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WHITE PAPER: Benefits of the Adoption of Structured Content and Digital Pesticide Labels

U.S. Environmental Protection Agency

Office of Chemical Safety and Pollution Prevention

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Executive Summary

The Office of Pesticide Programs (OPP) is seeking input on the creation, submission, review, approval, and distribution of structured content pesticide labels. Structured content is information or content that is organized in a predictable way and is digital content, which is typically organized with metadata. Currently, the pesticide registration process is mostly manual, which leads to time consuming reviews, potentially inconsistent approval of language, and high cost to both registrants and regulators. The increasing complexity of pesticide labels and inconsistency across label language and placement of information on labeling are challenges for pesticide users and the public seeking information about how to use the products. Structured content digital labels would streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders.

OPP is in the developmental stage of creating both a structured label and structured digital label. The structured label would provide the framework for consistent placement and order of the regulated portions of label information, and the structured digital label would use the framework of structured labeling and organize the contents as data. Using a structured digital label would streamline the submission and review process, improve consistency and readability of label language, and make information more accessible to pesticide users and the public. The standardized format would present information clearly and consistently, making it easier for pesticide applicators and handlers to identify necessary information on the label. In turn, the clarity would support adherence to label instructions and the protection of human health and the environment.

In addition to developing a framework for structured labels and structured digital labels, OPP is also planning to identify key fields needed for the structured digital label during the process phases. OPP is requesting public comment on all aspects of the structured label content, including but not limited to the anticipated benefits, risks, challenges, key fields, and proposed phases of adoption.

What are Structured Labels and Structured Digital Labels?

A structured label is a template for consistent placement and order for all required label information and would be available to use for all registered pesticide types. EPA expects that structured labels would be submitted as PDFs for review and registration processes.

A structured digital label is a digital framework that organizes the contents of labels as data (including metadata) which can be reorganized, searched, and displayed in multiple outputs according to the needs of any user, including regulators, registrants, NGOs, enforcement officials, end users, and the public.

What do they have in common?

Structured labels and structured digital labels will have the same fields in common and will contain the same required information for registration. Examples of required fields would be active ingredient, product name, company name, and use sites. Both label types would require a change from the narrative structure of pesticide labels to utilizing more direct language and tables, most notably for application rates.

How are they different?

A structured label will provide a standard framework for key fields specifying the location and placement of information within the pesticide label. The structured digital label will have the same fields as the structured label and further provide the underlying field metadata providing greater context, search capability, and adaptability. A structured label would be a static file, while a structured digital label would be a data file that could be rendered in multiple formats.

Background

OPP has previously announced four label registration digitization programs: the Central Database Exchange (CDX) for pesticide registration submissions, Web-distributed Labels, the Electronic Confidential Statement of Formula Application (e-CSF), and the Office of Pesticide Programs Electronic Label (OPPEL) pilot.

CDX[1] was first introduced by the Agency in 2002 for secure submission of data to the Agency across programs. Since 2020, essentially all studies and label registrations are submitted to OPP through CDX. The widespread adoption of CDX for pesticide submissions streamlined the process by essentially eliminating the physical paper submissions that required hand delivery, scanning, and processing.

In May 2021, the Agency publicly launched the e-CSF[2] application, an online tool to create and submit confidential statement of formula electronically on CDX. Features of e-CSF include a structured standardized format, drop down menus with pre-approved vocabulary, and self-validation checks to confirm key fields are populated prior to submission. The validation checks provide significant time savings for both the Agency and registrants, preventing lost time between initial review and additional submissions.

Web-distributed labeling for pesticide products[3] was announced in 2014 with guidance to registrants for the voluntary adoption of making pesticide labeling available via the internet. With this approach, registrants could distribute pesticide products with a label that includes a

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[1] https://cdx.epa.gov/

[2] https://www.epa.gov/pesticides/epa-launches-new-electronic-confidential-statement-formula-application

[3] https://www.epa.gov/pesticide-labels/web-distributed-labeling-pesticides#:~:text=Labeling%20available%20online%20%2D%20called%20web,than%2030%20pages%20of%20instruction.

website link that refers users to legally valid labeling they could download with the most current version of state- and site-specific labeling. The Agency expects that web-distributed labeling would make it easier for pesticide users to better understand and comply with pesticide labeling. One barrier that has prevented adoption of web-distributed labeling is the lack of standard digital label development and submission systems.

In 2014, OPP piloted a program called the "Office of Pesticide Program Electronic Label" (OPPEL[4]). The pilot was a partnership of nine stakeholders working together to develop a standardized digital label format. Most of the label contents were structured and standardized, but sections such as the application instructions were not. The allowed a large amount of customization within the application instructions. Having to complete the structured sections of the labeling and a separate portion for the application instructions created duplicative work for both registrants, at the label creation stage, and EPA at the label review stage. While this project laid important groundwork for terminology and structure for structured labeling submissions, the Agency does not intend to propose the adoption of the current OPPEL system.

Other Federal Label Standardization and Digitization and Efforts

Consumers in the U.S. have become accustomed to seeing the nutrition information in a standard format on food products. Prior to the late 1960's, labels rarely included nutrition information or any standard format. Beginning in the 1970's, there was a steady progression of voluntary guidelines and rulemakings on claims, but no standard was developed. Dr. Louis W. Sullivan, then Secretary of the U.S. Department of Health and Human Services stated, "The grocery store has become a Tower of Babel and consumers need to be linguists, scientists and mind readers to understand the many labels they see."[5] The Agency's current pesticide labels contain a similar lack of standardization in the pesticide marketplace.

The Food and Drug Administration (FDA) implemented a standardized labeling for food nutrition content in 1993[6] and for medicine in 2002[7]. The standard required electronic label submissions in 2004[8] with regular updated guidelines and requirements as of 2019[9]. U.S. consumers have continued to benefit from the clarity, consistency, and improved safety achieved through these standardization efforts.[10] The Agency expects to achieve similar gains in understanding with the standardization of pesticide labels.

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[4] https://www.epa.gov/pesticide-registration/office-pesticide-program-electronic-label-oppel-pilot
[5] National Library of Medical History of Nutrient Labeling: https://www.ncbi.nlm.nih.gov/books/NBK209859/
[6] Nutrition Labeling and Education Act (NLEA) of 1990. Final regulations were published on January 6, 1993.
[7] Federal Register of March 1999, the Food and Drug Administration published the OTC Drug Facts Label Regulation. Requiring the new format to be adopted by May 2002.
[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-content-labeling
[9] Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry (2019).
[10] https://labels.fda.gov/

Challenges with the Current Approach

The Office of Pesticide Programs' label submission and review processes pose several challenges. Currently, labels are submitted as PDF files using the CDX without any standardized format. Submissions must include all of the necessary elements and follow the minimum placement requirements at 40 CFR part 156[11], but the submitter has discretion to arrange some of the elements. This variability in placement and formatting results in extended review times for the submission since the required elements may be in different locations. Furthermore, there are often multiple iterations of submitted labels with rearranged components, requiring the review of the entire package, lengthening the review process, and creating unnecessary redundancy. Similar situations also occur when reviewing marketing claims on labels and other language that is not required.

The current label submissions present downstream challenges to identifying key information for risk assessments and regulatory review documents. Under federal law, all pesticide active ingredients are required to be re-evaluated every 15 years.[12] As part of this process, the Agency needs to compile risk-associated information, such as application rates, personal protective equipment (PPE), reapplication timing, and efficacy. This information is often presented throughout the label and may be difficult to locate. Currently, the Agency compiles information from each label and enters it into various assessments, models, and regulatory documents. This process is manual and involves creating summary documents requiring significant Agency resources. This is inefficient and increases the likelihood of errors since the documents must be manually updated with each new submission or added use.

The number of new registrations and label updates for existing registrations have increased steadily over the past decade, which when combined with lower staffing levels has amplified the inefficiencies with the current processes. Registration actions may also include non-PRIA label updates, language related to the Endangered Species Act (ESA), or required text associated with the registration review process. Given the large number of registered products, and the long lifecycle of registration review, there is a need to explore ways to make the process more efficient while maintaining protections for human health and the environment.

The pesticide marketplace and user experience are hindered by the lack of label standardization. Technical innovations are currently limited due to the variability of labels. States and NGOs that offer pesticide training and certification programs spend time and resources educating users to navigate labels to find the necessary information rather than focusing the curriculum on terminology or best practices.

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[11] Front panel placement requirements: https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-156
[12] https://www.epa.gov/pesticide-reevaluation/registration-review-process

Benefits of Structured Labels

Increased Registration Accuracy, Quality, and Efficiency

Structured labels and the structured digital labels offer benefits for regulators, users, the regulated community, and the public. A structured label could enhance label accuracy, quality, review efficiency, and consistency. The initial use of standardized labels could improve the review process by utilizing standard structures to eliminate the need for reviewers to hunt through the document to find the required sections and language. Furthermore, structured digital labels could improve label quality with validation checks, vetted terminology, and optional pre-populated fields with consistent label language, potentially even including marketing claims associated with the selected active ingredient. A structured digital label submission could be compared electronically to previous submissions, highlighting changes to allow for a focused and streamlined review. Both structured labels and structured digitals labels would allow OPP and state regulators to focus on comparing substantive changes rather than spending time and resources reviewing labels in their entirety.

The significant effort of mining the label text for information needed for risk assessments would be reduced through the adoption of a structured label with a use rate table incorporated within the label's instructions. The current manual transcription process used to compile information from use rate tables would be eliminated with a structured digital label. Submissions could be validated electronically against approved use rates to indicate whether a new risk assessment is necessary. The structured digital label would have key fields identified for a risk assessment in an exportable, quantifiable format, eliminating the potential for the risk assessment values to differ from the label instructions.

Structured digital labels could offer self-certified fields, such as contact numbers, incident reporting information, links, QR codes, and language translations. If the automated label review only identifies changes in the self-certified fields, the label could be approved without the need for a manual secondary review. Structured digital labels could also offer the option to use suggested language from EPA (e.g., language from the label review manual, pesticide registration notices, new guidelines, or ESA mitigation[13]). Automated review could identify that the label includes mandated language and validation could confirm it is appropriate to the product, reducing the need for manual secondary review. While registrants would have the option to use customized language in their submission, this would be flagged during the automated review for additional manual review. The availability of a tool that contains statements already accepted by EPA for use on labeling would improve consistency across regulatory decisions and product labeling.

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[13] Regulations.gov OPP ESA Work Plan: https://www.regulations.gov/docket/EPA-HQ-OPP-2022-0908

Regulatory Consistency

The digitization of labels would enable OPP to build a comprehensive database of registrations that can be cross-referenced against upcoming decisions to ensure consistency in rates, mitigation measures, and marketing claims. With data and metadata from registrations, OPP staff could identify whether labels are in line with current standards and more easily identify which product labels need to be updated as part of the registration review process. If labels need updates, digital labels could allow for automated notification of all affected registrants. This automated process would also reduce the time between identification of risk mitigation measures during registration review and implementation of labeling updates that result in strengthened protections in the field. Similar notification processes could be used to address human or environmental risk mitigation as necessitated by legislation, rulemaking, or litigation. There is potential under this scenario to automate the entirety of such changes, thereby eliminating the need for additional manual review.

International Harmonization

A structured label both as a PDF and digital label could improve readability, consistency, and clarity for labels within the United States; international harmonization could further improve consistency and clarity between multiple markets. Label harmonization could also promote trade and further increase regulatory efficiency by allowing regulators to cooperate and utilize shared standards and guidelines, reducing the time and resources required for individual regulators. Standardized vocabulary (e.g., names of pests, diseases, use sites) could also facilitate the translation of labels for international markets, ensuring consistent information dissemination across countries. Registrants could gain cost savings by reducing the time to develop different product labels, reducing transportation burdens, and increasing the possibility of the same physical label being sold in multiple markets.

Enforcement

The Agency anticipates that standardized structure and vocabulary would reduce likelihood that labels with unclear or unenforceable language are registered. The creation process for structured digital labels should further reduce this likelihood by offering a library of EPA-accepted language for different label sections. While the Agency would continue to allow registrants to submit custom language, the language would be flagged for manual review. Using language already reviewed and accepted by EPA should reduce the number of products with unclear or problematic language, decreasing product misuse and enforcement issues in the marketplace.

Connecting the Active Pesticide Product Registration Informational Listing (APPRIL) with structured label would enhance the accessibility, and availability of information. Digital labels could be validated and searched. This would facilitate faster and improved compliance for various labels required for the commercial production, transportation, and sale of pesticides.

Structured digital labels could be added to application records. A digital environment can maintain a log of usage with more detail than the current paper-based application records. The additional detail would be helpful in both enforcement activities and incident investigations.

Safety and Stewardship

The adoption of structured digital labels is expected to improve health and ecological stewardship by enhancing user-friendliness and reducing the likelihood of misuse and incidents, which can pose risks to human health and the environment. Embedded links and updated contact information in a digital label would make it easier to report incidents, enabling prompt responses from state and regional offices.

Structured digital labels could enable equipment manufacturers and third parties to develop software that interfaces with their equipment, facilitating planning, loading, spraying, and disposal of the pesticide in specific regions and for the user's equipment. One potential opportunity is the creation of apps that allow downloadable label information databases, accessible without an active internet connection in the field.

The availability of a searchable database would empower users to find products effective against public health diseases such as SARS-CoV-2 and Norovirus, and disease vectors such as rodents and mosquitoes, or to find "Design for the Environment" products, which have been determined to meet certain rigorous criteria for efficacy and effects on human health and the environment, contributing to overall health and environmental well-being.

Digital labels have the capability to embed spatial data, allowing for the programming of buffers around listed species or sensitive habitats. When combined with GPS-enabled spraying equipment, these labels could enable automatic avoidance of sensitive areas, minimizing potential harm to non-target organisms and ecosystems. Moreover, digital labels could be linked with Bulletins Live Two! (BLT) and potentially replace the current system. This integration addresses the limitations of BLT in handling the large number of endangered species and designated critical habitat GIS files expected to be created by the Agency in the coming years.

End Users and Stakeholders

The Agency hosts the Pesticide Product and Label System (PPLS)[14] and APPRIL[15]. Both are public-facing repositories of all active pesticide registrations. With PPLS, the public can search for the PDF label by a product name, company name, or chemical name and their numeric equivalent codes. While this repository is useful, it is best suited for people to gain access to an electronic version of a label that they are already aware of, not a way to search for products to use. Launched in August 2022, APPRIL allows users to search for pesticide products using a wide

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[14] Pesticide Product and Label System: https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1
[15] Active Pesticide Product Registration Informational Listing (APPRIL):
https://ordspub.epa.gov/ords/pesticides/f?p=APPRIL_PUBLIC:2

array of fields, such as pesticide categories, use pattern, and pests. However, these keyword tags are not fully populated for all registrations and are not yet standardized. Lastly, the Agency hosts a website that does allow users to search by need for insect various repellents. The "*Find the repellent that is right for you*"[16] site is a useful demonstration of the utility of allowing the public to search products based on need rather than a product number. With the adoption of structured digital labeling, the Agency could replace or expand PPLS/APPRIL to allow users to search for products by numerous key fields and associated metadata. The Agency anticipates this would be a valuable tool for the public. Individuals facing new pest pressures could search the database for all registered products that meet their needs, including products effective against public health pathogens and their vectors. Similarly, those implementing resistance management strategies through rotating modes of action can search for products based on their modes of action, enabling them to select a rotation that suits their requirements. Additionally, during periods of supply constraint, end-users would be able to search for alternative products.

Just as PPLS/APPRIL is utilized by other stakeholders, the Agency anticipates this publicly available database could be utilized by others to provide additional benefits to the end users. Agricultural extension programs or NGOs could provide additional guidance on product efficacy, resistance management, and localized factors that the end user should be aware of.

In addition to helping users find the right product to meet their needs, a robust, searchable product database would allow improved accessibility in the field. Either through the Agency website, third-party apps or third-party websites, improved access and readability of the label is anticipated. Instead of a static PDF, technologies could allow the option for users to access a version of the labeling with the necessary information relevant to the user's specific crop, site, application method, or pest. This approach would improve label readability, as traditional labels can span hundreds of pages, requiring users to navigate between distant sections. Embedded features could include unit conversions, optimization for mobile devices, hyperlinks to factsheets, label translations, and other helpful tools.

A standardized label structure, whether in digital or non-digital format, would enable third-party companies, states, stakeholder groups, and NGOs to enhance their training programs. Existing labels do not have consistency in terms of placement and language for key information. With a standardized label structure, the training can move from helping applicators and handler figure out where on each label information can be found to understanding the content and meaning of keywords.

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[16] Find the Repellent that is Right for You: https://www.epa.gov/insect-repellents/find-repellent-right-you#search%20tool

Supporting Emerging Agricultural Technology

Emerging agricultural technology has the potential to shift the agricultural market to a safer and more sustainable future. Examples of emerging technology include variable pesticide application determined by spatial data, targeted applications utilizing visible recognition and utilizing autonomous/unmanned systems. These advancements in application technology have the potential to reduce overall pesticide application tonnage, increasing effectiveness while also avoiding application to ecologically sensitive areas. The existing narrative form of application instructions that vary from label to label hinder such possible innovations from being adopted in the marketplace. Adopting a structural digital label could promote the development and adoption of emerging agricultural technology. For additional details on of emerging technology and Pesticide Program Dialogue Committee (PPDC)'s recommendations for actions the Agency should take, please review the PPDC Emerging Agricultural Technologies Working Group 2022 – 2023 Final Report.[17]

Anticipated Reception and Overcoming Concerns
Why Now?

Pesticide registration applications have severe backlogs, leading to outdated information on labels and a slowdown in business. The registrant community wants regulatory certainty and clarity, as well as registration decisions informed by data. State agencies and inspectors want clear, enforceable language. Stakeholders including non-governmental organizations, pesticide safety educators, and farmworker advocacy organizations want faster incorporation of additional protections for human health and the environment. These factors, combined with limited Agency resources that necessitate efficiency, making digital labels a critical need for the pesticide marketplace.

The Agency is doing more work with fewer resources. OPP has embarked on a digital transformation and is rapidly building its ability to collect and analyze data. Costs of technology adoption are dropping and potential returns on investment are growing. Adoption of structured labeling and structured digital labeling would dovetail with the Agency's internal focus on digitizing data.

The convergence of these factors, along with the rapid technology development, makes it an ideal time to pursue development of structured labels and structured digital labels to meet the needs of all stakeholders.

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[17] Pesticide Program Dialogue Committee (PPDC) Emerging Agricultural Technology Working Group Final Report: https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/ppdc-emerging-technologies-workgroup

Addressing Technical Challenges

OPP anticipates concerns and acknowledges there are technical challenges that could be faced during the transition to a structured digital label. Some registrants may face challenges adapting their products to the new standardized structure and, later, full digitalization. Some of the challenges might include transitioning many labels from the current format to the structured label format, and developing a mechanism to compile and submit a structured digital label. OPP hopes that in the future, the Agency will have the resources to make available a label builder.

Another challenge is access to structured digital labels. Cellular coverage, while ever-expanding, is not yet universal, particularly in rural areas. So, while most end-users and inspectors can use mobile devices to access labels, OPP plans to ensure that the necessary information is still printed on the product containers.

Potential Use of Artificial Intelligence (AI) Tools

Recent developments in AI have shown the ability to organize and process unstructured text and data. However, complex narrative documents still present a challenge that is far beyond the capabilities of today's AI tools. Labels are unique and do not follow a standard format for organizing the information. Multiple application rates and instructions are given depending on various field conditions specified in narrative text. Matching the correct application rate with intended conditions and required mitigation is something the Agency is not confident current AI tools can do reliably at this point. Organizing labels in a structured manner where automated tools could verify if required information is present is more likely to succeed and facilitate a searchable database of both structured PDF labels and structured digital labels. However, as AI tools advance, the Agency will reevaluate this position.

Next Steps
Partnerships and Harmonization

OPP has been reaching out to various stakeholders and international groups to cooperate while creating a structured digital label. Other regulators worldwide are dealing with the same inefficiencies caused by the submission of static unstructured PDF labels and are at various stages of developing digital labels. OPP has been reaching out to multiple trade partners and is seeking to collaborate efforts and harmonize labels as much as possible.

Implementation and Adoption

Stakeholders, registrants, and fellow regulators want to know how the structured digital label will be adopted and whether it will ultimately become mandatory. Making structured digital label submission mandatory would require OPP to revise the regulations through rulemaking. While OPP does not anticipate making structured digital label submissions mandatory in the

near future, the Agency will encourage its adoption. Although CDX digital submissions are not required, CDX label submissions are the only way labels have been submitted since 2020. Just like CDX, OPP expects that the inherent benefits of using structured digital labels would drive adoption. As the label review efficiencies and time savings of structured and digital labels become quantified, it is possible that the Agency will set new estimated timelines for structured labels and structured digital labels as compared to traditional unstructured labels.

Anticipated Phases

OPP is considering the following phases in moving towards adoption of structured labeling and structured digital labeling.

1: Request Use Rate Table

The Registration Division of OPP regularly requests a "Use Rate Summary Table" (fields are listed in the Key Fields section in Appendix 1) with "new use" label submissions. This table helps clarify the use site and application rates that are being proposed in the new label. The first step towards an improved label review would be to request a "Use Rate Summary Table" along with the initial submission for all new registration actions.

2: Test Digital Submission Tools

The Agency is seeking digital submissions tools to evaluate from various stakeholders and will report on progress as the evaluations take place.

3: Propose Standardized Label Format for Public Comment

The Agency is currently collaborating with multiple stakeholders on both structured label designs and structured digital labels. EPA plans to consider the outcome of the various collaborations, along with the comments on this publication, in developing a single structured label proposal that will be issued for public comment.

4: Allow for the voluntary submission of labels utilizing the standardized structure and request that traditional labels be submitted with a supplementary site-index

Following adoption of the structured label format, the Agency could allow for the submission of labels utilizing that format. If registrants would prefer to submit labels in the current, unstructured format, the Agency would request that they submit their PDF labels along with a site-index that includes all use sites, rates, applications methods, and mitigation that would impact risk assessments.

5. Launch a pilot program allowing for submission of structured digital labels

OPP is working with multiple stakeholders developing structured labels and structured digital label tools. Following the testing outlined in step 2 and using comments on the proposed

standardized label format outlined in step 3, OPP would launch a pilot program for receiving and reviewing digital product labels as part of the registration process.

6. Launch a public structured digital label builder

If the pilot program of step 5 is successful, the Agency plans to allow submission of digital labels from all stakeholders. The framework for the structured digital label would be based on the feedback received under step 3. Recognizing that some registrants may not have sufficient resources to transition their products to use structured digital labeling, OPP hopes that in the future, the Agency will have the resources to make available a publicly available label builder that could be used by registrants to ease the burden of transition.

7. Update the Pesticide Product and Label System (PPLS) and Active Pesticide Product Registration Informational Listing (APPRIL)

PPLS and APPRIL are the Agency's pesticide label repositories; they store PDF labels for all federally registered pesticides. As digital labels are registered, the Agency plans to expand PPLS and AAPRIL to capitalize on the capabilities of structured digital labels. PPLS currently only has a few searchable terms, like product name and active ingredient. Digital labels will allow more searchable terms, most notably use sites, mode of action, and pests.

Request for Public Comment

With the publication of this white paper, OPP seeks feedback on all aspects of this document, along with feedback on previous digitalization efforts referenced in this document.

Requested Comment Topics:

1. Are there additional benefits to the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.
2. Are there additional challenges associated with the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.
3. Please provide feedback on the anticipated phases of OPP's work towards structured labeling and structured digital labeling.
   o Can any of anticipated phases be done concurrently?
   o Is there a different order to the phases? If so, please provide a suggestion and rationale for reordering.
   o Are any activities necessary in the development of structured labels and structured digital labels not accounted for in the anticipated phases? If so, please describe.
4. Are there additional efforts underway around development of structured labels or structured digital labels that EPA should be aware of? If so, please provide information for EPA's consideration.

5. Are there elements of the current "narrative" labels that could not be translated into structured labeling or structured digital labeling? If so, what are the elements and what are the barriers to their adoption?
6. Please comment on the key fields listed in Appendix 1.

Appendix 1: Key Fields

Anticipated Fields for a Use Rate Summary Table

- Use Site
    - Use Site
    - Use Location
    - Formulation(s)
    - Max Application Rate
    - Max Applications a Year
- Scenario
    - Application Target
    - Application Type
    - Application Equipment
    - Application Timing
    - Max Finish Spray Concentration
    - Max Single Rate
    - Max number of applications per crop cycle
    - Max number of crop cycles per year
    - Max number of applications per year
    - Mass Rate per year
    - Minimum retreatment interval (MRI)
    - Preharvest Interval (PHI)/ Pre-grazing Interval (PGI) Preslaughter Interval (PSI)
    - Site Specific Personal Protection Equipment (PPE)
    - Geographic Restrictions
    - Other Site/Scenario Specific Restrictions & Limitations
    - Registration Numbers

Anticipated Fields for the Structured Digital Label Fields

The Organisation for Economic Co-operation and Development published the *Report on OECD Surveys on Pesticide Product Labels Data Elements to Support the Sharing of Pesticide Labels Data* on March of 2023[18]: this report listed out key fields that were mostly shared between Canada, Australia, United Kingdom, European Food Safety Authority, New Zealand and Germany. These are also all fields that OPP has determined to be essential and will incorporate them in any future structured label so that international harmonization is as seamless as possible. Below are the key fields that OPP is proposing to serve as a foundation for future structured digital label.

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[18] Organisation for Economic Co-operation and Development. *Report on OECD surveys on pesticide product label data elements to support the sharing of pesticide label data*:
https://one.oecd.org/document/ENV/CBC/MONO(2021)44/en/pdf

1. Document Information:
   - File name
   - Company Name/Logo
   - Agency (EPA, PMRA and so on) Company number
   - Product number
   - Document ID
   - Version
2. Restricted Use Pesticide Statement
3. Ingredient Statement
   - *Mode of Action*[19]*
   - *Active Ingredients**
   - Ingredient Statement
   - Identified Inert Statement
   - Deterioration/Expiration Statement
   - *Product Density (required for liquids)**
   - *Mass Product per Miscellaneous Application**
4. Child Hazard Warning/Signal Warning
   - Signal Word
   - Child Hazard Warning/Signal Word Statement
   - Signal Word Qualifiers (Optional)
5. Product Profile
   - *Primary Brand Name**
   - *Packaged Form**
   - *Pesticide Classification(s)**
   - Alternative Name(s)
   - Product Profile Statement
   - Product Formulation Information
   - Legal Statements
6. Precautionary Statements
   - Precautionary Statements
   - First Aid Statement
   - Hazards to Human and Domestic Animals Statement
   - Personal Protective Equipment Statement
   - Engineering Controls Statement
   - User Safety Recommendation Statement
   - Environmental Hazards Statement
   - Physical or Chemical Hazards Statement

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[19] Fields that would be included in a Site Index are marked with "*" and in *italic*

7. Directions for Use
   - Directions for Use Statement
   - Agricultural Use Requirement Statements
   - Resistance Management Statement
   - Spray Drift Management Statement
   - Rotational Crop Intervals Statement
   - Seed Bag Labeling Requirements Statement
   - Storage and Disposal Statement
8. Use Site Application Instructions
   - Use Site/Commodity
   - Use Site Locations Application Instructions Statement
   - Warranty/Disclaimer Statement
   - Marketing/Advertiser Claims
   - Public Health Claims
   - Marketing/Advertising Claims Statement
   - Certification(s) and Seal(s)
   - Additional Documentation and Label Screen   (file upload)
   - Tank Mix/Adjuvant Information
9. *Product Identification**
   - *Restrictions/Limitations (repeated for Product/Site/Scenario if necessary)*
       i. *Geographic Areas*
       ii. *Use Site Food Relationships*
       iii. *Maximum AI Rate Across Products per Time*
       iv. *Rotational Crop restrictions apply to this product.*
       v. *Applicator Class Restriction(s)*
       vi. *Personal Protection Equipment (PPE)/Engineering Control(s)*
       vii. *Re-Entry Interval (REI)*
       viii. *Minimum Retreatment Interval (MRI)*
       ix. *Pre-Harvest Interval Restrictions*
       x. *Pre-Grazing/Pre-Feeding Interval Restrictions*
       xi. *Pre-Slaughter Interval Restrictions*
       xii. *Buffered Areas*
       xiii. *Max Release Height*
       xiv. *Max Wind Speed*
       xv. *Application Temperature Range*
       xvi. *ASABE Droplet Sizes(s)*
       xvii. *Soil Incorporation Depth and Time*
       xviii. *Restricted Soil Type(s)*
       xix. *Minimum Percent Soil Organic Matter*
       xx. *Minimum Age of Animal to Be Treated*

xxi. *Minimum Weight of Animal to Be Treated*

xxii. *Bulletins Live Two Statement on the label*

xxiii. *Endangered Species Mitigation Requirements*

xxiv. *Water Protection Statement(s)*

xxv. *Restrictions which limit Secondary Manufacturing of materials treated using this product.*

xxvi. *Restricted Use Site Location(s)*

xxvii. *Restricted Application Target(s)*

xxviii. *Restricted Application Type(s)*

xxix. *Restricted Application Equipment*

xxx. *Restricted Application Timing (Time of Day)*

xxxi. *Restricted Application Timing (Timing of Pest)*

xxxii. *Restricted Application Timing (Use Site Status)*

- *Use Site Information* (Including ag and non ag application locations)*
    i. *Use Site Attributes*
    ii. *Use Site/Commodity*
    iii. *Use Site Location(s)*
    iv. *Use Site Yearly Rate*
        1. *Use Site Yearly/Crop Cycle Rate*
        2. *Maximum Number of Applications per Site per Time*
        3. *Maximum Site Application Rate per Time*

- *Scenario Information* (Use variations depending various factors including target pest, timing or site conditions)*
    i. *Action(s) Against Pest*
    ii. *Action(s) Against Plant Disease*
    iii. *Plant Regulator(s)*
    iv. *Single Application Minimum Rate*
    v. *Single Application Maximum Rate*
    vi. *Use Rate Explanation*
    vii. *Acre Rate for Non-Standard Target Measures*
    viii. *Minimum Diluent/Carrier or Maximum Finish Spray Volume per Area*
    ix. *Residence/Contact Time*
    x. *Maximum Number of Applications per Scenario per Time*
    xi. *Minimum Application Rate per Scenario per Time*
    xii. *Maximum Application Rate per Scenario per Time*
    xiii. *Maximum Number of Crop Cycles per Year*

- *Scenario Attributes**
    i. *Form As Applied*
    ii. *Application Target(s)*
    iii. *Application Type(s)*

iv. *Application Equipment*
 v. *Application Timing (Site Status)*
vi. *Application Timing (Time of Day)*
vii. *Application Timing (Timing of Pest)*
viii. *Application Placement Instructions*
ix. *Application Rate Explanation*
 x. *Application Rate Conditions*