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LIABILITY CONCERNS ASSOCIATED WITH WEB-DISTRIBUTED LABELING

CropLife America

This paper identifies a number of potential liability concerns relating to EPA's proposed creation of a web-distributed labeling ("WDL") system for FIFRA-registered pesticide products. "Liability" in this context encompasses two broad categories: (i) liability for violation of FIFRA and/or corresponding state pesticide laws ("enforcement liability"), and (ii) state-law damages suits, primarily for product liability and/or misapplication of pesticides ("product/tort liability"). As discussed below, several fundamental aspects of the proposed WDL system raise serious concerns regarding the liability exposure of registrants, distributors, dealers/retailers, and applicators/users.¹ The objective of flagging these liability concerns early in the WDL planning process is to promote discussion among EPA and stakeholders so that liability risks can be addressed and mitigated rather than impair or impede the system's adoption and implementation.

Types of Labeling-Related Liability

Because labeling plays a pivotal role in the registration, distribution, promotion, sale, and use of pesticides, it is a significant source of potential enforcement and product/

¹ This paper does not attempt to assess the Federal Government's own potential liability, if any, under the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b)(1) & 2680, if, for example, an EPA-hosted WDL system were to fail to provide parties in the chain of distribution or use with timely access to a product's current labeling.

tort liability. The following briefly summarizes the some of the principal types of labeling-related liability that pesticide registrants, distributors, retailers, and applicators or users endeavor to avoid.

1. Enforcement Liability

FIFRA enumerates at least three unlawful acts that are specifically directed to labeling:

- § 12(a)(1)(E) makes it unlawful “for any person ... to distribute or sell ... any pesticide which is misbranded.” *See also* § 2(q) (multi-part definition of “misbranded”).
- § 12(a)(2)(A) makes it unlawful “for any person ... to detach, alter, deface, or destroy, in whole or part, any labeling required under [FIFRA].”
- § 12(a)(2)(G) makes it unlawful “for any person ... to use any registered pesticide in a manner inconsistent with its labeling.” *See also* § 2(ee) (definition of “[t]o use any registered pesticide in a manner inconsistent with its labeling”).

FIFRA also specifies at least two additional unlawful acts that can implicate a product’s labeling:

- § 12(a)(1)(B) makes it unlawful “for any person ... to distribute or sell any registered pesticide if any claims made for it as part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under FIFRA § 3.” The § 3 “statement” required for registration includes the product’s labeling. *See* FIFRA § 3(c)(1)(C).
- § 12(a)(2)(S) makes it unlawful “for any person ... to violate any regulation issued under [§ 3(a)].” One such regulation is 40 C.F.R. § 152.130(a), which provides that “[a] registrant may distribute or sell a registered product with the ... labeling currently approved by the Agency.” *See also* § 2(gg) (definition of “[t]o distribute or sell”).

State pesticide statutes contain analogous provisions. *See, e.g.*, Cal. Food & Ag. Code § 12992 (prohibition against misbranding); N.Y. Env. Cons. Law § 33-1301(e) (same).

From a registrant's viewpoint, the most significant, labeling-related enforcement liability pitfall probably is FIFRA's broad prohibition against misbranding, which prohibits, *inter alia*, "false or misleading" statements, and requires label warnings and use directions to be "adequate to protect health and the environment." FIFRA § 2(q). EPA long ago stated that § 2(q), "which defines a 'misbranded' pesticide and enumerates specific labeling deficiencies that constitute misbranding," represents "[t]he statutory standard that is the basis for Agency regulation of pesticide labeling." 49 Fed. Reg. 37960 (Sept. 26, 1984). More recently, in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Supreme Court indicated that despite EPA's initial approval of a product's labeling, pesticide registrants "have a continuing obligation to adhere to FIFRA's labeling requirements," including the requirement that a product's "label complies with the statute's prohibition on misbranding." *Bates*, 544 U.S. at 438. Further, although FIFRA § 24(b) ("Uniformity") establishes EPA's primacy over pesticide labeling, the Court indicated in *Bates* that "[a]s part of their supplementary role, States have ample authority to review pesticide labels to ensure that they comply with both federal and state labeling requirements." *Id.* at 442. This would include, for example, "a State ... making the violation of a federal labeling ... requirement a state offense," or "imposition of state sanctions for violating state rules that merely duplicate federal requirements." *Ibid.*

The § 12(a)(1)(B) prohibition against advertising or promotional statements that "substantially differ" from a product's labeling also directly affects registrants, as well as

pesticide distributors and retailers. EPA has indicated that this “differing claims” prohibition extends to “collateral information,” including television, radio, and print advertisements, and website content. *See* Draft PR Notice 2007-B at 4. The distinction between “collateral information” and “labeling” as defined in § 2(p)(2), however, is not always clear.

Without question, a principal enforcement liability concern of pesticide applicators and users is avoiding the § 12(a)(2)(G) prohibition against using a pesticide in a manner inconsistent with its labeling. Because “[a] pesticide label is the user’s direction for using pesticides safely and effectively,” 70 Fed. Reg. 12276, 12281 (Mar. 11, 2005), EPA long has focused on the enforceability of label language. *See, e.g.*, EPA PPDC Workgroup Discussion Paper on Enforcement of Web-Distributed Labeling (June 5, 2009); PR Notice 2000-5 (Guidance for Mandatory and Advisory Labeling Statements). Inasmuch as FIFRA § 26(a) affords the States “primary enforcement responsibility for pesticide use violations,” state pesticide enforcement personnel need to possess or access, and often must interpret, the requirements set forth on a product’s EPA-approved labeling. As a practical matter, interpretations of the same nationally uniform label language can vary from state to state. Further, some states do not “recognize” FIFRA § 2(ee), which defines use inconsistent with labeling in a way that, in many instances, affords applicators flexibility to use a product for unlisted pests, at rates lower than the labeling specifies, or by methods of application that are not listed.

2. Product/Tort Liability

Damages suits alleging injury (e.g., personal injury; crop, environmental, or other property damage; consumer fraud) resulting from sale, distribution, application, or use of FIFRA-registered pesticides arise under state law. Nevertheless, there often is a link between state-law liability and a pesticide's EPA-approved product labeling.

For example, virtually every state's product liability law, whether established by statute and/or common-law judicial precedent, recognizes a cause of action for selling or distributing potentially hazardous products with inadequate instructions or warnings. *See generally* Restatement (Third) of Torts § 2 (1997). But because pesticide labeling is comprehensively regulated by EPA, it falls into a special category. *See generally Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 613 (1991) (discussing "FIFRA's historic focus on labeling"). The Supreme Court held in *Bates* that FIFRA § 24(b) ("Uniformity"), which prohibits a State from imposing "any requirements for labeling ... in addition to or different from those required under [FIFRA]," expressly preempts state-law causes of action against pesticide manufacturers for failure-to-warn, provided that a product is not misbranded under FIFRA. *See Bates*, 544 U.S. at 454. The Court indicated that "[i]f a defendant so requests, a court should instruct the jury on the relevant FIFRA misbranding standards, as well as any regulations that give content to those standards ... a manufacturer should not be held liable under a state labeling requirement subject to [§ 24(b)] unless the manufacturer is also liable for misbranding as defined by FIFRA." *Ibid.*

Further, even as a matter of state tort law, a pesticide registrant's compliance with EPA labeling requirements can serve as the basis for a regulatory compliance defense. *See* Restatement (Third) of Torts § 4 cmt. e (1997).

State-law suits alleging that a pesticide was misapplied also are directly linked to product labeling, and more specifically, to compliance with precautionary measures or directions for use. Claims that a pesticide was applied in a manner inconsistent with its labeling may serve as the basis for negligence-based causes of action against commercial or private applicators. Conversely, proof of compliance with a pesticide's labeling can provide a persuasive, if not dispositive, defense to such claims.

Pesticide labeling also often includes warranties, disclaimers, and/or limitations of liability, which EPA reviews for certain purposes. *See OPP Label Review Manual* (3d ed.) at 12-6. Such statements, whose force and effect are governed by state law, play an important role in the legal and commercial relationships between pesticide registrants and users.

Areas of Concern

A WDL system structured or operated in a manner that increases the exposure of all or some registrants, distributors, dealers/retailers, or applicators/users to the types of enforcement or product/tort liability discussed above would undermine the attractiveness and utility of the proposed WDL system. For this reason, it is important that EPA work with industry stakeholders in addressing and reducing potential liability concerns relating to the system.

Because the WDL system still is in a formative stage, it is difficult at this point in time to identify specific sources of potential liability with precision. Nevertheless, the following general list of liability concerns relating to the proposed system provides a basis for initial consideration and discussion:

1. Voluntary vs. Mandatory System — A level playing field for product labeling is very important to pesticide registrants, who produce and distribute competing products. In particular, each registrant is responsible for developing in accordance with EPA requirements, submitting for review and approval, and disseminating, its own product labels and labeling. But now EPA not only is proposing to become directly involved in the process of making product-specific labeling available to the chain of distribution and use, but also is recommending that the WDL system be *voluntary*. EPA has indicated that under a voluntary system, each registrant would decide whether or not to participate, and possibly which of its products would or would not be included. According to EPA, while a mandatory program would ensure that only one system is being used, it would require rulemaking and would be more difficult and time-consuming to implement.

The issue of whether the WDL system should be voluntary or mandatory has many potential enforcement liability and product/tort liability implications. In particular, a voluntary system likely would produce an uneven playing field. Depending upon the circumstances, a voluntary system could increase potential liability exposure for registrants that choose to participate (e.g., in the event that an EPA-hosted system fails to provide timely access to a product's most current labeling), or increase liability exposure

for those registrants that do not (e.g., in the event that a non-participating registrant's marketed product labeling already in the chain of distribution is not as current as a competing product's labeling that is readily accessible through the WDL system).

In contrast, a mandatory system would have the force and effect of law, and the labeling of all registrants' similar or competing products presumably would be accessible in the same manner and at the same time. Under a mandatory, EPA-hosted system, however, registrants would be required to cede to EPA at least some control over dissemination of their own product labeling. If such a mandatory system nevertheless permitted registrants to continue physically distributing labeling (in addition to making the same labeling available through the WDL system), that could diminish some of the perceived benefits of the system.

Similar potential liability issues may arise in connection with utilization of the WDL system by distributors, dealers/retailers, and commercial or professional applicators. For example, under a voluntary system, an applicator's decision to use a product and follow labeling that has not been placed on the system, rather than using a product and following labeling that is on the system, potentially could have liability consequences. With a voluntary system, any tort lawsuit against an applicator, distributor, dealer/retailer and/or registrant could focus on the question of why the product/label at issue was not included in the system. Additionally, in a voluntary system, those products and labels that participate in the system could be unfavorably compared to those that are not included in the system.

As these examples illustrate, a voluntary vs. mandatory WDL system is a complex question from a liability viewpoint. It warrants considerable further analysis and discussion.

2. Scope of WDL System — EPA has recommended that the WDL system encompass pesticide products that are for agricultural or non-agricultural professional or commercial use. Further, while EPA has indicated that general-use consumer/residential products should continue to have their full labeling accompany product containers, individual registrants could choose, in addition, to have their product labeling posted on the WDL system.

From a liability prevention viewpoint, it is essential that EPA not only identify with greater precision the categories or types of products that would or would not be covered by the WDL system (regardless of whether it is voluntary or mandatory), but also set forth the rationale for inclusion or exclusion. In addition to developing a better definition of the scope of the system, there should be a mechanism for registrants to obtain from EPA a prompt and definitive determination whether a particular end-use product or type of product is covered by the system.

As to excluded products (i.e., products that must be physically accompanied with container labeling), EPA's suggestion that an individual registrant nevertheless may choose to post product labeling on the WDL system is a potential source of confusion and also creates the specter of an uneven playing field between residential-use product registrants that choose to post labeling on the WDL system and those that do not.

3. Definition of “Web-Distributed Labeling” — To help minimize liability, the types of labeling or labeling information that should and should not be uploaded into the WDL system need to be specified with clarity and precision so that contents of the system are consistent and predictable. Up to this point, EPA has identified various types of product-specific materials and information which *could* be made accessible through the WDL system. For example, in addition to the most current version of “state-approved” marketed product labeling, EPA has suggested that other informational materials, ranging from Material Safety Data Sheets, to technical bulletins, to rate calculators, could be made available. The Agency has indicated that a product’s master labeling (i.e., labeling containing all approved uses) also could be made available through the system.

Allowing each registrant to decide for itself what types of product-specific information to include in the WDL system and/or on labeling physically attached to a product’s container would engender lack of uniformity, and in turn, produce potential liability concerns. As with a voluntary system, a lack of uniformity in which type information is provided in a WDL system would result in different types of review in tort liability lawsuits. There needs to be a clear and uniform set of definitions, rules, or procedures regarding what information must appear on the label, what information must be included on labeling physically attached to a product’s container, and what labeling or labeling information would be accessible through the WDL system. EPA also needs to draw a clear line of demarcation between labeling and non-labeling “collateral information.”

4. Operation of the WDL System — One of the most fundamental potential liability concerns in connection with the WDL system is that registrants would be relying upon an EPA-hosted WDL system to provide distributors, dealers/retailers, and applicators/users with access to important parts of their product labeling (e.g., allowable uses; directions for use; supplemental technical information). If the EPA system, due to circumstances beyond the control of the registrant, were to fail to provide timely access to a product's current labeling, it is unclear to what extent, if any, the registrant, distributor, dealer/retailer, or applicator/distributor would have liability exposure for the WDL system's shortcomings.

A corollary to this issue is whether registrants or other parties in the chain of distribution or use that voluntarily participate in or utilize the WDL system, first would be required, from the viewpoint of product liability prevention, to perform some sort of due diligence on the system's capabilities and performance.

At the very least, EPA would need to construct a highly durable and efficient system from both a technological and human resources viewpoint, and provide the necessary assurances of performance capabilities to potential participants and other stakeholders. The concept of a limited pilot program appears to afford a viable way of testing the system while still in an incipient stage. But even a pilot program (i.e., a program involving a limited number of products), should be consciously designed in a way that minimizes potential liability.

Similar concerns would arise if EPA, rather than hosting a WDL website, were to require each registrant to post its own labeling on its own website. At a minimum, EPA

would have to establish a uniform set of technological and operational guidelines that, to ensure a level playing field, each participating registrant would have to follow.

Registrants' adherence to such guidelines should represent a "safe harbor" for EPA enforcement purposes, but issues could arise about some registrants' financial ability to construct and maintain a WDL-compatible website that complies with EPA's guidelines. Further, under such a system of registrant-hosted websites, issues could arise about third-party liability (e.g., vendors that construct and maintain WDL websites under contract with individual registrants).

5. Allocation of Responsibilities — The WDL system would need to clearly delineate and allocate functional responsibilities among EPA, registrants, distributors, dealers/retailers, and applicators/users. For example, EPA would have to specify exactly what its own role would be in operating and maintaining the system (e.g., whether EPA or EPA contractor personnel would upload labeling into an EPA-hosted system, or whether that function would be performed by individual registrants that log into the system). As another key example, the responsibility and timing for downloading and printing a product's labeling to get it into the hands of applicators/users would have to be clarified. A third example is the responsibility for monitoring and replacing labeling, which would have a limited lifespan on a WDL system.

In allocating responsibilities, the WDL system must preserve registrants' free enterprise commercial prerogatives. These include, for example, business decisions regarding which particular end-use labels (i.e., products) to market, and when.

The rules not only have to be clear, but also need to be carefully considered and formulated, because they may have potential liability-shifting consequences. For example, what would be the potential liability consequences for different parties within the chain of a product's distribution and use if the registrant's only responsibility regarding web-distributed labeling were to ensure that most current versions have been uploaded into the system, and distributors or dealers/retailers have the responsibility for downloading, printing, and disseminating the appropriate and current labeling to applicators? Such issues must be considered in advance so that the system is designed in a way to minimize liability throughout the chain of distribution and use.

6. Role of the States — EPA has suggested that one of the WDL-system's principal functions should be to provide access to "state-approved labeling" for a specific product. As a result, EPA has indicated that users must be able to conduct labeling searches by state.

It is essential that the WDL system not confuse a State's authority under FIFRA § 24(a) to register a pesticide product (or deny registration to a pesticide product) that has been granted a registration by EPA, with a State's lack of authority under FIFRA § 24(b) to regulate the content or format of pesticide product's labeling. The Supreme Court in *Bates v. Dow AgroSciences LLC* made it clear that *only EPA* has authority to require that "manufacturers label ... their products in any particular way." 544 U.S. at 444. The Court explained that § 24(b) "retains a narrow, but still important role ... it pre-empts competing state labeling standards - - imagine 50 different labeling regimes prescribing

then color, font size, and wording of warnings - - that would create significant inefficiencies for manufacturers.” *Id.* at 452.

Thus, a State cannot directly, or indirectly, regulate the content or format of pesticide labeling. The only product labeling that a State has authority to “approve” is labeling that is identical to the labeling that EPA already has approved. (Even § 24(c) special local needs labeling is subject to EPA review.) For example, a State cannot condition the granting of a state pesticide registration on changes that it would like a registrant to make to a product’s EPA-approved labeling; that would be tantamount to the State regulating the product’s labeling and is expressly preempted by § 24(b).

Some States can and do require every separately marketed end-use product (including products marketed with “subset labeling”) to receive a separate state registration. A WDL system that provides access to a marketed product’s subset labeling, and also indicates which states have registered that product, seems appropriate. But for the reasons discussed above, the WDL system should not purport to provide access to a product’s “state-approved labeling.” This is more than a matter of semantics; it goes to the heart of § 24(b) and EPA’s congressional mandate to establish and maintain a system of nationally uniform labeling for each pesticide product. It also has liability implications for pesticide registrants, who, in accordance with § 24(b), look solely to EPA to regulate the content and format of their product labeling, and raise § 24(b) as an affirmative defense in state-law product-liability suits alleging failure to warn of inadequate labeling.

7. Need for Common Understanding Regarding Nature, Scope, and Operation of the WDL System — As suggested by many of the areas of concern described above, to help avoid or mitigate potential liability, everyone involved in the WDL system (e.g., EPA personnel; state regulators; registrants, distributors, dealers/retailers; applicators/users) would need to have a common understanding regarding the nature, scope, and functioning of the WDL system. The best way to foster such an understanding may be for EPA to issue, following adequate opportunity for stakeholder and public review and comment, a comprehensive and detailed WDL Operational Manual or similar document. The manual should be made available in final form well in advance of the WDL system's launch, and should be supplemented with EPA-sponsored technical briefings. As experience with the system is gained, the manual can and should be revised.

Recommendation

In designing a WDL system, EPA, in consultation with industry and other stakeholders, should carefully explore the system's potential enforcement and product/tort liability implications, and should construct and operate the system in a way that minimizes potential liability exposure.