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EPN Comments on EPA's White Paper Describing Benefits of Structured and Digital Content Labels for Pesticide Products

Docket No.: EPA-HQ-OPP-2023-0562

March 14, 2024

The Environmental Protection Network (EPN) harnesses the expertise of more than 600 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

I. Introduction and Overview

EPN appreciates the opportunity to offer comments on EPA's "WHITE PAPER: Benefits of the Adoption of Structured Content and Digital Pesticide Labels" (White Paper). The White Paper identifies multiple issues related to the labeling of pesticide products. Broadly, these issues include how to:

- make the submission, review, and approval of labeling of pesticide products more efficient;
- make the review and approval of labeling across pesticide products more consistent;
- make the extraction of data from labeling for use in EPA risk and benefits assessments more accurate and efficient;
- improve the enforceability of labeling;
- improve the clarity and readability of labeling for users;
- improve users' compliance with labeling; and
- provide the ability to search labeling of pesticide products to find desired information.

The White Paper sets forth, at a very high level, a vision of a new system for the creation, submission, organization, storage, review, approval, and dissemination of labeling content that could address each of these problem areas. EPN wholeheartedly agrees that these are areas of EPA's regulatory program that need attention and, more importantly, that changing the way the agency and the regulated community handle pesticide labeling could make significant improvements in all these areas. And all these changes, in turn, could contribute meaningfully to better protection of human health and the environment.

The White Paper is a useful addition to the public discussion about how to address multiple issues related to the labeling of pesticide products. But we suggest that EPA follow up on the White Paper with another document that addresses two important areas in much greater depth. The first would be a description of the history of EPA's work in this space. Doing so would be valuable for all stakeholders in understanding both the accomplishments to date and the challenges ahead. The second would be a detailed implementation plan for developing the envisioned structured digital labeling system. The plan would contain sufficient detail for the public to understand how EPA expects to develop its structured digital labeling system – details that EPN feels are essential for the effort to succeed. Because a great deal of work has already been done and because the benefits are obvious, developing structured content and digital labels should be a high priority for EPA. EPN comments on each of these areas in the balance of these comments; our ideas are summarized below.

- Acknowledging the history. At least 20 years ago, EPA recognized the potential of a computer-based system for capturing and reviewing pesticide labeling information. The agency has been working in earnest to create such a system since at least 2014 and has invested considerable money and staff time in the effort. Thus, given how much attention this effort has received and how valuable such a system would be, EPN is disappointed that the White Paper does not acknowledge the agency's accomplishments or address in depth the lessons learned from this work and the important remaining questions about how to finally build a structured digital labeling system. For example, the White Paper does not fully describe the agency's creation of several categories of controlled vocabulary, nor does it explore the reasons why EPA still does not have a prototype system. These would be important topics to cover as EPA and its external stakeholders move ahead.

  Although EPN volunteers do not have detailed familiarity with the agency's work on the structured digital labeling system in recent years, we bring insights from many years of experience working at the agency. Our collective experience informs the observations in these comments about the challenges of creating a structured digital labeling system that meets the myriad needs of the regulatory program and the external stakeholders.

- Laying out a detailed plan. While the White Paper offers a grand view of the many benefits a structured digital labeling system would bring, in our view, the White Paper does not present a clear path forward for realizing the vision. This confusion about how to make the system a reality is evident in two ways. First, the description of potential benefits assumes a structured digital labeling system that has many different capabilities of varying complexity and sophistication, but the White Paper does not clearly identify which capabilities could be achieved relatively quickly and which will need many years to realize. Second, a constructive plan should lay out reasonable expectations about what products will be produced at each stage of building the system, but the White Paper offers only a very sparse description of proposed phases of EPA's overall plan. Because EPN thinks that building a structured digital labeling system is critically important for the long-term success of EPA's regulatory program, our comments will offer our ideas about how to achieve this vitally needed transformation of pesticide labeling.

  EPN believes that EPA needs to have a considerably more detailed plan for creating the final structured digital labeling system. Most importantly, the plan should identify the essential, foundational components of the system needed to eventually allow and support the full vision described in the White Paper. In addition, to demonstrate progress, gain acceptance, and build momentum for the work, EPN believes it is important to recognize what is possible in the near term and to produce early, useful components that will eventually fit into a comprehensive system. We offer our specific suggestions about a stepwise approach to building the components.

Our comments are organized as follows. First, we will define some key terms used throughout these comments. Second, we will discuss each category of proposed "benefits" described in the White Paper. Our discussion will identify the specific system capabilities needed to realize the benefits. Third, we will discuss the challenges listed in the White Paper, as well as a critically important, additional challenge that confronts the successful creation and adoption of a new system – how to achieve universal participation. This will include our understanding of the problems encountered in EPA's effort to build the "Office of Pesticide Programs Electronic Label" (OPPEL) system. To the extent we see possible ways to overcome these challenges, we will offer our suggestions. Fourth, we will comment on EPA's proposed development plan for

building the new system. We will suggest a path forward that, we think, would bring more benefits more quickly. Finally, we present comments on the relationship between structured labeling content, a structured digital labeling system, and the display of labeling content for users, both labeling attached to accompanying products in the channels of trade, and as Web-Distributed Labeling (WDL).

II. Terminology

The agency has formed the Label Reform Work Group (LRWG) under the auspices of its Pesticide Program Dialogue Committee (PPDC). The LRWG is trying to develop a template for submission of structured labeling. EPN participation in the LRWG over the last six months has revealed that an impediment to progress on building a structured digital labeling system is that EPA staff and stakeholders often have different understandings of the meaning of key terms. For purposes of EPN's comments, we offer the following definitions and observations.

A. Statutory Terms

Label/Labeling. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2 (p)(1) defines "label" as the "written, printed, or graphic matter on or attached to the pesticide or device or any of its containers or wrappers." "Labeling" according to FIFRA Section 2(p)(2) includes "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made … ." Thus, these definitions draw a distinction between the matter attached to the pesticide container – the "label" – and any written material, e.g., a pamphlet or booklet, that accompanies the container or is referenced – the "labeling." Notwithstanding these statutory definitions, most stakeholders refer to both a physical label on the container and a pamphlet accompanying the product as "the label." For purposes of these comments, however, we use "label" and "labeling" as they are defined in FIFRA Sections 2(p)(1) and 2(p)(2)(A). In these comments, unless otherwise noted, the term "labeling" does not include material referenced in labeling that does not accompany the pesticide container in channels of trade – FIFRA Section 2(p)(2)(B) materials.

B. Terms concerning labeling provided to users of pesticide products

Master label. This is the term commonly used to describe the version of all FIFRA 2(p) matter – the physical container label, the labeling, and any other referenced Section 2(p)(2)(B) matter – that is initially submitted by a company as part of an application, and the version approved by EPA as part of the registration of a pesticide. The version submitted with an application may be presented as typescript in a word processing software file or as a .pdf file and may lack the formatting that appears when the product is sold or distributed[1].

Final Printed labeling. This is the version of the master label that is submitted to EPA following approval of the product, and it shows the full contents of the master label as it would be formatted when the product is distributed.

[1] See 40 CFR 152.50(e).

Marketed product labeling. This is the version of the labeling that accompanies the pesticide when the product is in channels of trade. At the discretion of the registrant, the marketed product labeling may contain more limited directions for use than appear on the EPA-approved master label.

Web-distributed labeling. This is a version of the master label or the marketed product labeling that is available from the internet using a QR code, website address, or similar link that appears in the marketed product labeling. The website accessed in this manner gives the user options to obtain an electronic file containing all required labeling content from the approved master label that is necessary the way the user intends to use the pesticide. The constraints on registrants and users who choose to use WDL appear in EPA's Pesticide Registration (PR) Notice 2014-1.

Labeling content. This term refers to the substance of the written, printed, and graphic matter that appears in labeling.

Labeling display. This term refers to the visual appearance of labeling content on marketed product labeling or in WDL .

C. Structured Digital Labeling System Terms

Structured labeling. This term refers to a fixed sequence for presentation of the labeling content of the master label, the marketed product labeling, and WDL. The White Paper refers to this as a "structured label."

Label sections/data fields. EPN uses the term "label section" to refer to the portions of labeling addressed in EPA's Label Review Manual (LRM). Generally, a label section will cover several different types of information and often can be quite large. Examples of label sections include: Ingredients Statement, Precautionary Statements, Directions for Use, Storage and Disposal, and Warranty Statements. The White Paper appears sometimes to use the term "data fields" to refer to label sections.

Data elements/data fields. The term "data element" refers to the distinct, discrete pieces of text or an image in the labeling content of a pesticide. Its meaning is carefully defined and named with metadata in a way that allows agency staff or other stakeholders to search EPA's database for the content associated with the data element. A data element can consist of a single word, a numerical value, a sentence or longer body of text, or an image. Typically, a label section will contain several or even many data elements. In addition, a data element can contain sub-elements or data units that can be a combination of these types of entries. For example, the label section "Ingredients Statement" lists the name of each active ingredient in the product and its percentage by weight. The name of an active ingredient and its associated percentage would be two separate data units in a single data element. The White Paper sometimes uses the term "data field" to mean "data element."

Framework/Template. This refers to a fillable form to capture the data elements of a product's labeling in the structured sequence. The LRWG uses the term "template." The White Paper appears to use "framework" with the same meaning.

Metadata. This term refers to data that gives information about other data. In the context of a structured digital labeling system, metadata means the searchable electronic "tag" that specifies a particular type of

labeling content that appears in a master label. For example, a pesticide label may bear the signal word "Danger" based on the toxicity of the product formulation. The metadata for this data element would be "signal word" and the content would be "Danger."

Structured digital labeling. Structured digital labeling means an electronic file that attaches metadata to each data element in the framework for structured labeling. Adopting the common usage of "label" to include matter covered by the statutory terms defined in FIFRA Sections 2(p)(1) and 2(p)(2)(A), the White Paper refers to structured digital labeling as a "structured digital label."

Structured digital labeling system. This term refers to the combination of computer software and hardware that enables the creation, submission, storage, organization, retrieval, comparison, review, and dissemination of structured digital labeling.

Picklists/Libraries. These terms refer to lists of acceptable words or phrases that EPA has reviewed and found acceptable for use in master labels. The White Paper refers to "libraries," and the LRWG uses the term, "picklists," with the same meaning. A picklist would be associated with a specific data element and contain two or more choices of acceptable labeling content. In many cases the choice of a word or phrase from a picklist would be subject to a rule that would depend on characteristics of the pesticide. For example, there are four choices for the required signal word on pesticide labels; the acceptable choice depends on the toxicity of the pesticide formulation.

Controlled vocabulary. This term refers to the designation in EPA guidance of certain words or phrases that labeling should use. Controlled vocabulary is an example dof a picklist. For example, EPA has a recommended vocabulary list that should be used in labeling to describe the physical form of a pesticide formulation. The list for a product packaged in a solid form states the labeling may use: "crystalline," "dust," "powder," "encapsulation," "granule," "impregnated material," "pellet," "tablet," "rodlet," "briquette," or "solidified agar." Each has a definition. While an applicant could propose other terms, these would be an automatically accepted word or phrase for labeling.

Automation tools. This term refers to the capability of the computer software in the structured digital labeling system to execute certain functions that EPA staff now perform during a review of a master label. These tools could include automatically inserting content for a data element into the structured digital labeling, based on information about the product, e.g., inserting the name and percentage of the active ingredient into the corresponding data element for the Ingredients Statement. A tool could also extract the labeling content, e.g., the types of personal protective equipment and clothing required for applicators, from structured digital labeling and put that information into a risk assessment algorithm.

III. Benefits of Structured Labeling and Structured Digital Labeling

EPA's White Paper contains a substantial discussion of various categories of benefits that would come from implementing a system to handle structured digital labeling. EPN agrees that each category of benefits, except "international harmonization," would be worth pursuing and are achievable in various time frames. Having described what a structured digital labeling system might bring, we think it is vital to look beyond this broad vision to understand and identify the capabilities of a system that would be necessary to deliver these benefits. The agency needs to understand exactly what the desired system will have to do so that it can design a system with those functions. (Because there is some overlap and repetition in the ideas mentioned

in the different sections of the benefits discussion, we have combined several sections for purposes of these comments.)

A. Increased Registration Accuracy, Quality, and Efficiency and Regulatory Consistency

EPN agrees that some of the biggest gains from a system capable of handling structured digital labeling would be an extraordinary increase in efficiency, accuracy, and consistency in EPA's review of pesticide labeling. The first two sections of the benefits discussion identify four different examples of how a structured digital labeling system could benefit actions taken during the agency's review processes:

- Being able more easily to find relevant labeling content in structured labeling;
- Conducting accurate comparisons of labeling content in different versions of the structured digital labeling for a product to identify changes;
- Using computer software to check whether structured digital labeling contains only controlled vocabulary and EPA-approved text for specific data elements; and
- Extracting necessary information from structured digital labeling for use in EPA risk and benefits assessments.

As EPA knows, almost every Office of Pesticide Programs (OPP) staff person in its regulatory and science divisions must refer to the approved master label for pesticide products in the form of document files. Improving labeling and how it is handled will, therefore, help almost all of OPP.

The payoffs for the regulatory divisions are clear. During their review of applications for registration of new pesticide products or for amendments to currently registered products, staff in OPP's registering divisions review electronic files (e.g., .pdf or .doc files) that present the content of master labels for the products. These reviews have many different functions. One essential piece is ensuring the labels contain regulatorily required elements in the proper location, e.g., the Registration Number, the Establishment Number, an Ingredients Statement, the Child Safety Statement, and more. Staff also work with risk assessors to determine what warnings and restrictions must appear on the master label to protect human health and the environment. When EPA determines that master labels need to add or modify restrictions, registrants are required to show they are making the required changes, and EPA staff review the submissions to confirm the registrants' compliance. Staff often examine a new version of a label to see how it differs from the version that EPA most recently approved. Staff may also review labels to compare the directions for use on different products to decide whether an application is a "me-too" product or presents a new use and therefore whether EPA may need additional data to reach a registration decision. With automation tools and a structured digital labeling system, a computer could perform most of these functions, thereby freeing up staff resources to do other important work.

Benefits for the science staff are also clear. Product labeling is the source of much of the data needed by the science divisions to conduct human health and environmental risk assessments and to prepare usage reports and benefits analyses. Gleaning the necessary information from dozens to thousands of products containing the same active ingredient takes time and is prone to error. Using a computer to extract the information would be faster and more accurate, leaving the science staff to spend time dealing with more complex issues. Further, the science staff could also benefit from getting more standardized labeling, thereby reducing the chance that they give different meanings to the same wording on different products.

Finding labeling content easily. A "structured label" would bring immediate benefits. Pesticide companies present label content in different formats and sequences, and the same company may change the format and sequence from product to product and even version to version for the same product. This variability makes it difficult for reviewers to easily find the label data elements that are important to review. Having a consistent format and sequence for the presentation of label data elements in an application will reduce search time considerably. A consistent format would also enable reviewers to ignore portions of the structured label for which the registrant has nearly complete discretion and review is rarely, if ever, needed. (As noted in the White Paper, these would include, for example, contact numbers, QR codes, and website addresses.)

It is essential, however, that the framework for a structured label covers all label sections and data elements that reviewers in registering divisions might need to examine. Since the agency can regulate any statement in labeling deemed false or misleading, EPN recommends that EPA try to create a framework for the structured label that covers as many different data elements as possible with a goal to define data elements that capture all (or, at the very least, nearly all) of the content of every pesticide product's master label. Moreover, each data element would be defined with sufficient detail that applicants will correctly place labeling content in the location that reviewers will expect to find it. This means that EPA needs to define data elements in a way that avoids long blocks of text covering multiple important data elements. Consequently, EPA would need to subdivide most, if not all, label sections into many discrete data elements, for which EPA will need to specify the order of presentation. This need is immediately obvious when dealing with various types of warnings, directions for use, and marketing claims.

More efficient and accurate comparisons. The White Paper posits that structured digital labeling could enable a newly submitted version of the master label to be compared to the version most recently approved by EPA. Making this comparison, obviously, assumes that the most recently approved version of the master label is itself structured digital labeling. As its first step, EPA needs to transform the structured labeling into structured digital labeling. EPA would need to establish the parameters and computer software to accept, store, organize, retrieve, read, compare, and comment on two different structured digital labels. The software would require submission of a structured, computer-readable file with each data element of labeling content associated with metadata identifying the type of content. The capability of using a computer to compare different versions of labels would not only accelerate the review process for subsequent versions by obviating the review of unchanged labeling content but also bring greater accuracy to the process by ensuring no changes would escape notice.

Checking label content. The White Paper also envisions a "structured digital label" system that would employ "validated checks, vetted terminology, and optional pre-populated fields." Creating such a system would represent a significant and very complicated step beyond a "structured label." The agency would also need to have established libraries or picklists of terminology, labeling text, and images that EPA would consider acceptable. Then the computer software would need to be able to compare the labeling content associated with a data element to the acceptable choices in the picklists or libraries.

Further, to conduct accurate comparisons, EPA would, in many cases, need to have programmed the computer software to recognize that there would be variations across products depending on the composition of the products and the results of testing. For example, many products need a "Signal Word." The choice of the signal word, however, depends on the results of acute toxicity testing with the product. Thus, the validation checks would need to link the results of the acute toxicity studies on a particular

product with its labeling. Given that applicants are allowed to cite studies submitted by other companies, establishing that connection would need to account for the possibility that the relevant acute toxicity studies might have been conducted on a different product. Other examples could be even more challenging, for example, when the acceptable choices for a data element depend on the application rate of the active ingredient, which could vary from product to product or even use to use of a product. Finally, to the extent that the validation process refers to a picklist, there probably would still be a need for human staff consideration of whether the acceptable language chosen from the picklist is actually appropriate for the particular product.

This capability could be very useful, however, in the product-specific review stage of registration review. When EPA issues a decision in registration review that requires registrants to add new text or modify existing text on products' labeling, EPA needs to confirm that registrants actually make the changes. Both structured labeling and structured digital labeling would make it easier for EPA to check for compliance. With structured digital labels, EPA could likely use computer software to make the compliance determination.

Otherwise, the resource savings for EPA might be limited because only a comparatively small portion of pesticide labeling is subject to EPA requirements or guidance that specifies the use of specific language. The largest part of many pesticide products' labeling is the directions for use (DFU). DFU may contain some content for which EPA has directed the use of specific statements, e.g., the Worker Protection Standard (WPS) statement or bee hazard warnings, but these may represent only a minority of the DFU labeling content. And, unless EPA expands its guidance substantially, the first generation of computer checks are not likely to improve accuracy significantly. In EPN's view, registrants and EPA reviewers rarely make mistakes on labeling text when there are clear guidance statements or regulations governing labeling content. More sophisticated automation tools would be needed to catch inconsistencies such as labeling that sets a maximum annual cap on amount of product applied, but purports in other data elements to allow application of a greater amount.

Extracting label content for risk assessments. The White Paper notes the "significant effort of mining the label text for information needed for risk assessment" and points out that this could be reduced by adoption of a structured label with a "use rate table." It also points out that this work could be accomplished by computer programs if content were submitted as a structured digital label. EPN agrees that this could save EPA resources and improve the accuracy of its risk assessments, particularly if implemented for the registration review program.

Extracting label content for risk assessment occurs in several stages of EPA's work —- in review of applications for new active ingredients, applications for new uses, and in registration review —- and each of these would require the system to have different capabilities.

- For a new active ingredient, OPP needs to examine only one submission —- the master label for the new product. Structured labeling would make the process marginally more efficient; structured digital labeling could allow the automatic transfer of the label information directly into a database for use in risk assessment algorithms. To provide meaningful efficiencies, however, the extraction process would need to include developing software to extract and store information accurately, to retrieve the information from a searchable database, and to input the information into the risk assessment algorithms. The software design could be challenging because it would need to handle

the expression of application rates in different units (e.g., pounds per acre and ounces per square foot) and the calculation of the amount of active ingredient applied, taking into account its concentration in the product and any instructions about preparing use dilutions.

- For a new use, extraction of risk assessment information needs to be able to identify which portions of the labeling refer to the new use; this would benefit, if not require, the ability to compare different versions of a product's master label, as described earlier. This comparison would identify the information that represented a new use of the applicant's product, but the agency would also need to compare the new use of the applicant's product to uses on other registered products to determine whether it constituted a "new use" for risk assessment purposes. To realize meaningful efficiencies, EPA would need to have not only the applicant's label in a structured digital format, but also other products containing the same active ingredient. Having this capability would also improve EPA's ability to assign applications to the appropriate PRIA category. If the labeling content of an applicant's product matched that of other registered products, the application would be classified as a "me too" and treated accordingly.

- For registration review, extraction of risk assessment information could and should cover all products containing the same active ingredient. Currently, as the Biological and Economic Analysis Division (BEAD) prepares a usage report, it looks only at a representative sample when there are large numbers of products containing the same active ingredient. The current practice carries the risks of missing products that have atypical use directions or misinterpreting the DFU in an unintended manner. Thus, clearly defined data elements, together with a computer-based extraction system, would save resources, be faster, and prove more accurate than the current process. It is a capability that would be very valuable for EPA. For structured labeling or a structured digital labeling system to offer the greatest benefits for extraction of risk assessment data during registration review, however, it will be necessary for all (or nearly all) products to have submitted structured digital labels.

B. International Harmonization

The White Paper asserts that "international harmonization could further improve consistency and clarity between multiple markets." EPN questions that conclusion. Although the White Paper posits that "[international] label harmonization could promote trade and further increase efficiency by allowing regulators to cooperate and utilize shared standards and guidelines," EPN believes there are far too many differences across countries to expect any meaningful harmonization.

First and foremost, harmonization has promise only where countries write, speak, and read the same language and use the same systems of measurement. World-wide, only the U.S. uses English but not the metric system. (Liberia and Myanmar/Burma are the only two other countries not on the metric system, although Myanmar plans to change soon.) Therefore, it is likely that no labeling approved in the U.S. will be accepted by a competent regulatory entity in other countries for use in their country, and vice versa. This would mean that companies exporting from the U.S. or importing to the U.S. would need to have different labeling for the products sold in each country. Even if the English-to-metric system conversions could be surmounted, English is the native language in relatively few other large countries – England, Canada (which also requires French on pesticide labeling), Australia, and New Zealand. And in these countries, there are

frequently different words or phrases for the same object or activity. (As George Bernard Shaw wrote, "England and the United States are two countries separated by a common language.")

Apart from the language and measurement obstacles to international harmonization of pesticide labeling, the past experience of EPN volunteers who worked on international harmonization of regulatory standards and guidelines raises cautionary flags. Harmonizing guidelines and standards is slow, long, hard work. Developing common guidelines for conducting studies to support the registration of pesticides has taken decades, and that effort was probably easier than harmonization of labeling guidelines. Labeling of pesticides necessarily reflects the risk management decisions of regulatory authorities, and there is wide disagreement across countries about how to control pesticide use to mitigate risk, not to mention no consensus on what level of risk to accept.

To the extent there is promise in the field of international harmonization, it might lie in creating the framework for structured labeling. If the labeling of pesticide products presented data elements in the same sequence, it might facilitate comparisons of risk assessment and risk management decisions across countries and facilitate work-sharing between the U. S. and other countries.

C. Enforcement, Safety and Stewardship, and Supporting Emerging Agricultural Technology

The White Paper devotes three sections of the benefits discussion to how a structured digital labeling system will improve enforcement, as well as safety and stewardship, by supporting emergent agricultural technology.

Enforcement. The White Paper asserts that enforcement would benefit in several ways. First, "standardized structure and vocabulary would reduce the likelihood that labels with unclear or unenforceable language are registered." Such improvements in clarity and enforceability would, in turn, reduce "misuse and enforcement issues." EPN questions these conclusions. Second, having searchable digital labels would improve "compliance for . . . commercial production, transportation, and sale of pesticides." We do not understand that conclusion and hope EPA will elaborate on its thinking about this alleged benefit. Third, structured digital labeling could be linked to other software to improve users' knowledge and record keeping, as well as to automate application equipment.

As EPA acknowledges, to see this type of benefit will require that the agency develop comprehensive libraries or picklists of acceptable language for use in labeling and to make sure the language is clear and enforceable. EPN feels it would be worthwhile for the agency to pay greater attention to the wording of labeling language and should carefully review the choices included on picklists. To the extent that EPA carefully curates the content of picklists, it may decrease the number of "enforcement issues" faced by EPA and state compliance programs.

However, EPN would give this effort a lower priority. We suspect that clarity and enforceability issues are more likely to arise in connection with data elements that do not have libraries of accepted text choice and almost certainly not with controlled vocabulary lists or the wording of picklist choices. Consequently, human staff review, rather than computerized validation, will be the primary way these problems are rectified.

Safety. As discussed more fully below, EPN feels the use of WDL will improve users' willingness to read labels because such a system will provide users with streamlined, but complete, labels. However, EPN does not think less vague, more enforceable text will have significant impacts. EPN doubts that misuse incidents

arise from the users' lack of understanding of use directions. Anecdotally, most users do not read pesticide labeling, and so confusion over the meaning of terms or use directions is likely only a small factor. Although EPN is unaware of any useful information about what factors lead users to commit misuse violations, we suspect that misuse actions mostly result from a lack of knowledge of requirements or a user's conscious decision to ignore the labeling to be able to control a pest problem effectively. Before EPA invests time and resources in this area, EPN recommends the agency acquire a better understanding of why users do not comply with pesticide labeling.

EPN agrees that, in the distant future, EPA and the private sector could build software applications that link structured digital labeling with record keeping programs and with pesticide application equipment. Having pesticide labeling in digital form is significantly easier to copy, store, and retrieve than printed labeling that is attached to or accompanies the physical container. If an electronic labeling file can "communicate" with recordkeeping software, records will contain more and more accurate information and that information will be more readily available to the user. Similarly, if the file can "communicate" with application equipment, pesticide use is more likely to comply with labeling instructions. All of this would be beneficial.

It will take a long time, however, to reach the state where users can experience these benefits. No one is likely to develop such software until EPA has built a structured digital labeling system, a large number of products have submitted their master labels using the system, and EPA has put the data into the new system. Thus, all of the hurdles to building the system have to be overcome before there is any prospect that developers will pursue software linking structured digital labels to other software programs.

Further, because EPA has relatively few record-keeping requirements regarding pesticides —- only users of restricted use pesticides are obligated to maintain use records —- this imagined future state will not benefit the agency directly. It may prove to save resources for users in states that have record-keeping duties beyond those of the federal government. In any case, EPN does not think that the agency should invest EPA resources in developing such software; if there is adequate demand from users or equipment manufacturers or insurers, private entities will create the software.

Finally, EPN notes that, to the extent better labeling produces improvements in safe use of pesticides, it reduces the potential liability of registrants for selling products that arguably fail to warn users about potential risks and to tell users how to avoid them.

D. End-Users and Other Stakeholders

EPN feels that the benefits of a well-functioning structured digital labeling system will accrue primarily to EPA as it makes the process of reviewing master labels and extracting data from product labeling more efficient, accurate, and consistent, and as the resulting changes advance EPA's goal of making labeling more enforceable and readable. Such process improvements will lead to general benefits for all stakeholders. EPA should be able to review and reach decisions on applications more quickly, an important benefit for the pesticide industry. Freeing up EPA resources will enable the agency to spend more time on its fundamental mission of protecting public health and the environment. But for external stakeholders other than registrants —- particularly state authorities and end-users —- such benefits may not be as immediate or obvious.

State agencies responsible for regulating pesticides could realize some of the same efficiencies as EPA if they can implement systems that parallel that being developed by EPA. Therefore, it will be important for the states to have access to the technology underlying the structured digital labeling system EPA is building. In addition, EPA may need to provide financial support and training to states in order to prepare them for the transition to the new system. Further, given that states have the primary responsibility for enforcing the "misuse" provision of FIFRA, EPA should involve state regulators in the review of controlled vocabularies and picklists so that the acceptable choices are enforceable.

The people who use pesticide products will experience benefits as product labeling changes. The modifications to the physical labeling of products likely to be most useful will affect the readability of labeling content. It will be easier for users and crop consultants to find information in labeling when all labeling is organized using a standard structure for the sequence of label sections and data elements. Likewise, changes that clarify, standardize, or simplify the wording of labeling text may make directions and warnings more readily understood. The use of WDL could also offer numerous benefits —- shorter labeling with only the content necessary for a user's specific needs (including information from referenced websites), translation of the text into the user's preferred language, and links to instructional videos or advice on integrated pest management.

Finally, the general public will benefit if users' compliance with labeling requirements improves. Human health and the environment will be better protected. Further, to the extent that EPA can provide public access to the structured digital labeling system, it may enable people to select products that better meet their pest control needs. Thus, EPA will need to consider how and to what extent the system's database will be searchable by the public.

IV. Challenges in Developing and Implementing a Structured Digital Label System

The idea for a structured digital label system has been discussed widely in OPP for decades. Senior management and staff have long recognized the potential benefits of an "electronic label" for every pesticide product, as the concept was initially named. Later, OPP began to work more earnestly on turning the idea into a reality. Subsequently, the concept has been referred to as the "smart label" and as the "Office of Pesticide Programs' Electronic Label" or OPPEL. Over the years, OPP has invested significant energy and money into the project and made notable progress. However, OPP still does not have a working structured digital label system.

This section of EPN's comments begins with observations about why OPP's work has not produced any fundamental changes in the way the agency reviews the content of pesticide labeling. Understanding the reasons for the slow progress should inform how OPP proceeds with the development of a structured digital labeling system. Then we address the single most important challenge before the agency can realize its goals —- how to get all registrants to submit their master labels as structured, digital files.

A. Lessons Learned from Past E-Label Efforts

Building an E-Label system is hard. Because there are so many quite different kinds of pesticides, each with distinctive labeling, and because any individual product can have very complex labeling, developing a structured digital labeling system is very, very difficult.

The White Paper refers to efforts by the Food and Drug Administration (FDA) to standardize how labels of food and pharmaceuticals present nutritional information and drug information, respectively. The White Paper provides little sense about how long, how controversial, and how difficult it was for FDA to institute these changes. Moreover, any comparison of nutritional and drug product labels with pesticide labels would reveal a striking difference in the breadth of information that is covered. A food label lists 19 discrete nutritional facts. A typical drug label, which has only one use, treating a human, is divided into seven sections with rules about the type of information to be placed in each section. The same basic structures for nutritional labels and drug labels work for all types of food and all types of drugs. By contrast, a typical master label for a pesticide has ten or more general sections of information and can cover dozens or scores of use sites. Each label section, especially the directions for use, can have many subsections. For example, the listing in Appendix 1 of the White Paper identifies 21 data elements for a "Use Rate Summary Table" and nine different anticipated "fields" with 51 categories of information and 59 subcategories of data elements. Not only are there many more types of information, but EPN doubts that one framework will be suitable for the enormous variety of pesticide products. Consequently, EPN believes creating a system for structured digital labeling is at least a couple of orders of magnitude more challenging than the effort to standardize labeling of food and drug products.

It is unclear to EPN how well EPA has appreciated the size of the challenge. In fact, it could well have been difficult to anticipate all the challenges until EPA was well into the early stages of the effort. To the extent it has failed to do so, the agency may have underestimated the planning and resources needed to succeed. In any case, because building a structured digital labeling system is so difficult, EPA should now recognize upcoming challenges and develop a plan that tackles the effort carefully, in a logical series of manageable steps that progressively produce a coherent, functional system. In section V of these comments, EPN offers its recommendations for such a plan.

EPA may not have ensured that the design side and the information technology (IT) side coordinated effectively. As discussed above, pesticide labeling is very complicated, and because there are so many different types of products, labeling contains a wide array of varying instructions. In addition, OPP's regulatory approach necessarily recognizes these variations and uses different strategies for different kinds of products. Consequently, building a structured digital labeling system will require deep, detailed knowledge about the labeling and regulation of pesticides. People whose expertise lies in designing IT systems, even those within OPP, do not have the requisite regulatory knowledge.

At the same time, the structured digital labeling system will require a very sophisticated IT framework. Designing a user-friendly framework to allow registrants to easily input the content of master labels will be the first and a very large challenge. As noted above, it will be important to capture essentially all of each product's master label in a structured format. Users could easily be overwhelmed by the inclusion of data elements needed for the labeling of special categories of pesticides – e.g., metal-working fluid treatments, bird repellents, or pheromone traps – data elements which do not apply to the large majority of products. IT specialists will know how best to design the graphical user interface (GUI) so that inputting the data for a product is logical and straight-forward[2]. The second, daunting challenge is building libraries of acceptable language that make it more efficient to create and review labeling. Much work has already been done as part of OPPEL, but more and more difficult work remains. This will be challenging because the picklists will often depend on the characteristics of a specific active ingredient, product, or use pattern. Subject matter

[2]See EPN's ideas about how to address this challenge in section V.A.1 below.

experts may know the rules that determine which picklist options are acceptable, but not how to capture the rules in computer code.

In sum, experts in the subject matter of pesticide labeling and regulation of pesticides will need to work closely with IT experts at every stage of the creation of structured labeling and structured digital labeling systems. Although EPN does not have information on how closely these two groups collaborated, anecdotal information suggests that at times the collaboration was insufficient to allow for integration and success. Reportedly, subject matter experts asked for a system that IT could not build, and IT built components of a system that would not meet internal or external stakeholders' needs. Consequently, EPN stresses the importance of having active, effective cooperation between the subject matter and IT experts during every step of building the systems.

EPA may not have funded the effort adequately. EPN appreciates that the combination of appropriations, registration fees, and maintenance fees have not kept pace with the demands on OPP's regulatory programs. Consequently, backlogs of registration applications and delays in the registration review program have grown. Meeting the legal deadlines for regulatory decisions in these two fundamental programs has proven impossible. Yet, understandably, the agency continues to devote a very significant portion of its inadequate resources to that statutorily-mandated work. The resource demands for registration and registration review must necessarily have limited the size of the investments OPP could make in building a structured digital label system.

At the same time, EPN also appreciates that the leadership of OPP recognizes the enormous benefits that will come from a "digital transformation" of the work processes of registration and registration review. And accordingly, we know OPP has invested considerable time and energy in projects, like the Confidential Statement of Formula (CSF) and the OPPEL outputs, to leverage computer technology in its day-to-day work. The thoughtful White Paper and the staff time devoted to working with the LRWG are further evidence of OPP's understanding that a structured digital labeling system could be the most impactful transformation of pesticide regulation since the Food Quality Protection Act (FQPA) was enacted in 1996.

While EPN thinks that OPP is aware of the enormous promise of a structured digital labeling system, clearly OPP has not devoted enough resources to make it a reality. There is a consensus in the LRWG that the technology exists to build the system. There is also a consensus that EPA needs to fund the IT systems to receive, store, retrieve, review, and disseminate structured digital labeling information. This will be costly, and EPA needs to make the investments in time and personnel to build the systems.

The agency has not produced a "minimally viable product" that could build support within EPA and with external stakeholders. Because of the complexity and scope of the undertaking, it will likely take EPA many more years to build out a fully functional structured digital labeling system. It is understandable that both the agency and its external stakeholders will become frustrated with that effort unless there is clear progress toward the vision – progress which takes the form of a functional product that demonstrates how the eventual completion of the system will provide benefits.

In addition to the length of time that OPP has been working on versions of an e-label system, there is another reason why people are frustrated. The structured digital (or electronic) e-CSF project, unfortunately, has not gained common use and has not provided the kinds of positive impacts hoped for. EPN has heard anecdotal reports that a sizable number of unstructured CSFs still contain obvious errors, such as the

percentages of ingredients adding to a total other than 100% —- errors that could easily be caught and corrected by a computer check of a structured digital file. The lack of adoption means that the e-CSF project has not produced the expected efficiencies.

EPN feels that it is essential for EPA's further work to plan how to implement components of a structured digital labeling system before the entire system becomes fully operational. These components should be useful for agency reviewers and provide measurable efficiencies. In the past, agency design staff and the IT staff may not have had a shared, settled understanding about the development plan for the structured digital label system. Consequently, disagreements about how fully developed a particular component should be before it was made operational may have meant that EPA did not launch any significant, viable project. To avoid this problem and to build and maintain support for the work, EPN strongly recommends the planning for the project should identify at each stage what useful components could be made operational. As discussed in more detail further below, EPN feels that structured labeling within a digital framework and the capacity to perform computerized comparisons would be two early, useful, "minimally viable products" that the agency could design and implement. EPN offers additional recommendations for other minimally viable products in section V.

B. Gaining Universal Participation

Many of the benefits discussed in section III of these comments will occur only if there is universal or near-universal participation in the structured digital labeling system. Achieving such a high level of participation could be even more difficult than designing the system itself.

EPN anticipates there will be resistance from pesticide companies and their trade associations. This prediction comes from three experiences. First, the agency has already developed a digital system for submitting and reviewing one essential part of an application for registration – the CSFform. Despite having been available for more than a year, very few applicants are choosing to use the new e-CSF. (Applicants regard it a duplicative of the paper/.pdf file that they also routinely complete.) The agency should try to understand why the regulated community does not submit e-CSFs so that it can avoid a similar disappointment with structured digital labeling. Second, EPA has been requesting applicants for registration of conventional agricultural pesticides to submit a "Use Rate Table" in addition to their proposed master labels. The inclusion of a Use Rate Table is voluntary, and many applications for new product registrations do not contain the requested summary information. Again, the reason appears to be that applicants regard it as duplicative of information that is in the proposed master label. Third, the LRWG, which has many more members who work for the pesticide industry, seems ready to recommend that use of the structured label the Work Group has developed is *voluntary*. There seems to be a reluctance on the part of the larger companies in the regulated community for EPA to require structured labeling, much less structured digital labeling.

EPN believes that starting with a voluntary system is sensible, but eventually the submission of master labels using a standard structure must become mandatory. EPN feels the agency could make a reasonably strong argument that structured labeling is necessary for risk mitigation. Thus, as part of the risk mitigation step of registration review, the agency could begin to direct companies holding product registrations for single active ingredients to revise their labeling using a structured labeling framework. Under the current law, Section 25(a)(1) of FIFRA also gives the agency the authority to issue a regulation requiring all registrants to submit structured labeling and structured digital labeling, both as part of applications and during the

registration review process. EPN appreciates that the FIFRA rulemaking process is long and difficult. Alternatively, the agency could support an amendment to FIFRA, perhaps as part of future legislation to extend authorities under the Pesticide Registration Improvement Act (PRIA 6). In any case, given the typical amount of time needed for either rulemaking or legislation, EPN recommends that the agency begin now to consider how it would write a rule and/or statute allowing it to require submission of structured labels and structured digital labels.

In the meantime, EPN suggests that EPA identify incentives making it attractive for applicants and registrants to submit structured labeling (and, when the system is ready, structured digital labeling). For applicants, the biggest incentive would be an expectation that submission of structured labeling or structured digital labeling would significantly shorten the time EPA takes for review of an application. Clearly, the inclusion of a structured labeling will somewhat shorten the review of an individual application. EPN encourages the agency to develop and publicize information showing how much time could be saved. However, individual timesaving may not be a sufficient incentive. Therefore, EPA may want to consider other possible incentives such as whether EPA could place applications containing structured labels in the review queue ahead of applications that did not have such labeling[3].

V. Path Forward

EPN recommends that the agency develop a detailed plan for building the different components of the structured digital label system. Below we offer a range of recommendations about the different aspects of the plan and the logical steps that EPA may follow. We note that some of the steps may overlap and could be pursued concurrently.

A. Recommended Stages for Developing a Structured Digital Label System

1. A Comprehensive, Adaptable Structured Label with High Resolution of Data Elements

EPN agrees that the first step in building a structured digital label system is to agree on the framework for structured labeling. The LRWG has produced a framework covering many components of a structured labeling approach. Although not comprehensive, EPN considers it a useful start. The framework is logically organized and seems to fit all types of pesticide products. The framework references the sections of EPA regulations, as well as PR Notices, similar policy statements, and sections of OPP's Label Review Manual. These sources contain OPP's published requirements and guidance for acceptable labeling content. Using the LRWG's framework would make it very easy for EPA reviewers to know where to find important pieces of information that need to appear as labeling content. Further, it would make comparisons of different versions of the labeling for the same product relatively straight forward.

However, EPN feels the LRWG's framework could be improved upon. It needs to be more comprehensive in terms of covering all labeling content; it needs greater resolution in terms of data elements; and it needs to have separate DFU sections for different types of pesticide products.

[3] If, under current law and policy, EPA determines that it could not give higher priority to applications with structured labels, it could at least consider establishing separate PRIA categories for such applications, with shorter review goals, for PRIA 6.

Complete coverage of labeling content. To fulfill the vision for the structured digital labeling system, the framework for structured labeling needs to capture all pesticide labeling content, except referenced content material which does not accompany the product during distribution prior to sale to the end-user. Thus, the structured labeling should identify data elements that cover as close to 100% of the labeling as possible. EPN agrees with the LRWG recommendation against having a "catch-all" or "miscellaneous" data element into which registrants could be tempted to put any text and images which do not readily fit into another data element. (EPN believes it would be smart to include such a data element for early pilot tests of the structured labeling frameworks as a way of identifying labeling content for which the framework lacks a clear home.) If there is no "catch-all" data element, however, EPA needs to ensure that there is a data element home for every type of text and image that appears on any of the nearly 20,000 registered pesticide products.

The best way to ensure that the framework for structured labeling eventually covers 100% of the labeling content is to conduct extensive Beta version testing, ideally by multiple registrants for each type of product covered by a framework. Because of the constraints of the Paperwork Reduction Act (PRA), EPA cannot easily ask more than nine respondents to "test drive" a draft framework for structured labeling. Nor is it practical for EPA itself to conduct essential testing of the framework; that would consume too many resources. Instead, EPN strongly recommends that the agency ask the LRWG, which is not constrained by the PRA, to work with companies in the industry trade associations to get feedback on the workability of whatever frameworks need to be tested. The trade associations could reach a wide range of registrants, including big and smaller companies, and could ask for registrants to test the framework with a wide range of products. Such pilots should answer several important questions: 1) do the data elements of the framework capture all labeling content? 2) how easily do registrants put their labeling content into the framework? and 3) how reliably do registrants put the content of labeling into the appropriate data elements of the framework? EPA could set performance standards for accuracy and coverage, and there would be multiple pilots with each category of products until the performance standards are met.

Granular resolution of data elements. The framework needs a high level of resolution of the data elements; this may be the most crucial aspect in designing structured labeling. In EPN's view, the LRWG's current draft would not adequately separate elements into manageable and searchable units. For example, the current version framework would capture the names of all active ingredients as a single data element. EPN suggests that the framework capture the name of each active ingredient as a distinct item of data. When coded with metadata, this will make searches easier and faster. The need for greater resolution is particularly important for the DFU section of labeling, and the White Paper implicitly recognizes this. Appendix A lists as separate pieces of information many different data elements that would be part of the DFU. Unfortunately, the current version of the LRWG's structured labeling framework treats DFU as a single data element. Unless changed, this would mean that EPA could not readily extract information needed in risk assessment or for other regulatory functions. Even locating important information would be challenging if it is contained within long blocks of text. LRWG may understand the need to subdivide the DFU and possibly other sections of its framework into more distinct data elements but, like EPA, may be struggling to find a good approach, given the complexity of DFU.

Separate DFU frameworks for different types of pesticide products. As noted above, it is important to have a framework that is both comprehensive and has high resolution of the data elements. A single framework would probably be adequate to capture the data elements for most label sections, everything except the directions for use. The LRWG also has reached a similar conclusion and has worked on a template, intended

for every type of pesticide, that covers all elements except DFU. EPN believes a single framework will not be feasible for DFUs.

In EPN's view, the biggest challenge for developing a usable framework for capturing DFU data elements is that the diversity of DFU reflects the extraordinary variety of kinds of pesticide products. The DFU for products used for wood preservation will differ from DFU on sterilants for treating medical equipment, and both will be different from DFU on the labeling for materials preservative products and soil fumigants. A host of other types of products —- e.g., toilet bowl sanitizers, topically applied insect repellents, plant-incorporated protectants, predator control products, swimming pool treatments —- would have DFU that differ significantly from each other, as well as the first four product categories mentioned above.

Developing one framework that would cover all DFU data elements in these examples would either require a very general framework that lacks sufficient resolution or a much more detailed set of data elements, many of which would not apply to other types of products. The former would leave EPA without the ability to find, review, and extract information. The latter would overwhelm registrants trying to put their labeling content into the structured framework.

The solution to the challenge, EPN believes, is to have separate DFU frameworks for different types of pesticide products. Because the product management (PM) teams in the registering divisions continually review the labeling on these varying kinds of products, they have the knowledge and expertise to determine how to design initial DFU frameworks. Therefore, EPN recommends that OPP start by asking each PM team to develop one or more DFU frameworks for the variety of products they manage. It is possible, even likely, that there may be enough similarity between the frameworks built by different PM teams that some could be merged. For example, EPN expects the framework for outdoor use herbicides, insecticides, and fungicides will be sufficiently alike that one framework could work for all three types of products. But there may be such large differences in DFU for non-food indoor use insecticides and outdoor, food-use insecticides that each type may need one or more separate frameworks.

The design of a framework for DFU faces an additional challenge —- how to efficiently and accurately capture data elements that are sufficiently granular. Broadly speaking, DFUs cover a number of steps in the process of handling a pesticide including, for example, storage, mixing, loading, application, and disposal. In addition, DFU also include restrictions of various kinds, including, for example, protections for humans engaging in the application process, protections for bystanders, and environmental protections. This is further complicated by the inclusion on a master label of many different use sites. Some elements of the DFU will apply irrespective of the sites on which the product could be used. Other elements will apply only to a subset of the use sites on the master label.

EPN feels that the design of DFU frameworks needs to capture this information efficiently. This will be important both for applicants and EPA. For the agency, the DFU framework will need to be able to identify all aspects of the DFU – both the product handling directions and the warnings, limitations, and restrictions on use – that apply to the use of the product on each site. At the same time, companies will want to be able to input labeling content easily. An overly complex or lengthy input process for DFU data elements will encounter resistance, just as apparently has happened for the much simpler e-CSF framework. Thus, the framework must find a way to avoid making the registrant repeatedly input information for each use that applies to all uses.

EPN suggests the framework will need to be able to sort data elements into four different categories. Refer to the table below.

	Applicable to all Use Sites and Application Methods	Applicable to a Subset of Use Sites and/or Application methods
Product handling instructions, e.g. mixing, loading, application directions	A	C
Warnings, Limitations and Restrictions on Use	B	D

Data elements in categories C and D would need to link the individual DFU elements to the particular use(s) to which they apply. This is conceptually similar to the approach developed by OPPEL. OPPEL handled this challenge by using a hierarchy: product, site, scenario. Labeling content information could be entered at one level and automatically applied to all the levels below it. It will be especially important for the IT support to work closely with the subject matter experts to ensure the format delivers the needed information while also being easy to use by registrants.

Another approach suggested by the White Paper is a "Use Rate Summary Table" (USRT). EPN thinks that the URST in the White Paper is an interesting proposal that should be considered further, but it appears to have at least two limitations. First, it seems appropriate for most (if not all) agricultural use pesticides, but not for other types of products. Second, some of the data elements need greater resolution. For example, there is a data element for "Geographic Restrictions." Does this single data element cover limitations relating to soil type, restrictions relating to well-setbacks, buffer zones around sensitive ecological features, and temporal prohibitions against use in habitats of threatened and endangered species? We have similar concerns about other data elements in the URST. Expanding the URST to provide greater resolution may make the tables unwieldy; combining discrete data elements may undermine the usefulness of the tables.

No matter how the DFU data elements are organized, it is important that EPA also think about the needs of pesticide users when developing the structure. The DFU data elements should be logically organized in a way that will make sense to the user. In Appendix A, we offer a possible sequence of DFU data elements for agricultural use products; the data elements are placed in the order of the steps DFU requirements may direct a user to take.

Apart from how EPA designs the DFU framework(s), EPN notes that the pilot testing of the framework for structured labeling probably should proceed in separate steps, especially if EPA adopts the approach of having separate DFU frameworks for different categories of products. Thus, for example, to test whether the framework would work for registrants, EPA could develop and test a framework for residential use antimicrobial products with the Household and Consumer Products Association at one point and, separately

and at different times, test frameworks for industrial biocides with the American Chemistry Council's Biocides Panel, and a framework for agricultural use insecticides with Crop Life America. Then, pilots should test the framework with users of these products to make sure that the material is presented in a manner that makes sense to them.

2. Build Structured Digital Label System Foundation to Manage Data from Labeling Files

The step listed above could be implemented without implementing a fully functional structured digital labeling system. EPN, however, recommends that once the agency has successfully piloted a framework for creating structured labeling for a category of products, EPA should move to convert master labels presented in the "structured labeling" framework into "structured digital labeling." EPN thinks this would simply involve assigning metadata tags to the distinct data elements in the frameworks.

Then, the agency could start to receive and manage files containing structured digital labeling for individual products. EPA will need to decide at this stage how much care it should give to ensuring that the structured digital labeling for a previously registered product matches the most recent, EPA-approved version of the master label. When FDA implemented its structured labeling approach for drugs, it allowed companies to certify that the new digital version matched the prior, FDA-approved version. EPN recommends that the agency follow the same approach. Based on past experience, we expect the regulated industry would be very careful about complying with the requirement to faithfully transfer master label content into a structured digital labeling format, especially since knowing submission of a false structured digital labeling file would violate FIFRA Section 12(a)(2)(M). Alternatively, EPA could review the "translation" step to confirm the accuracy of the new structured digital labeling files. Although the agency could also use the process to address common labeling issues like missing data elements, unenforceable text, and use of language different from the controlled vocabulary, validating every submission would require a very significant investment of resources. In the long run, EPN anticipates that the structured digital labeling system will implement automation tools with the capability to perform some of these functions. Therefore to save scarce resources, EPN does not recommend this alternative.

When EPA begins to receive structured digital labeling files, the agency will need to have a structured digital labeling system. Submission of files in which data elements are digitally tagged is far from a fully functional structured digital labeling system. Among other things, the full system would need to be able to store individual master label files, search and retrieve files containing specific elements, compare the content for specific data elements with established rules, extract data from individual files for use in risk assessments, and more. In designing the structured digital label system, it will be essential to anticipate the many functions that EPA and external stakeholders would like the system to perform and then to ensure that the foundations being built are adequate to support those functions when they are ready to be added to the system's operation.

3. Develop a Comparison Tool

The first automation tool for EPA to develop should be a "comparison tool." As discussed in the White Paper benefits section, EPA reviewers could be more efficient if they had the IT capability to efficiently compare the labeling content of two products or the content of two different versions of the labeling of the same product. Once the agency has developed a usable framework for structured digital labeling, EPN recommends the agency's next step should be to implement an IT capacity to compare the submissions of

two different structured digital labeling files. A computer could very rapidly identify and highlight any text or images that were different in the two files being compared.

4. Identify Libraries/"Picklists" for Key Data Elements

Most of the second generation of automation tools will require that the digital labeling system have additional features. For computers to be able to check whether a human needs to review the labeling content for a particular data element, the computer must be able to compare the text from the master label with text which EPA recognizes as automatically acceptable for that data element. Therefore, EPA needs to designate controlled vocabularies, build libraries, and compile picklists of acceptable text for key data elements.

EPA's OPPEL project and the PPDC LRWG have already made some important progress on this step in the design process. EPN acknowledges the work done on the OPPEL project to produce controlled vocabularies for certain types of terms that appear in pesticide product labeling and to place them in EPA-maintained digital "libraries." EPN also salutes the work of the LRWG to compile picklists of text, taken from existing EPA regulations, guidance documents, and other sources.

EPN offers some recommendations about how to develop the vocabularies, libraries, and picklists so they have maximum usefulness. EPA should seek the support of registrants to compile candidate text versions for inclusion in picklists for different data elements. EPN suggests that registrants be asked not only to identify the wording of the labeling data element, but also the registration number of the pesticide product on which the text appears. Once EPA has the submissions of picklist candidates for a particular data element, EPA should look to choose the best examples for retention on the agency's validated list. The selection of the acceptable choices should ensure that the wording is enforceable, if intended to establish a requirement. The wording should also be understandable, and EPA could use existing software tools to evaluate the reading level necessary to comprehend the meaning of the text. These compilations then should undergo a process of public comment before they become accepted EPA guidance.

Further, the agency should recognize that libraries of controlled vocabulary and picklists of optional acceptable text will need to evolve. If a company thinks that the choices offered by EPA's libraries of controlled vocabulary and picklists do not adequately fit the company's product, the structured digital labeling data element should give the option of entering "free text." Obviously, OPP staff would need to review the proposed text to determine its acceptability, an action that would delay decision-making compared to a computer-assisted review. If accepted, registrants' alternative "free text" should be added to the libraries or picklists, together with any necessary IT rules, so that all other registrants will have the freedom to use language that EPA has approved for one registrant. This approach will bring greater consistency to regulatory decision-making about acceptable (and unacceptable) labeling content.

Finally, because this process is likely to proceed slowly, EPA will need to prioritize its work. EPN recommends the agency focus first on those data elements which have only one acceptable version of the text, for example the child hazard warning, "Keep Out of Reach of Children," or the misuse warning,"It is a violation of federal law to use this product in a manner inconsistent with its labeling." When there are more than a limited group of candidate submissions that cannot be reduced to a single acceptable version, the agency may need to develop IT rules for which text is acceptable. For example, there are only four choices for the signal word data element – "Danger," "Warning," "Caution," and leaving the data element empty because no signal word is needed. These four choices depend on the results of acute toxicity testing of a

relevant product formulation. A computerized check on acceptability of the chosen signal word will require IT rules linking the acceptable choice to the results of appropriate toxicity study results. The LRWG is developing an application capable of making this link.

As the output of these efforts grows and is publicly adopted by the agency, it should improve the quality of pesticide labeling submissions in terms of enforceability, readability, and consistency. Better labeling should, in turn, lead to better compliance and safer pesticide use.

5. Promote the Use of Web-Distributed Labeling

WDL was originally conceived as a means for streamlining lengthy labeling of agricultural use pesticides so that users would be able to access only the labeling content needed to meet their individual needs. Discussions of WDL quickly identified other ways in which WDL could prove helpful for users[4]..

EPN believes that early adoption of WDL could also support the implementation of a structured digital labeling system by showing how electronic tagging of labeling content could produce efficiencies for EPA reviews. As explained in more detail below, WDL systems would enable a user to specify for a particular product the discrete sites and pests to which they intended to apply the product and the application method they would use. Rather than render the labeling content for the use of the product on all sites, against all pests, and by all methods, a WDL system would give the user the content that applied only to the user's choices. This capability would also be helpful to agency staff preparing usage reports. Rather than having to search labeling of multiple registrants' products, agency staff could use the WDL function to obtain the labeling content specific for each use of a product. Then, by comparing the extracted use-specific labeling, OPP could easily compile a comprehensive and accurate usage profile of products containing the same active ingredient. Agency staff using WDL would thus need to spend less time obtaining data compared to the effort needed to find necessary information buried in current product labeling.

6. Develop Automation Tools for More Efficient Review of Labeling Content.

In addition to the "label comparison" function discussed above, EPN recommends that, early in the process, EPA develop one or more of five basic tools that will bring efficiencies to the label review and risk assessment processes.

Extraction of risk assessment data. Mining the files of digital master labels for information needed in EPA's risk assessments would speed up the review of applications for registration of new active ingredients and new uses. When the essential information appears only on a single master label, EPA would be able to extract the data easily and put it directly into a risk assessment algorithm. Eventually, the function of this tool could be expanded to extract the relevant data from all products containing the same active ingredient and build the equivalent of a LUIS/PLUS report listing the highest use rates for each crop on which the product is approved for use.

Check the content of specific data elements for a master label against EPA's controlled vocabularies and picklists. EPA should build the IT capacity of the system to determine whether a master label uses text for a data element that is drawn from the library of accepted text for that data element. This would be particularly

[4] Section VI.B. of these comments describes several of those potential benefits

useful when EPA has determined that there is a single accepted way to word a particular warning or restriction, e.g., the "Keep Out of Reach of Children" statement, the bee hazard warning, or statements that a product does not contain bleach or DEET. EPN agrees that, in most cases, applicants should be free to propose different wording, but it will save reviewers time if they need to look at a data element only when the applicant does so. This would also be especially useful when final registration review decisions direct registrants to make specific changes to individual data elements. EPN notes, however, that the single statement situation will be much easier to design than a situation when there are multiple acceptable ways of expressing a piece of label content and the choice may depend on the characteristics of the product.

Translate the content of an e-CSF into the required Ingredients Statement. EPA regulations require the label of pesticide product to contain an Ingredient Statement identifying the active ingredient(s) and their percentages in the product formulation, as well as the total amount of intentionally added inert ingredients. An applicant is also required to put this information (and more) on a CSF form. The agency has designed and made available a structured digital CSF that could be directly linked with the data elements for the Ingredients Statement and ensure that they match properly.

Automatically check the Signal Word, Precautionary Statements, and First Aid Statements based on the toxicity categories for the product. EPN thinks another, easily built tool could use data on the toxicity categories seen in acute toxicity studies for the product formulation to select the appropriate Signal Word, Precautionary Statements, and First Aid Statements that are required according to EPA's labeling regulations in 40 CFR part 156. EPN notes that one of the members of the PPDC LRWG has already built the prototype of such a tool; EPA may already have such a tool.

Automatically check the Storage and/or Disposal Statements on the Master Label based on characteristics of the product and its packaging. This tool would operate in a manner like the tool for the Signal Word. The applicant (or EPA reviewer) would enter the relevant characteristics of the product and its packaging into the software and the software would automatically determine what text was required to appear on the product's master label.

B. IT Capabilities of Structured Digital Labeling System

EPN volunteers have limited expertise in the design of new IT systems. That said, our experience leads us to think that the structured digital labeling system will need certain features in order to function well. Although not comprehensive, we believe the system will need to:

Be User friendly. The frameworks need a GUI that is easy to follow. The Turbo Tax software is used as an example of a program whose GUI compares favorably with the forms and directions available from the IRS. The frameworks need to make it easy for companies to fill in data elements and for EPA reviewers to find the information they seek. The search, retrieval, and comparison capabilities must also operate in a straightforward manner.

Have Robust Data Management Capabilities. There are approximately 20,000 registered pesticide products, and EPA receives several thousand applications every year to register new pesticide products or to amend the registrations of existing products. Given the number of data elements needed to capture the labeling content for a single product, this represents an enormous database. The system needs to be designed to

provide adequate storage, quick retrieval, efficient comparisons of multiple files, accurate data extraction, and robust search functions.

Be Flexible. As discussed elsewhere, the rules and policies, as well as technologies in the pesticide space, are constantly evolving. Those changes will directly shape the content of pesticide labeling. The structured digital labeling system needs to be capable of accepting additions and modifications to reflect these changes.

Be Platform Neutral. The registrant community has expressed a concern that the software system for the structured digital labeling system not be tied to any existing technology provider. They draw the analogy to writing and sending email. There are multiple providers – Microsoft, Google, Apple – that offer programs for drafting email messages. Companies want to be able to choose among providers how to generate structured digital labeling files that EPA would accept.

C. Public Participation

Implementation of a structured digital label system will work a profound change on the entire EPA program for regulation of pesticide products. The regulated industry will need time and education to accept the change such a system will necessitate in their work processes and businesses. Likewise, many other stakeholders, especially the users of pesticide products, will want to understand how the new system works and how it affects them. Therefore, EPN strongly recommends EPA make a robust effort to engage the public at every stage of the development of the structured digital label system. Such engagement will improve the chances that the new system is accepted and that it becomes operational as quickly as possible. In addition, external stakeholders may provide useful feedback that will prevent EPA from making mistakes that impair the usefulness of the system or slow its development.

VI. Improving the Display of Marketed Product Labeling

Although the White Paper does not expressly address issues relating to the appearance of the physical labeling that accompanies the pesticide in the channels of trade, it is obvious that there are ways in which establishing structured labeling and a structured digital label system will affect marketed product labeling. Because EPN is concerned about how well users comply with pesticide labeling, this section of our comments addresses how the implementation of a structured digital label system can improve the user's experience of working with physical labeling accompanying a product.

A. Apply the framework of Structured Labels to Marketed Product Labeling

EPN believes that having consistency in the presentation of labeling content across products will improve a user's ability to find desired information. If it is easier to find information, perhaps users will turn to labeling content more often and thereby know what requirements apply to the handling of the product. Thus, once EPA chooses the order in which to present labeling content in applications —- the structured labeling framework —- the agency should encourage (and eventually require) registrants to follow the organization of the structured labeling framework on their marketed product labeling.

The use of the organization of information on the physical labeling of pesticides will have many benefits. Obviously, pesticide users can learn where to find the different types of labeling content on all types of products; they won't need to familiarize themselves with the organization and designs used by different

registrants. In addition, having a standardized format will enable pesticide safety educators to use labeling to communicate critical information to users taking certification and other training courses. Finally, putting marketed product labeling in the structured label format will build support for a structured digital labeling system.

B. Direct Use of WDL to Solve Physical Labeling Problems

In addition to the benefits of WDL for building the structured labeling system, WDL has enormous potential benefits for users, as well as efficiencies that will be useful for registrants. It can shorten labeling, improve readability, and provide information that users currently need to access from websites. Because of the increasing complexity of labeling, particularly in the agricultural sector, its use will eventually become essential. EPA, however, should consider requiring registrants of products with lengthy labeling content to offer WDL now.

Shorter labeling. WDL offers the obvious benefit of giving users a way to receive only the portions of labeling relevant to the user's intended use. The master labels for many agricultural-use pesticides contain DFU for multiple uses. Master labels can be over 100 pages long. Because of marketing considerations, it is common for marketed product labeling to retain many, if not all, of the uses approved for the master label. Yet many users are interested in using a product only on a single crop by a particular application method. Thus, the labeling information for different crops and application methods will be of no value to the user. Worse, the presence of the additional, unhelpful labeling content will make it more difficult for the user to find needed information. A trial with a sample master label showed that a WDL system could reduce the amount of labeling content from over 100 pages covering multiple uses to six to eight pages covering a single use. EPN believes that shortening labels by over 90% would promote greater compliance by users with labeling content.

Improving readability. There are potential ways WDL can improve readability. Importantly, WDL could render the text of labeling in different languages. PRIA 5 already requires, over the coming years, that all pesticide products provide certain types of labeling content in Spanish. Spanish translations are typically about 25% longer than the corresponding English text. Making labeling bilingual will only exacerbate the problem of overly lengthy labeling. PRIA 5 offers the option to registrants of providing bilingual labeling through the use of QR codes or other links. WDL would be an efficient way for registrants to comply. Moreover, the option of having labeling in a different language need not be limited to Spanish; WDL could provide any language that users might find easier to read and understand. Given the demographic characteristics of the agricultural workforce, there are large numbers of pesticide handlers and workers for whom neither English nor Spanish is their native language. The ability to provide labeling in different languages would significantly advance the agency's environmental justice goals in the field of pesticide regulation.

In addition, because WDL would be presented in a digital format, it could provide other types of aids to promote the users' understanding. For example, WDL could highlight changes to the content of data elements compared with approved versions from the previous year. Such visual highlights could draw the user's attention to the changes and increase the chances of compliance. WDL could also include links to demonstration videos that covered challenging aspects of the mixing, loading, or application process.

Eliminate the step of checking websites. EPA's current approach to protecting threatened and endangered species is to develop species- and site-specific restrictions on the use of pesticides. Rather than putting these restrictions into master labels, EPA is requiring registrants to add to their labels an instruction for users to check the agency's Bulletins Live Two (BLT) website where it has compiled all these restrictions. Computer programs in WDL software could link geographical metadata entered by the user —- for example, the county, HUC, or zip code for the intended application site —- with BLT maps containing information relevant to the proper use of the product. Such geospatial information could include the geographic restrictions needed to protect threatened and endangered species that users now access in BLT or soil classification maps prepared by USDA.

Finally, a product that uses WDL could make changes that reach customers —- the ultimate users —- much more quickly. For registrants, this could cut months off the timeline required to design, print, and affix new labeling to containers, which then would need to be distributed through wholesalers and retail sales channels to reach customers. The shorter period could make the difference of a year in terms of when a product reaches a new market. Likewise, WDL could reflect the inclusion of new risk mitigation measures which justify EPA imposing a shorter time frame on dissemination of required changes.

C. Improve Other Aspects of Marketed Product Labeling

EPN suggests that EPA pay attention to and improve other aspects of the display of the labeling that physically accompanies pesticide products. While the use of WDL will address many problems, there will still be many people who do not have access to reliable broadband internet service, and they will not be able to take advantage of WDL. Consequently, for the foreseeable future, printed labels on products and paper labeling accompanying pesticides will be the only way some users will have access to critical labeling content. Currently these physical labeling materials are poorly organized, overly long, not standardized, and printed in fonts and colors that are barely legible. It is no wonder that many users freely acknowledge they do not read product labeling.

We recommend that EPA consider guidance or regulations addressing several aspects of labeling display. (EPN notes that use of WDL could resolve the first two issues listed below.)

- The font size of essential text is too small on many labels. EPA's regulations require that all labeling text be in 6-point or larger type. Given that substantial numbers of the user population is in their 60s or older, reading text in such a small font size is often very difficult. (EPN notes that the mean age of farmers in the United States is 57.5 years old. One third of farmers, approximately 300,000 in number, are 65 years old or over.) Most books are printed in 10- or 12-point font sizes[5]. If publishers think readers will not be comfortable with smaller type sizes, neither should EPA.
- EPA should also address the use of background color and text color. Some pesticide labels are made very difficult to read because the two do not provide sufficient contrast. EPN volunteers have seen labels with white letters on a pale orange background, red letters on a yellow background, and text and background in two shades of blue. All were difficult to read.
- EPA should consider requiring a Table of Contents for any product that has attached labeling longer than five pages. These comments have already referred to the difficulty users have in finding needed

[5] See https://www.papertrue.com/blog/best-fonts-for-books/#:~:text=The%20standard%20book%20font%20size,works%20in%20the%20same%20genre

information, and the White Paper reports that EPA reviewers encounter similar challenges. This problem could be reduced by including a Table of Contents that directs users to different pages of the labeling to find information on specific uses. Syngenta has developed and successfully uses a Table of Contents approach on its products.

Finally, EPN notes that in the 1980s EPA worked with external experts to develop a report called the Consumer Label Initiative. This report contained many recommendations about the display aspects of pesticide labeling that would improve overall readability. EPN recommends that EPA obtain and review that report and adopt useful recommendations as guidance.

These comments were prepared by William Jordan, with the support of Jack Housenger, Mardi Klevs, Tina Levine, Robert Perlis, and Nelson Thurman, on behalf of EPN.

Appendix A

SUGGESTED FRAMEWORK FOR THE USE DIRECTIONS PORTION
OF AN END-USE, AGRICULTURAL PESTICIDE PRODUCT'S LABELING

1. SITE
   A. Food sites – imbed Excel list of crop sites
   B. Agricultural, non-food sites covered by WPS
   C. Agricultural, non-food sites not covered by WPS

[Computer Programming Note: Certain DFU information is likely to be the same for all (or at least more than one) use sites; other information will vary by use. The framework should allow the easy entry of information to be tied to a specific use site and information that applies to most or all use sites.]

2. TARGET PESTS

3. MIXING DIRECTIONS
   A. Diluent/diluent prohibition
   B. Dilution rate: minimum diluent/carrier
   C. Equipment specifications
   D. PPE for mixers
   E. Mixing site conditions (e.g., need for/size of impervious pad, no surface water flow, distance from wells & water bodies, etc.)
   F. Storage of mixed product

4. LOADING DIRECTIONS
   A. Equipment
   B. Tank mixes allowed/prohibited (e.g., fertilizer, other pesticides)
   C. PPE for loaders

5. APPLICATION DIRECTIONS
   A. Pre-application conditions/requirements
      1. Scouting for pest pressure level
      2. Use of other pest control methods,
      3. Advance notice/consultation with neighbors/government agencies
      4. Other(?)
   B. Method(s): specified/prohibited [FIFRA 2(ee)]
   C. Equipment
   D. PPE for applicators
   E. Application rate:
      1. maximum across specified time interval
      2. maximum for a specified unit of area or a non-standard target site (e.g., tree or row)
      3. minimum [per FIFRA 2(ee)]
   F. Application placement instructions
      1. Minimum soil incorporation depth
      2. Placement in tree

3. Other

G. Minimum reapplication interval
H. Total daily/annual acreage treatments
I. Allowed number of treatments/maximum allowed treatment or quantity, together with the application equivalence for products with multiple AIs

6. APPLICATION RESTRICTIONS
   A. Who can apply (e.g., RUP pesticide, veterinarians, only by government employees)
   B. Timing limitations of when application may occur:
      1. Application start/cutoff dates
      2. Stage of plant/animal/pest growth
      3. Time of day
      4. Temperature
   C. Geographic limitations on where application may/may not occur
      1. Restrictions in Endangered Species Bulletins Live Two
      2. Buffer zone requirements (e.g., distance from water bodies, residences, etc.)
      3. Site characteristics (e.g., soil type, soil organic matter content, slope, erodibility, need for vegetative buffer strips, impervious surfaces, drains)
      4. Restrictions applicable to specific active ingredients (e.g., prohibition on use of atrazine in HI, AK, USVI, PR, & certain counties of NY)
   D. Equipment requirements
      1. Nozzle types
      2. Droplet size spectrum
      3. Release height
      4. Boom/wing length
   E. Weather conditions
      1. Wind speed
      2. Temperature
      3. Forecast for precipitation
      4. Other (?)
   F. Other
      1. Application of other pesticides (e.g., prohibition of treating sorghum crop with atrazine and propazine)
      2. Limitations on manufacturing other products
      3. Protections for flaggers

7. OTHER RESTRICTIONS/REQUIREMENTS
      A. Applicability of Worker Protection Standards (40 CFR part 170)
      B. Post-treatment restrictions on treated site activities
         1. Early entry PPE
         2. Restricted Entry Interval (REI)
         3. Pre-Harvest Interval (PHI)
         4. Pre-slaughter interval
         5. Rotational crop interval/restrictions
         6. Plant back restrictions
         7. Grazing/feeding restrictions

        8. Maximum number of crop cycles per year
    C. Post-treatment monitoring (e.g., measuring residue levels, assessing treatment efficacy)

8. Animal treatment restrictions
    A. Minimum age of animal
    B. Minimum weight of animal

9. OTHER WARNINGS/RESTRICTIONS
    A. Physical/Chemical Hazards
    B. Resistance management warnings/restrictions
    C. Environmental hazards
        1. Groundwater protections
        2. Surface water protections
        3. Pollinator protections
        4. Endangered Species protections

NOTE: These data elements seem to fit with a pesticide applied to agriculture sites where crops are growing vs. pesticides that are applied to harvested/processed/stored crops.