November 10, 2022

Submitted Via Email to PFASproducts@maine.gov

Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333

Re: Comments on "Second Concept Draft for the Maine PFAS in Products Program," Implementing Reporting Provisions of 38 MRSA Section 1612

To whom it may concern:

Thank you for the opportunity to provide comments addressing the Maine Department of Environmental Protection's ("DEP") "Second Concept Draft for the Maine PFAS in Products Program" ("Concept Draft") described during the October 27, 2022, stakeholder meeting.

Pesticides should be exempt from 38 M.R.S. §1614

CropLife America and RISE (Responsible Industry for a Sound Environment)® reiterate their request that DEP exempt pesticides from the requirements of 38 M.R.S. §1614. Pesticides undergo a rigorous scientific assessment process as part of the U.S. Environmental Protection Agency's ("EPA") registration procedures. All pesticides distributed or sold in the United States must be registered (licensed) by EPA. Pesticides include active ingredients, and any inert or other ingredients that constitute the whole formulation; these ingredients are described on the Confidential Statement of Formula ("CSF").

Pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), under which pesticides are regulated, EPA independently evaluates chemical-specific data for active ingredients and all of the components of the formulation to ensure that pesticides can be used safely and without unreasonable adverse effects to the environment[1] when label directions are followed. EPA's rigorous data review supports the registration of active ingredients and the inert and other ingredients. Importantly, EPA is also required to review each registered pesticide at least every 15 years to ensure that each pesticide continues to meet FIFRA requirements. As part of this registration review, EPA often seeks additional scientific information from registrants to

[1] FIFRA defines the term "unreasonable adverse effects on the environment" to mean: "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act."

ensure that EPA has the necessary scientific information to conduct its review, based on the best available science.

CSFs are already provided to the Board of Pesticides Control and therefore do not need to be submitted to DEP under the notification requirements of 38 M.R.S. §1614

In light of LD 264, directing the Maine Board of Pesticides Control ("BPC") to collect information on PFAS, BPC now requires the submission of the Confidential Statement of Formula ("CSF") in conducting registration or reregistration reviews of pesticides. In an effort to help ensure that confidentiality of information is maintained, the BPC recently upgraded its existing registration platform to collect CSFs.

BPC also requires the submission of two affidavits, one of which is most relevant to DEP's ongoing efforts to implement 38 M.R.S.§1614: "a completed and signed form provided by the Board at the time of application for product registration review or reregistration which attests that the pesticide formulation does or does not contain perfluoroalkyl or polyfluoroalkyl substances as defined by the Board […]."[2]

Thus, as noted by BPC, "The newly enacted affidavits, in combination with the new CSF submission requirements, provide a mechanism to identify all pesticide products containing intentionally added PFAS."[3] (emphasis added). It, therefore, would be entirely redundant for DEP to similarly require pesticide registrants to submit CSFs to DEP for pesticides that contain intentionally added PFAS, especially when DEP has not provided assurances that the information contained in the CSF will be kept confidential. Moreover, other information on pesticide manufacturers, such as company name, address, point of contact, and phone number, is currently publicly available on EPA-managed websites, and thus DEP should waive the need to submit this information.

Complying with 38 M.R.S. §1614 is predicated on forthcoming regulations, not a Concept Draft

Section 10 of 38 M.R.S. §1614 requires the Department of Environmental Protection ("DEP") to "adopt rules to implement this section [1614]." Other sections of the statue also anticipate regulations. For example, Section 2.A(5) empowers DEP to expand notification requirements to include: "Any additional information established by the department ***by rule*** as necessary to

[2] Board of Pesticide Control Regulations, Special Provisions, Chapter 20, Section 1.F.2.

[3] Board of Pesticide Control Regulations, Report to the 130th Maine State Legislature on LD 264 Resolve, Directing the Board of Pesticides Control to Gather Information Relating to Perfluoroalkyl and Polyfluoroalkyl Substances in the State, Legislative Report, FY 2021, available at: https://www.maine.gov/dacf/php/pesticides/documents2/legislative%20reports/LD_264_Report_to_the_130th_Maine_State_Legislature.pdf

implement the requirements of this section." (emphasis added). DEP acknowledges that it is "in the process of developing a rule to clarify the upcoming reporting requirements. During the rule development process there will be an opportunity for stakeholder input on the implementation of the program."[4] DEP also underscores the importance of rulemaking as a means to clarify notification requirements. Although DEP has not yet developed its online reporting system for products subject to 38 M.R.S. §1614, DEP nonetheless reassures impacted stakeholders that "[t]he database will be available to the affected manufacturers by the effective date of the Department's finally adopted rule."[5]

Even the Concept Draft for the Maine PFAS in Products Program ("Concept Draft"), acknowledges that the "rule would detail the notification requirements and sales prohibitions for products containing intentionally added PFAS under Maine's *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution,* 38 M.R.S. §1614." (emphasis in original).

To be clear, DEP has only issued a Concept Draft, which, of course, does not substitute for legally binding regulations pursuant to section 10 of 38 M.R.S. §1614. Until regulations have been formally proposed and adopted by DEP, the regulated community is forced to navigate ambiguity and uncertainty on key compliance issues, including: (1) whether products are exempt from 38 M.R.S. §1614; (2) whether notification requirements will be waived; (3) if notification is required, how to comply with 38 M.R.S. §1614; (4) what information will DEP consider to be confidential; and (5) the products in which the use of PFAS is currently unavoidable and, therefore, not prohibited from sale in Maine.

Given the lack of clarity to the regulated community on these and other issues, compliance with 38 M.R.S. §1614 must await proper promulgation of statutorily mandated regulations. The procedural due process protections afforded to submitters by both the U.S. and Maine constitutions demand nothing less.

In promulgating regulations, DEP should ensure that the regulations are **not** inconsistent with or in conflict with BPC's regulations regarding protection of CBI, including CSFs. If compliance with DEP **and** BPC regulations are impossible, section 8059 of the Maine Administrative Procedure Act will be triggered, under which **compliance with either regulation is deemed compliance with the other regulation**.

The Concept Draft is Ineffectual and Impermissibly Deviates from 38 M.R.S. §1614

Under section 2.A of 38 M.R.S. §1614, a manufacturer of a product for sale in Maine that contains intentionally added PFAS must submit a written notification to DEP, "[b]eginning

[4] Maine Department of Environmental Protection, Frequently Asked Questions, at: https://www1.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html

[5] *Id.*

January 1, 2023." The plain meaning[6] of "beginning," as defined by Merriam-Webster is "the point at which something begins."[7] Although the Concept Draft includes the words "beginning January 1, 2023," DEP impermissibly qualifies this language by adding "and prior to the sale or distribution for sale in Maine of a product that contains intentionally added PFAS." Not only does this additional language eviscerate the plain meaning of section 2.A, but it also effectively eviscerates the January 1, 2030, deadline of section 5.D., for the sale, offer for sale or distribution for sale in Maine of any product that contains intentionally added PFAS. Based on DEP's Concept Draft, failure to submit a notification by January 1, 2023, would prohibit the sale or distribution for sale in Maine of a product that contains intentionally added PFAS on January 1, 2023, a full seven years earlier than the January 1, 2030, deadline in 38 M.R.S. §1614.[8]

In addition, under the Notification requirements of the Concept Draft, a manufacturer must submit the product's Global Product Classification ("GPC") brick category and code. The Concept Draft, however, does not accommodate those manufacturers who do not use or rely on GPC or prefer to use another classification system. DEP should permit other forms of notification including, for example, by Chemical Abstracts Service Registry Number.

The Concept Draft Provides Insufficient Assurance that CBI Will be Protected from Public Disclosure

Consistent with 38 M.R.S.§1614, the Concept Draft requires manufacturers to notify DEP of "The amount of each of the PFAS as a concentration […] of each PFAS in the product or any product component reported as an exact quantity […]." For pesticides, this information is found in the Confidential Statement of Formula ("CSF"), which, as its name indicates, is confidential information and therefore not subject to public disclosure.

The Concept Draft includes a note that "Claims of Confidential Business Information may be made at the time of reporting and will be managed under the Uniform Trade Secrets Act 10 M.R.S. 1542(4)(A) & (B)." But the referenced sections of the Act are definitional and provide no information as to *how* specifically DEP will manage trade secrets, let alone delineate what information DEP would deem to be trade secrets. Even more concerning, elsewhere DEP asserts that one of the intended purposes of the notification system for intentionally added PFAS is to "allow for easy identification by all parties, including consumers, of which products contain

[6] Courts review an agency's interpretation of its statute by looking to the plain language of the statute. *Bankers Life & Cas. Co. v. Superintendent of Ins.*, 60 A.3d 1272, 2013 Me. 7 (Me. 2013)

[7] https://www.merriam-webster.com/dictionary/beginning

[8] DEP's Frequently asked questions also reiterates the erroneous assertion that by January 1, 2023, DEP must receive notice of all products that contain intentionally added PFAS. https://www1.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html

PFAS and if so, how much."[9] Based on this language, it appears that DEP may publicly disclose CSF submissions.

We ask that DEP finalize the rulemaking before requiring compliance to ensure proper internal protocols are in place for CBI and trade secrets in accordance with state and federal law. Such legal protections could be forfeited by using email to transmit CBI information, so time is also needed to develop and provide access to a secure portal for accepting CBI information from manufacturers and to set a process for accepting submissions by Federal Express with a cover letter clearly stating the enclosed information is CBI.

DEP must protect CBI from public disclosure

As DEP continues developing regulations to clarify the upcoming reporting requirements pursuant to 38 M.R.S.§1614, DEP must ensure that CBI will be fully protected from public disclosure. Without protections firmly in place, neither EPA nor the BPC will be able to meet their legal obligations under other statutory regimes to safeguard CBI.

Under Maine's Pesticide Control Act the submission of confidential information, "data submitted […] that have been determined confidential by the Administrator of the United States Environmental Protection Agency ["EPA"] in accordance with 7 United States Code, section 136h, (FIFRA section 136h) are confidential and may not be available for public inspection." 7 M.R.S.A. §607(5-A).

Section 136h of FIFRA[10] establishes the types of information that may be afforded confidential business information ("CBI") protection when submitted to EPA under FIFRA and how that protection may attach. Generally speaking, section 136h prohibits, with limited and rare exception, the public disclosure of information which in the EPA Administrator's judgment contains or relates to trade secret, commercial, or financial information that is obtained from a person and privileged or confidential. CBI includes for example, the concentrations of chemical constituents of the pesticide (i.e., Confidential Statement of Formula); manufacturing or quality control processes; details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide; and the identity or percentage quantity of any deliberately added inert ingredient of a pesticide.[11]

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[9] Maine Department of Environmental Protection, Frequently Asked Questions, at: https://www1.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html

[10] 7 U.S.C. § 136h.

[11] 7 U.S.C. § 136h(d)(1). Disclosure is permitted only if the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

In the unlikely event that EPA proposed to release information claimed to be protected, the Administrator must provide notice to the registrant, in writing, by certified mail 30 days prior to the information release. During this 30-day window, the registrant may institute an action in the appropriate district count for declaratory judgement as to whether the information at issue is, indeed, subject to protection.[12]

CBI Regulations - 40 C.F.R. Part 2, Subpart B

The confidentiality of business information regulations (40 C.F.R. Part 2, Subpart B) set forth the basic rules governing business confidentiality claims, how EPA handles such claims, and determinations by the Agency as to whether information is entitled to confidential treatment for reasons of business confidentiality.[13] Under these provisions, "reasons of business confidentiality" is defined to include three aspects of confidentiality.

First, "reasons of business confidentiality," includes the concept of trade secrecy and other related legal concepts. These concepts provide business with the right to hold their business information as confidential and limit use or disclosure of this information by others to retain business advantages derived from the information's exclusivity. In addition, the term also encompasses any concept that authorizes a federal agency to withhold business information under the Freedom of Information Act ("FOIA") exemption 4, which, as discussed in greater detail below, applies to "trade secrets and commercial or financial information obtained from a person and [is] privileged or confidential."[14]

Finally, the term "reasons of business confidentiality" applies to any concept that requires EPA to withhold information from the public under either the Federal Trade Secrets Act or any of the statutes identified in 40 C.F.R. § 2.301-309. FIFRA is among the statutes referenced. As for the Federal Trade Secrets Act, information subject to federal disclosure protection includes, "concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof."[15]

For companies selling products at retail, requirements for reporting sales volume must be amended to reflect that such data has Confidential Business Information protections. Also, with retailers exempt from reporting requirements, companies would need to know the volume of their products entering the state and ensure those reports are accurate to comply in a meaningful way. Currently, this information is not tracked by manufacturers on a state-by-state basis, and

[12] 7 U.S.C. 136h(c).

[13] 40 C.F.R. § 2.201.

[14] 5 U.S.C. 552(b)(4).

[15] 18 U.S.C. § 1905.

likely could not be known by January 1, 2023, given the complexity of distribution and retail supply chains and this unprecedented requirement.

FOIA also protects information from public disclosure

Federal protection of confidential business information also is embedded in Exemption 4 of the Freedom of Information ("FOIA"), which protects two distinct categories of information present in federal agency records: (1) trade secret information; and (2) information that is (i) commercial or financial, (ii) obtained from a person, and (iii) privileged and confidential.[16] For purposes of

FOIA's trade secret protections, the Court of Appeals for the District of Columbia Circuit has adopted a common law definition of "trade secret" which encompasses "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort."[17]

Information that does not qualify as trade secret may still be protected as commercial or financial information, which addresses a much larger category of information. While "commercial or financial" information is not defined under FOIA, courts have generally construed information relating to business or trade as "commercial or financial." In particular, the Court of Appeals for the District of Columbia Circuit has held that records should be considered "commercial" to the extent the submitter has a "commercial interest" in them, and that the term should not be narrowed to include only records that "reveal basic commercial operations."[18]

For example, a commercial interest has been found in information pertaining to how a corporation implemented its regulatory compliance program, the quantity of available water rights, favorable market conditions, and export insurance applications containing detailed information on goods and customers.[19] As for "financial" information, this term has been held to apply to both economic data generated solely by corporations or other business entities, as well as personal financial information.[20]

PFAS Definition

While we believe FIFRA-regulated pesticides should be exempt from reporting under 38 M.R.S.§1614 given duplicate reporting within BPC and public access to pesticide information,

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[16] 5 U.S.C. § 552(b)(4).

[17] *See Dept. of Justice Guide to the Freedom of Information Act: Exemption 4,* p. 1-2, https://www.justice.gov/oip/page/file/1207891/download.

[18] *Id*. at p.4-5.

[19] *Id*.

[20] *Id*. at p. 9.

we urge DEP to establish in its rulemaking regulatory alignment across federal and state definitions of PFAS. The EPA working definition should apply for consistency and to avoid confusion. EPA's definition is: a structure that contains the unit R-CF2-CF(R')(R"), where R, R', and R" do not equal "H" and the carbon-carbon bond is saturated.

Analytical Standards

The Concept Draft notes "any commercially available analytical standard," however, DEP has not developed or described a strategy or provided guidance for such a "standard," which is essential for the broad range of materials included in 38 M.R.S.§1614. Again, we continue to urge DEP to extend the compliance date for all sectors so that DEP can fully address these complex issues in rulemaking. For some materials there are currently no commercially available validated test methods available from EPA or elsewhere and where methods are available significant commercial lab capacity must be added in the United States to address Maine's 38 M.R.S.§1614 requirements.

Thank you for your consideration of our comments on this topic that is critically important to our industry and to the growers, consumers and professional applicators in Maine who rely on these products to manage pests. Please contact us if we may provide further information.

Sincerely,

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