prepare to address these issues effectively.

[36] *See* FIFRA § 3(c)(2)(D); 40 C.F.R. § 152.85.
[37] 74 Fed. Reg. at 17568.
[38] *Id.*
[39] *Id.* at 17569.
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.* at 17574.
[48] *Id.* at 17562.