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SUBMITTED THROUGH REGULATIONS.GOV

Alexandra Dunn
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
OPP Docket
Environmental Protection Agency Docket Center (EPA/DC)
1200 Pennsylvania Ave, NW
Washington, DC 20460-0001

Re: Proposed Renewal of EPA ICR No. 02277.20, OMB Control No. 2070-0060 "Application for New and Amended Pesticide Registration" – Formulator's Exemption Statement (EPA Form 8570-27) Docket ID No. EPA-HQ-OPP-2019-0644

Dear Ms. Dunn:

Undersigned counsel, on behalf of pesticide research and development companies Bayer CropScience LP, Corteva Agriscience, and Valent U.S.A. LLC ("the Companies"), submits the following comments in response to the Agency's proposed renewal of the Information Collection Request entitled "Application for New and Amended Pesticide Registration" published on February 6, 2020 (85 Fed. Reg. 6944). The Companies request that the Agency implement certain changes to the Formulator's Exemption Statement (EPA Form 8570-27) (Exhibit A) and the Agency's process for reviewing formulator's exemption applications in response to the practice of obtaining unlawful product registrations through false certifications of the purchase of registered sources. The Companies also request that the Agency correct the regulatory citations in the Formulator's Exemption Statement to conform to the current regulations.

A. Introduction and Requested Revisions

The formulator's exemption functions as intended in most cases. However, a minority of companies persist in the practice of obtaining unlawful registrations for end-use products by

falsely certifying that the applied-for product is formulated with a registered pesticide product that "is purchased" to formulate the product when in reality they have no commercial access to the registered product and no intention of ever purchasing it. In most instances, these companies do not even contact the registrant to attempt to secure supply, and in other cases they certify the use of the purchased product even after supply inquiries are flatly rejected. Instead, they plan to amend the registration to reflect the actual intended source once it is subsequently registered by EPA, or to abandon the registration altogether in favor of a subsequent, legitimately-registered product (with a similar product name) in order to inappropriately begin marketing and offering product for sale before it is legitimately registered by EPA.

These false registrations, sometimes called "paper registrations," are unlawful and inconsistent with sound public policy for many reasons:

- They rely on and are obtained through the knowing submission of false certifications in violation of 18 U.S.C. § 1001 and FIFRA § 12(a)(2)(M), 7 U.S.C. 136j(a)(2)(M).

- They burden the agency with processing applications and approving registrations that serve no lawful commercial purpose and with the subsequent amendments or duplicative registrations required by the scheme.

- They burden the agency with petitions to deny or cancel the illegitimate registrations, filed by the original registrants seeking to protect their commercial and data rights.

- They allow companies to obtain a registration without offering to pay data compensation to the original registrant and without purchasing the product that is claimed as the registered source of active ingredient, violating the letter and purpose of the formulator's exemption and the original registrant's data compensation and property rights.

- They complicate policing of the import, sale, and advertising of unregistered products, and can be used to disguise the unlawful import or manufacture of products using unregistered sources of active ingredients.

- They are used to list, offer, and advertise a product for sale before that product is legitimately registered by EPA, circumventing the prohibition on offering a product for sale before it is registered and creating an unfair advantage against competitors who follow a lawful process.

- They are used to apply for state registrations before a legitimate federal registration is obtained, creating an unfair advantage against competitors who follow a lawful process.

- They send misleading signals to the marketplace, suggesting that the company has a business agreement with the original registrant or a viable independent registration, when neither is the case.

- Registrations based on false certifications that the product is formulated with a registered technical product raise significant data integrity issues when the applicant lacks access to the claimed technical and thus cannot produce a test substance that matches the certified Confidential Statement of Formula to conduct required product-specific data.

- Registrations based on false certifications that the product is a 100% repack of a registered product may not comply with FIFRA absent agreement by the original registrant, and would clearly violate general trademark and unfair competition laws.

EPA's actions to date have failed to curb the practice of obtaining registrations based on false claims of registered sources and have not resolved the significant legal, competitive, fairness, and transparency problems the practice creates. For these reasons, the Companies request that the Agency make the following changes to the Formulator's Exemption Statement form and the Agency's internal checklist and process for reviewing formulator's exemption applications.

- Add the following new paragraph (4) to the certifications required in the Formulator's Exemption Statement (Exhibit A) and renumber paragraph (4) as paragraph (5):

  (4) A signed letter from the registrant of each product identified in paragraph (5) stating that the registrant does not object to the applicant identifying the registrant's product(s) as the source of the active ingredient(s) in the product for which the formulator's exemption is claimed is attached to this statement.

- Update the 21 Day Content Screen Review Worksheet internal checklist (Exhibit B) to include an additional item under Item 4 "Formulator's Exemption" as follows:

  Letters of non-objection from registrant of each identified registered source product are attached to Formulator's Exemption Statement. – Yes/No/NA

- Update and supersede the guidance provided in the 1997 Memorandum issued by Jim Jones as Director of the Office of Pesticide Program's Registration Division (Exhibit C) to state that the practice of obtaining registrations under the formulator's exemption based on false certifications of the purchase of registered sources is unlawful, and that going forward EPA will not accept or process applications under the formulator's exemption unless supported by a letter from the registrant of the claimed registered source indicating that it does not object to the applicant identifying the registrant's product(s) as the source of the active ingredient(s) in the applied-for product.

The Formulator's Exemption Statement form has not been updated since June 2004. The formulator's exemption regulations were consolidated under 40 C.F.R. § 152.85 as part of the technical amendments to the pesticide data requirement regulations issued in 2007. Pesticide Data Requirements; Technical Amendments, 72 Fed. Reg. 61025 (Oct. 26, 2007). Paragraph 2 should be amended to conform to the current regulations, correct a grammatical omission, and accommodate the new paragraph (4):

> (2) Of these, each active ingredient listed in paragraph **~~(4)~~(5)** is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging **of** another product which contains that active ingredient which is registered under FIFRA Section 3**~~,~~ and** is purchased by us from another person **as required by 40 CFR section 152.85(c)(1)** and meets the requirements of 40 CFR Section **~~158.50(e)~~152.85(c)**(2) or (3).

B. Support for the Requested Actions

1. Requiring acknowledgment by the original registrant is consistent with the history and purpose of the formulator's exemption.

Courts have recognized that data submitters have property rights in the data they submit to EPA, subject to the terms of FIFRA's data citation and data compensation provisions. The adoption of FIFRA Section § 3(c)(1) in 1972 and its further amendment in 1978 provided EPA with the statutory authority to consider data in its files to support a new registration, but "only if the applicant has made an offer to compensate the original data submitter." *Thomas v. Union Carbide Agric. Prods., Co.*, 473 U.S. 568, 573 (1985). Thus, FIFRA "establishes a mandatory licensing scheme" whereby an applicant may cite data originally submitted to EPA by another person only "once [the] applicant has extended a proper offer to pay compensation . . . ." EPA, Procedures to Ensure Protection of Data Submitters' Rights, 49 Fed. Reg. 30884, 30889 (Aug. 1, 1984). Allowing companies to obtain registrations based on the original registrant's data in a manner not permitted under FIFRA would violate the original registrant's property rights. *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007 (1984) (FIFRA's data reliance provisions do not violate data submitters' property rights to the extent the data are used by EPA in a manner that is authorized under FIFRA).

The formulator's exemption, FIFRA Section 3(c)(2)(D), was enacted in 1978. Pub. L. 95-396, 92 Stat. 819 (1978) (codified at 7 U.S.C. § 136a(c)(2)(D)). It creates a limited exception to the core requirement that each application for registration of a pesticide product must be supported by data that are either submitted or cited by the applicant. The implementing regulations make clear that the exemption from data requirements is premised on the actual purchase and use of the identified registered product. 40 C.F.R. § 152.85(a), (b)(1)&(2), (c)(1) (establishing that the formulator's exemption "excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA-registered products which the applicant *purchases* from another person" and referring to "the *purchased product*," "the *purchase* from another person of an identified

registered product," and "the *use of the purchased product* in formulating the product") 40 C.F.R. § 152.85(a), (b)(1)&(2), (c)(1)-(3) (emphasis added).

The legislative history confirms that the formulator's exemption serves two purposes. First, it simplifies the application and review process for formulated products that incorporate registered sources of active ingredient:

> The Subcommittee agreed to the provision in S. 1678 authorizing the Administrator to make one safety finding on a basic ingredient that would apply to all pesticides using that ingredient.
>
> It was noted that once the Administrator made a finding that there were no unreasonable adverse effects to the environment caused by a basic ingredient, or "generic" chemical, it would be a waste of resources to review that decision each time an application was received for the registration of an end-use product containing the generic chemical and supported by the data base used to establish the original registration.
>
> Under the provision adopted by the Subcommittee, the formulator of an end-use product who uses a registered technical material would only furnish or cite data pertinent to the end-use and not have to cite data supporting the technical registration.

S. Rep. No. 95-334, at 8-9 (1977).[1]

Second, the formulator's exemption addresses the issue of compensation to the original registrant for the cost of the data required to support the registration of the purchased product. Under the exemption, formulators are "relieved of the need to offer to pay for the registration data [that support the registration of the purchased product] except in the purchase price of the basic pest control chemical." H. Rep. No. 95-663, at 19 (1997). Focusing on this aspect of the formulator's exemption, EPA later stated that "[i]t seems clear that the purpose of the formulator's exemption was to eliminate duplicative payment of data development costs." 49 Fed. Reg. at 30892. In other words, the formulator's exemption envisions a commercial business relationship between the formulator and the original registrant and understands that the original registrant can receive some form of compensation from the formulator who has relied on the

[1] *See also id.* at 19 (Section 3(c)(2)(D) creates a "simplified system"); H. Rep. No. 95-663, at 19 (1977)(explaining that "[f]ormulators who buy registered basic pest control chemicals from another producer to formulate [the] purchased pesticide into an end-use product would not be required to submit data requirements as to the basic best control chemical" and "[a]pplications will be simplified"); 49 Fed. Reg. at 30892 ("the formulator's exemption can result in a substantial reduction in the number of data requirements that must be listed for a significant number of applicants").

original registrant's data that ultimately supports the formulator's registration.[2] The requirement that the formulator actually "purchase" the identified product is a critical component of the formulator's exemption and a necessary justification for the exemption from the requirement to submit or offer to pay for data that supports the purchased registered product.

The false registration scheme devised and employed by some companies circumvents this requirement. These companies falsely certify that they will "purchase" the identified product for formulation into the applied-for product, with no intent of ever actually doing so. This false certification allows them to obtain a registration that they can exploit for their own purposes without submitting their own data, offering to pay compensation to the original registrant, or ever purchasing or paying for the product.[3] This violates the letter and intent of the formulator's exemption and denies the original registrant's right to data compensation under FIFRA.

2. The use of false certifications to obtain registrations is a longstanding and unresolved issue.

EPA has been aware of the use of false certifications of the purchase of registered products to obtain registrations under the formulator's exemption for many years. In the 1997 Memorandum, the Registration Division Director noted that EPA "has been receiving an increasing number of letters or formal petitions to deny a registration from registrants with technical or manufacturing use products . . . who claim a registrant has cited their product for a formulator's exemption" even though the basic manufacturer "do[es] not sell their product to the registrant who is citing their product." Exhibit C at 1. As discussed below, the guidance contained in the 1997 Memorandum has not been effective at curtailing the practice or redressing the harms it causes.

The scheme employed by some companies to obtain premature product registrations through false certifications of source has remained relatively consistent over time, and if anything appears to have increased in recent years. Such companies intend to enter the market with a new product that relies on its own new source of active ingredient that is not yet registered. While pursuing registration of the new technical source, they also apply for an end-use product under the formulator's exemption, certifying that the technical material used to formulate the product is purchased from an existing registered source (of which there is often only one, belonging to the original registrant of the active ingredient). In fact, the company has no access to the registered product, no ability to purchase it, and no intent to do so. In most cases, the company makes no effort to obtain the claimed source product, does not approach the

[2] This is consistent with how formulator's exemption registrants are treated by arbitrators in data compensation disputes. Formulator's exemption registrants, like other customers that purchase registered products, are not assigned an independent share of the data costs. Only companies that obtain or switch to their own independent registrations, supported by data, are assigned a share of the data costs in the form of data compensation.

[3] These companies also avoid bearing any of the costs of stewardship of the registered product, including any federal or state-imposed stewardship programs and requirements.

original registrant to inquire about purchasing it, and does not even inform the registrant that it has applied to register a product based on a certification that it "is purchasing" the registered technical.

Companies may also obtain false registrations by claiming that their product qualifies for registration under the formulator's exemption because it is a 100% repack of an existing registered end-use product, which (some companies have argued) could hypothetically be purchased "off the shelf" without the original registrant's consent. However, these companies have no access to the product at volumes and prices that are commercially viable for repacking and resale and no intent to ever actually do so. Indeed, it is not clear that repacking and reselling the original registrant's product without its consent is allowed under FIFRA, and relabeling and selling a another company's product as your own without their consent is unlawful under general commercial law.

The overall purpose of the scheme is to obtain a false "paper" registration that the applicant can exploit for its own purposes before the legitimate registration for the actually intended product is granted. Once that registration is approved, the company either amends its falsely-obtained registration to incorporate the newly registered technical source (as intended all along), or simply abandons it.

Although it appears that this ploy is employed by a minority of companies the false registration scheme remains persistent and widespread. The undersigned Companies are aware of several companies that have obtained multiple registrations in recent years based on false certifications of the purchase of a registered product. In recent years, at least five petitions to deny, cancel, or revoke registrations have been filed by registrants due to false certifications of the purchase of a registered product. To the Companies' knowledge, EPA has not responded to any of these petitions, some of which have been pending for years, yet registrants are forced to continue to file them to protect their rights and to combat the injuries caused by false paper registrations. Eliminating false certifications of source by requiring applicants to include statements of non-objection from the registrants of claimed source products will eliminate the practice of submitting false certifications to EPA, will protect the rights of original registrants and data submitters, and will relieve the burdens on the Agency of processing applications, amendments, and petitions regarding registrations that serve no lawful purpose. This remedy would create little or no administrative burden for EPA or applicants, while saving substantial EPA resources currently used to process duplicate applications and address petitions and disputes.

3. Submitting false statements in an application package undermines the integrity of the registration process and violates FIFRA and other federal law.

EPA requires all applicants to certify under penalty of law the truth, accuracy, and completeness of the information provided in a pesticide product application. *See* Application for Pesticide Registration (EPA Form 8570-1) (attached as Exhibit D). More specifically, the

Formulator's Exemption Statement requires applicants to submit signed certifications that the product "*contains*" an active ingredient that "*is present* solely as the result of" the use of that active ingredient in the manufacturing, formulation, or repackaging of another product that "*is registered* under FIFRA Section 3," "*is purchased* by us from another person," and that "meets the requirements of 40 CFR Section [152.85(c)(2) or (3)]." Formulator's Exemption Statement, Exhibit A (emphasis added). Applicants must also certify to the active ingredient, product name, and registration number of each registered product they are using to formulate their product and must provide EPA with a Confidential Statement of Formula that identifies the registered products that are incorporated into the formulated product. *Id.*; Confidential Statement of Formula (Form 8570-4) (Exhibit E). These certifications are not merely an academic exercise. As described above, the formulator's exemption and its implementing regulations require that the applicant actually purchase the registered product in order to be exempt from the requirement to submit or cite data in support of the registration.

EPA has long recognized that its obligation to determine that a pesticide will not "generally cause unreasonable adverse effects on the environment" under FIFRA Section 3(c) is dependent upon the accuracy of data and certified statements submitted by the registrant. *See, e.g.*, EPA, Termilind Ltd.; Notice and Order of Revocation of Registrations, 62 Fed. Reg. 61890, 61893 (Nov. 19, 1997). As the Agency has noted, its ability to make an accurate finding in its registration determinations is "directly related to the reliability of the material submitted." *Id.* Accordingly, EPA has determined that a "fitness" or "reliability" criterion is applicable to the registrant as an implied component of the "unreasonable adverse effects" standard and may therefore serve as the basis for cancellation or revocation of a product registration. *Id.*

More directly, it is illegal to "knowingly falsify all or part of any application for registration" submitted to EPA under FIFRA. FIFRA § 12(a)(2)(M). Likewise, it is a violation of federal law subject to civil and criminal penalties to knowingly and willfully "falsif[y], conceal[], or cover[] up by any trick, scheme, or device a material fact" or to "make[] any materially false, fictitious, or fraudulent statement or representation" in any matter within the jurisdiction of the federal government. 18 U.S.C. § 1001. Applicants that (i) certify on a Formulator's Exemption Statement that an active ingredient "is present" in the applied-for product due to a registered product that "is purchased" by the applicant when they have no access to the registered product and no intent to ever purchase it, and (ii) use such false certifications as a pretext to obtain premature registration under the formulator's exemption of a product they actually intend to market using a different source of active ingredient have violated FIFRA and other federal law by knowingly and willfully submitting false statements and representations in their application for registration. These actions are unlawful in themselves, regardless of whether the registrations so obtained are ever used to offer, advertise, import, manufacture or sell any product or for any other purpose. This is reason enough for EPA to adjust its practices and requirements to ensure that companies cannot continue to make such false certifications for their own benefit with impunity.

4. False certifications regarding the purchase of registered technical product create significant issues regarding data integrity.

Applicants that formulate their product using registered technical product are required to submit certain product-specific data, including product chemistry data. *See* 40 C.F.R. § 152.85 ("In general, data for which the required test substance is the product proposed to be registered are not eligible for the formulator's exemption."); 40 C.F.R. §§ 158.300-355 (Product Chemistry data requirements). Among other things, applicants are required to submit a Confidential Statement of Formula that identifies the specific registered source of active ingredient consistent with the statements and certifications made in the Formulators' Exemption Statement,[4] and to describe the starting materials and formulation process, discuss any impurities of concern, and provide certified limits regarding the amount of active ingredient in the product. 40 C.F.R. §§ 158.320-340.

Applicants are also required to analyze and report on the physical and chemical properties of the actual formulated end-use product, including information on the formulated product's corrosion characteristics, stability, flashpoint, particle size distribution, and other attributes. 40 C.F.R. § 158.310. These analyses are required to be conducted using the actual formulated end-use product as the test substance. *Id.* This is impossible for applicants who do not actually have access to the claimed source of technical material. Thus, there must be discrepancies between what the applicant represents as the contents of the product in its Confidential Statement of Formula, Formulators' Exemption Statement and product identity and composition study and the test substance actually used for the chemical and physical characterization study and the product chemistry data submitted to EPA to support the application. On information and belief, companies pursuing this false registration scheme have submitted data to EPA that falsely identifies or misrepresents the test substance. Indeed, by definition, companies pursuing the false registration scheme lack access to the formulation they are purporting to test.

EPA must be able to rely on the accuracy of the certifications and data submitted by applicants. EPA's ability to properly regulate pesticides depends on its ability to know that the product it reviews and approves for registration is the product actually offered for sale and use under that registration. Allowing applicants to knowingly submit false or misleading test results undermines the entire FIFRA regulatory process. Such actions are properly viewed by EPA as serious transgressions that warrant vigorous enforcement. This provides another reason to end the practice of obtaining registrations through false certifications of source.

[4] The instructions for the Confidential Statement of Formula state that the complete chemical composition of the pesticide "must be known so it can be evaluated for registration" and require applicants to list the components of a formulation "as actually introduced into the formulation." Exhibit E at 2, items 10, 13a.

5. Companies cannot lawfully repack another company's product and offer it for sale under their own label without that company's consent.

As described above, companies sometimes obtain registrations under the formulator's exemption by falsely claiming that the product is a 100% repack of a registered end-use product purchased from another company. They sometimes seek to justify this approach by claiming that they could hypothetically purchase the product "off the shelf" from a distributor or retailer, repackage it under their own label in their own containers, and offer it for sale as their own product, regardless of how commercially unreasonable it may be to do so. However, offering this pretext to conceal their true intent – obtaining a premature "paper" registration for a product they actually intend to sell using another source – is itself a false representation.

Furthermore, it is not clear that actually repacking and offering a product for sale in this manner without the original registrant's consent would comply with FIFRA. *See e.g.*, FIFRA § 12(a)(1)(F)&(a)(2)(A) (making it a violation "to detach, alter, deface, or destroy . . . any labeling required under this subchapter" or to sell or distribute "any pesticide which is . . . misbranded"). Repackaging and offering another company's product for sale as one's own product without that company's consent would constitute unlawful "reverse passing off" in violation of general trademark and unfair competition laws. *See, e.g., Universal Furn. Intern., Inc. v. Collezione Europa USA, Inc.*, 618 F.3d 417 at 438-440 (4th Cir. 2010) (finding that a company that offered a competitor's furniture for sale under its own name as its own furniture was guilty of was "'reverse passing off,' which occurs when a 'producer misrepresents someone else's goods or services as his own,'" in violation of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A) and the state Uniform Deceptive Trade Practices Act) (citations omitted).[5] In other words, applicants claiming the formulator's exemption based on claims that they could hypothetically purchase the registered source product "off the shelf" without the original registrant's permission are not only making certifications based on false pretexts but also proposing a course of action that would be unlawful if carried out.

[5] *See also Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 32 (2003) ("Section 43(a) of the Lanham Act prohibits actions like trademark infringement that deceive consumers and impair a producer's goodwill. It forbids, for example, the Coca–Cola Company's passing off its product as Pepsi–Cola or reverse passing off Pepsi–Cola as its product."); *CMSI, Inc. v. Pac. Cycle, Inc.*, 2006 WL 2942794, at *2 (W.D. Wash. Sept. 15, 2006) (quoting *Summit Mach. Tool Mfg. Corp. v. Victor CNC Sys., Inc.*, 7 F.3d 1434, 1437 (9th Cir.1993) ("Although courts have expressed the Lanham Act's prohibition on reverse passing off in various ways, all agree that the practice entails selling another's goods as one's own. In the prototypical case, a party 'purchases or otherwise obtains a second party's goods, removes the second party's name, and then markets the product under its own name.'").

6. Falsely obtained paper registrations are used for improper purposes.

Some companies have argued in response to petitions to cancel that registrations based on false certifications of source are harmless "paper registrations" that do not implicate any legal requirements and should not concern the Agency. That is incorrect. Companies obtain false registrations to exploit them for their own commercial advantage, including circumventing FIFRA requirements, misleading the market, gaining an unfair advantage, and concealing illegal activity. Among other things:

- Some companies have used falsely obtained registrations to conceal the illegal import, manufacture, or sale of product made from an unregistered source.[6]

- Except for certain exceptions not applicable here, FIFRA prohibits any person from offering for sale (advertising) any pesticide product without a valid registration for the product. *See* FIFRA §§ 2(gg), 3(a), & 12(a)(1)(A); 40 C.F.R. 168.22(b)(4). Registrants have used the cover of a falsely obtained "paper registration" to advertise or offer a product for sale before an actually viable registration is obtained.

- Companies use falsely obtained registrations to compete unfairly against other registrants. Falsely obtained end-use registrations mislead consumers by suggesting that the company has access to a viable and legitimately registered product. Customers may also wrongly assume the company is working in concert with the original registrant where no other registered technical source is yet available. Companies can use falsely obtained registrations to apply for state pesticide registrations, beginning that process earlier than they would otherwise be able to. This may, for example, allow them to obtain a state registration in time to sell the product for a growing season when following the rules would mean waiting until the following year. All these options give companies that obtain premature registrations based on false certifications an unfair advantage over competitors who follow a lawful process.

The Agency should adjust its formulator's exemption process and requirements as proposed to eliminate false certifications of registered source, protect the integrity of the FIFRA registration process, and ensure unlawful activity is not rewarded by unfair competitive advantages.

[6] *See, e.g.*, EPA, Termilind Ltd.; Notice and Order of Revocation of Registrations, 62 Fed. Reg. 61890 (Nov. 19, 1997).

7. The policy described in the 1997 Memorandum is inadequate to curtail false registrations and to address the problems they create.

To our knowledge, EPA's most recent guidance regarding false certifications of source was issued more than twenty years ago. Exhibit C. That guidance has proved ineffective. The 1997 Memorandum continued EPA's policy of presuming, absent objection by the basic manufacturer, that the applicant has access to the registered source product on grounds that there is "no way for [the Agency under existing processes] to know whether or not the registrant has access to the material" cited in its application and the Formulators' Exemption Statement "or just wants a paper registration." *Id.* However, nothing in the guidance authorizes the abuse of the formulators' exemption process to obtain "paper registrations" based on false certifications regarding the purchase of registered source products. Instead, the guidance states that if the Agency receives a letter or petition to deny from the original registrant before the registration is granted, the Agency will impose conditions on the registration requiring the applicant to provide '[t]he name and address of the entity from which the manufacturing product was obtained" and "[a] copy of the bill of sale," which will be reviewed and referred to the Office of Enforcement and Compliance Assurance as appropriate. *Id.* at 1-2. The guidance also indicates that "[p]etitions to revoke a registration due to concerns with the formulator's exemption will be handled on a case-by-case basis." *Id.* at 2. The policy does not permit companies to obtain a registration based on false certifications without an actual commercial source consistent with their certified representations to EPA.

The approach outlined in the 1997 guidance has proved inadequate for three reasons. First, the original registrant generally has no way to determine that an applicant has falsely claimed its registered product under the formulator's exemption until the registration is granted. Under existing EPA practices, the original registrant is not given notice of the identification of its registered product in a formulator's exemption application, EPA generally does not produce application materials in response to requests under the Freedom of Information Act until after a registration is granted, and information regarding the identity of product source materials, including Confidential Statements of Formula and the registered product(s) identified on the Formulator's Exemption Statement, would generally be redacted as confidential business information. Since false registrations are often sought in parallel with efforts to obtain registrations based on a new independent source, original registrants typically cannot discern based on public information provided in accordance with FIFRA (e.g. NPIRS) that a particular end use product application is based on a false formulator's exemption claim using their registered product. No data submissions are required for 100% repack applications, so the original registrant will typically have no indication that such a product was even applied for until it is granted. Thus, original registrants are typically not able to submit a letter or petition to deny a registration that relies on a false certification of source before it is granted.

Second, even if it could be invoked, the recourse provided under the 1997 Memorandum is inadequate. Requiring the applicant to provide a bill of sale before selling the product does not address the other ways in which companies exploit false registrations, including by prematurely offering the product for sale, applying for state registrations, and misleading the market.

Third, the policy's assurance that petitions to revoke registrations that falsely invoke the formulator's exemption will be "handled on a case-by-case basis" has proved hollow. The Agency has received numerous such petitions and has been unable or unwilling to issue a ruling on them. This has left original registrants with no effective recourse against falsely obtained registrations under current policies and processes.

The proposed remedy better addresses the concerns expressed in the 1997 Memorandum and its recognition that original registrants have the right to object to applications based on false certifications of the purchase of their products. The approach set out in the Memorandum does not condone false "paper registrations," but instead reflects the Agency's perceived inability and apparent reluctance to get involved in policing commercial transactions. The remedy proposed by the Companies addresses EPA's concerns more effectively and efficiently, does not require EPA to become involved in commercial matters, and completely preserves an applicant's ability to pursue legitimate applications.

8. Requiring formulator's exemption applicants to furnish a letter from the registrant of the claimed registered source product is an appropriate and effective response that on balance will reduce the administrative burdens on the regulated community and save EPA resources.

Given the persistent practice by some companies of applying for registrations based on false certifications of source, with no ability or intent to ever purchase and use the identified product, it is no longer practical or prudent for EPA to continue to operate on the presumption that certifications of source are genuine and that applicants have access to and actually intend to purchase the registered products identified in the Formulator's Exemption Statement. The ongoing willingness of some companies to abuse the formulator's exemption process and the Agency's trust requires a change in the process to prevent such false certifications.

As detailed above, this problem can be efficiently and effectively solved by simply (1) adding a requirement to the Formulator's Exemption Statement that the applicant provide a signed letter from the registrant of each product identified on the form and (2) changing the front end screening process for formulator's exemption applications to require confirmation that such letters have been provided before processing the application.

As discussed above, the formulator's exemption excuses applicants from the obligation to submit or cite data based on the purchase and use of the identified registered products in formulating their products and the presumed business relationship between the applicant and the original registrant. Requiring applicants to contact the original registrants and obtain, at a minimum, a simple statement confirming that they are aware of and do not object to the applicant's identification of their products in support of their application is consistent with the intent and requirements of the formulator's exemption. Allowing formulator's exemption applicants to obtain registration without even notifying the registrants of the products they claim to be purchasing is not. This approach also allows for commercial transactions to occur, or not,

as determined by the companies' ability to make a commercial agreement without holding up the registration process and causing undue delay where there is genuine collaborative interest.

The new requirement will impose a negligible up-front burden on the applicant and the original registrant. A legitimate applicant who intends to purchase the registered product as claimed would already be in contact with the original registrant anyway (if not already working under a supply agreement). A simple form letter suitable for the purpose can be developed and used in each case. Companies have developed standard letters that authorize a regulatory agent to act on their behalf for a specific application, and a similar approach would work for the required non-objection letters.

The notice from the applicant to the original registrant that would be required to obtain a non-objection letter does not implicate any legitimate confidentiality concerns. There is no legitimate commercial reason to keep claims that the applicant "is purchasing" a registered product confidential from the registrant of that product. Parties would not be required to disclose any details of their business arrangement, or even whether a final agreement has been reached or is likely to be reached. Information on the Confidential Statement of Formula and Formulator's Exemption Statement about the identity of the claimed registered source products can still be kept confidential from other parties, as can the required letter of non-objection. Requiring only a simple non-objection statement provides maximum flexibility to the original registrant and the applicant to conduct and manage their business relationship on their own terms and schedule. It does not require the parties to finalize an agreement or actually purchase the product in commercial quantities before applying for the registration. Importantly, this remedy does not involve EPA in any commercial matters whatsoever. EPA's role would be limited to simply confirming that the non-objection statement has been submitted as certified by the applicant, as part of the front-end screen of the application package.

9. The proposed remedy improves the efficiency and effectiveness of the formulator's exemption process and reduces burdens on EPA.

The proposed new requirement is consistent with the requirements and goals of the Paperwork Reduction Act. Requiring formulator's exemption applicants to submit letters of non-objection from the registrants of identified registered source products is a necessary and practical solution that serves to protect the integrity of the registration process against false certifications, ensure companies do not obtain unfair commercial advantages through unlawful practices, and protect the data and commercial rights of original registrants. 44 U.S.C. § 3508. The proposed remedy will improve the efficiency and effectiveness of EPA's review and approval of formulator's exemption applications while minimizing burdens on the Agency, applicants, and the registrants whose products they cite. 44 U.S.C. §§ 3501(3)&(5); 3502(2), 3506(a)(1)&(b)(1).

Confirming receipt of the non-objection letters can be easily incorporated into the existing 21 day screening process and requires minimal additional effort by the Agency, which already reviews and confirms the consistency of the products identified in the Confidential

Statement of Formula and the Formulator's Exemption Statement. After confirming receipt of a non-objection letter, the reviewer can proceed on the assumption that it is valid, just as it does for letters authorizing a regulatory agent to act on a company's behalf. The reviewer need not undertake any further fact investigations, review business documents or bills of sale, or impose or track any conditions of registration. The new requirement would screen out false certifications at the outset, eliminating the need for EPA to review, approve and manage the subsequent amendment or cancellation of duplicative false "paper registrations" that serve no legitimate commercial purpose and are not intended to be used to ever sell actual product. It would also eliminate the substantial burdens of processing and responding to petitions to deny or revoke such registrations after they are granted.

C. Conclusion

For the reasons stated above, the Companies respectfully request that EPA revise the Formulator's Exemption Statement and update its policies to require applicants that invoke the formulator's exemption to obtain and submit non-objection letters from the registrant of each claimed registered source product.

Sincerely yours,

Kathryn E. Szmuszkovicz
Anthony L. Michaels
David A. Barker

Counsel for Bayer CropScience LP,
Corteva, Inc., and
Valent U.S.A. LLC

EXHIBIT LIST

Exhibit A.	Formulator's Exemption Statement (EPA Form 8570-27)
Exhibit B.	21 Day Content Screen Review Worksheet
Exhibit C.	James Jones, Director Registration Division Memorandum re Formulator's Exemption and Letters or Petitions to Deny Registration (November 21, 1997)
Exhibit D.	Application for Pesticide Registration (EPA Form 8570-1)
Exhibit E.	Confidential Statement of Formula (EPA Form 8570-4)

EXHIBIT A

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
	Product Name
	Date of Confidential Statement of Formula *(EPA Form 8570-4)*

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number

Signature	Name and Title	Date

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5. hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

EXHIBIT B

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2017

21 Day Screen Start Date: _____

Experts In-Processing Signature: _____ Date_____ Fee Paid: Yes __

Division management contacted on issues No_____Yes _____Date _____

EPA Reg. Number:	EPA Receipt Date:

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type					
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)					
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)					
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					
	a) Selective Method (Fee category experts use)	**yes**	**no**			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**					
7	**Is the data package consistent with PR Notice 86-5**					
8	**Notice of Filing included with petitions**					

9	**If applicable for conventional applications, reduced risk rationale**			
10	**Required Data and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

EXHIBIT C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Registration Division Branch Chiefs

FROM: James Jones, Director Registration Division Signed 11/21/97

SUBJECT: Formulator's Exemption and Letters or Petitions to Deny Registration

The Registration Division has been receiving an increasing number of letters or formal petitions to deny a registration from registrants with technical or manufacturing use products (hereafter basic manufacturer) who claim a registrant has cited their product for a formulator's exemption. The basic manufacturers are claiming that they do not sell their product to the registrant who is citing their product and, therefore, the registration should be denied.

In the past the Registration Division has always registered products when they take a formulator's exemption and have a complete application. There is no way for us to know whether or not the registrant has access to the material or just wants a paper registration. In addition there generally is no evidence that the registrant will not be able to obtain the formulating product he has cited. Unfortunately, we also do not know if the registrant will use an unregistered technical of known or unknown quality in the event he cannot get the cited material. In a situation where the basic manufacturer has written us in advance of a registration to tell us he has no intention of selling his product to the registrant our confidence that the registrant will be using the cited material in his registered product is weakened.

In general, the Registration Division will continue its policy of continuing to register products based on the formulator's exemption with out accompanying proof of purchase. However, if the Agency has received a letter or petition to deny a registration which is relying on a formulator's exemption and it is submitted by the basic manufacturer who owns the cited product prior to a

product branch taking action on the registration request, the product will be conditionally registered. Conditions of registration will include:

The registrant must provide the Agency the following information prior to formulating their product:

1. The registration number and establishment number of the manufacturing or technical product from which their product is derived,

2. The name and address of the entity from which the manufacturing product was obtained, and.

3. A copy of the bill of sale.

The product branches should review this information and use their judgment in determining whether to refer it to OECA for action as OECA deems appropriate. Referrals should be sent to Phyllis Flaherty of the Agricultural Branch, Agricultural and Ecosystem Division (2225A).

Petitions to revoke a registration due to concerns with the formulator's exemption will be handled on a case-by-case basis.

This policy is effective as of the date of this memorandum.

EXHIBIT D

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification ☐ None ☐ Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant *(Include ZIP Code)* ☐ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
4. Typed Name	5. Date

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to **Director, Collection Strategies Division (2822T) U.S.Environmental Protection Agency,1200 Pennsylvania Ave, NW,Washington, DC20460.**

INSTRUCTIONS: This form is to be used all applications for new registration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-34)**.** [If not exempted by 40 CFR 152.81(b)(4)].
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Data Matrix.

Submission of Labeling -Labeling should first be submitted in the form of draft labeling with all applications. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 **x** 11 inch file**.** Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.
Submission of Data -Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with new registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amendments actions, resubmissions, notifications, reregistrations, etc., Sections I**,** II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - The section must be completed, as applicable, for all registration actions.

1. **Company /Product Number** - Insert your company number, if one has been assigned by EPA. This number rnay have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** -If known, fill in the name end PM number of the EPA Product Manager.
3. **Proposed Classification** -Specify the proposed classification of this product. For most products the classification would be "None".
4. **Product Name** -Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** -The name of the firm or parson and address shown in your application is the person or firm to whom the registration will be issued. If you are acting on behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in theUnited Statesmust have an authorized agent residing in theUnited Statesto act for them in all registration matters. The name rand complete mailing address of such an agent must accompany this application.
6. **Expedited Review** -FlFRA section 3 (c) 3 **(B)** provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II -This section must be completed for a11 applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. **The Explanation Section should be used for any additional information regarding Sections I and II.**

1. Subject of submission -Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for he submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by…"; "reregistration submission"; "general label revision of direction for use", `notification for…". Attach a separate page if additional space is needed.

SECTION III - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** -Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container**- Indicate type of container in which product will be marketed.
3. **Location of Net Contents** -Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** -Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** -Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** -Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) -This section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5.Self-explanatory
6. EPA Use Only

EXHIBIT E

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065)

Form Approved. OMB No. 2070-00 Print Form -31-98

United States
Environmental Protection Agency
Washington, DC 20460

A. ☐ Basic Formulation ☐ Alternative Formulation

B. Page ____ of ____

See Instructions on Back

Office of Pesticide Programs (7505C) - Confidential Statement of Formula

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*	2. Name and Address of Producer *(Include ZIP Code)*		
3. Product Name	4. Registration No./File Symbol	5. EPA Product Mgr/Team No.	6. Country Where Formulated
	7. Pounds/Gal or Bulk Density	8. pH	9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation
16. Typed Name of Approving Official				17. Total Weight	100%			
18. Signature of Approving Official		19. Title		20. Phone No. (Include Area Code)		21. Date		

EPA Form 8570-4 (Rev. 8-94)

White - EPA File Copy (original) Pink - Applicant

★ U.S. GPO: 1995-386-820/20414

Instructions and Paperwork Act Notice
Please Read Carefully Before Completing This Form

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.0 hour per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

Instructions

The complete chemical composition of each pesticide must be known so it can he evaluated for registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

This form is designed for reporting the ingredients used in the formulation of a pesticide product. It must be completed and submitted with each application for new registration of a pesticide and application for amended registration if the revision involves a formula change.

Block A: Check the appropriate action for which you are submitting the form.

Block B: Number all pages consecutively. Enter on each page the total number of pages submitted. If more than one page is required, number them "1 of 2", "2 of2", "3 of 3", etc.

1. Name and Address of Applicant/Registrant: Enter the name and address of your firm or authorized agent.

2. Name and Address of Producer: Specify the name of the producer and the address of the site where this product will be produced.

3. Product Name: Specify the complete name of this pesticide product as it will appear on the label. This name must be the same as that which appears on the application form.

4. Rcgistlation Number/Filc Symbol: Enter the EPA registration number or file symbol, if known for this product

5. EPA Product Manager/Team Number: Enter the name and team number of the EPA Product Manager assigned to this product, if known.
6. Country Where Formulated: Specify the country where this product is formulated

7. Weight per Gallon/Bulk Density: For a liquid product specify pounds per gallon of formulated product. For a powder or granular product, enter the hulk density of formulated product (as used). Enter weight per unit if the product is produced as a tablet, briquette, or other uniformly shaped product
8. pH: Enter the pH of aqueous formulations and products which are either dispersible or soluble in water. If not applicable enter "N/A".

9. Flash Point/Flame Extension: Specify the flash point as determined by the regulations for pressurized products and/or products known or suspected to burn. State the results of the flame extension test for pressurized products including positive flashbacks.

10. Components in Formulation: List as actually introduced into the formulation. For each component in your formulation, provide the product name, commonly accepted chemical, the trade name, and the Chemical Abstract (CAS) number for each identifiable ingredient present in the product. CAS numbers may be obtained from the Chemical Abstract Service of the American Chemical Society, Columbus, OH. For each original and alternate source of each active ingredient in the product, indicate the percent purity of the manufacturing use product, technical product, or other source of active ingredient. If one or more components will be obtained from more than one source, enter all alternate sources and all alternate EPA Reg. Nos. in blocks 10, 11, and 12 or on a separate attachment.

Attention: (*Special Instructions for Columns 10, 13, and 14*) Any impurities greater than or equal to 0.1% (or less than 0.1% if the impurity is toxicologically significant) which are associated with the active ingredient(s) of n technical grade (manufacturing or reformulating use) product or an end use product produced by an integrated formulations system should also be listed in column 10, and the corresponding amount, percent by weight, and upper certified limits in columns I3 and 14.

11. Supplier Name and Address: Provide the name and address of the supplier of each component in the formulation. If one or more components will be obtained from more than one source, specify the names addresses of the alternate sources also.

12. EPA Reg. No.: Specify the EPA registration number, if any, for each active ingredient in the formulation. If an unregistered active ingredient is used, have the suppliers submit the chemical specifications, as well as any data required under 40 CFR Part 158.

13. Each Component in Formulation a. Amount: Specify the quantity of each component as actually introduced into the formulation. Units (e.g., pounds, grams, gallons, liters) should be expressed as used in the formulation. If the quantity is a liquid measure, enter the volume and the specific gravity or the pounds per gallon of the component.

b. Percent by Weight: Specify the weight percentage of each component in your formulation. Check Your Calculations. Note that the weight percentage in many cases will not agree with that shown on the label ingredient statement where the weight percentage of the per active ingredient(s) must he declared.
Attention: Producers of Microbial Products: Special Instructions for Column 13b.) Please state the percent of active ingredient in British International Units (BIUs). International Toxic Units (ITUs). Polyhedral Inclusion Bodies (PIBs)(viruses), Colony Forming Units (CFUs)(Fungi), as appropriate, and include an equivalent statement of active ingredient per milligram, ounce, pound, etc. of product (e.g., a 50% active Bacillus thuringiensis product may have an equivalency value of 1.59 million Aedis aegypti ITU per pound of product.

14. Certified Limits: These limits are to be set based on representative sampling and chemicnl analysis (i.e., quality control) of the product.

a. **Upper Limit:** Specify the maximum percentage of each active ingredient, intentionally added inert ingredient, and any impurities greater than 0.1% to he permitted in the product.

b. Lower Limit: Specify the minimum percentage of each active ingredient and intentionally added inert ingredient to he permitted in the product.

15. Purpose In Formulation: Specify the purpose of each ingredient both active and inert. (For example, disinfectant, herbicide, synergist surfactant, defoamer, sequestrant, etc.) If space is insufficient, abbreviate.

16. Typed Name of Approving Offirial: Complete this item for identification of individual to he contacted if necessary

17. Total Weight: Specify the total weight of the batch (column 13a.)
18-21: Complete these items for identification of individual to be contacted if necessary.