ALSTAR
Accepted Labels State Tracking and Repository

White Paper
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This white paper examines the challenges and benefits that face stakeholders in developing a pesticide label management solution, and introduces the concepts of the ALSTAR approach. ALSTAR represents a collaborative effort that allows the regulated and regulator communities to effectively maintain and disseminate product label information using web-based technology solutions.

Introduction

The registration of pesticide products involves a rigorous exchange of information between regulatory agencies and registrant companies. The Accepted Labels State Tracking and Repository (ALSTAR) application will focus on the exchange of information between state regulatory agencies and registrant companies. While several state agencies request diverse data, documentation, and product labeling information from registrants, most states require identical or similar information. This specifically pertains to pesticide product labeling. Some states go through a review process and place a stamp of approval on product labeling, while other states merely "accept" labeling. The terms "approved" and "accepted" are used interchangeably in this paper and refer to whichever labeling process is applicable in a state. The ALSTAR application will provide the capability to both registrants and states to streamline the exchange and use of these common data.

Three major stakeholder groups will benefit immediately from ALSTAR:

1. Registrant Companies
   Companies will save on time and labor, as the number of product label submissions (one per state) will be reduced to a single posting to ALSTAR. Once posted, states will be electronically notified and the submitted label can then be retrieved for registration review, approval, or default acceptance. A potential benefit to companies is an expedited state review process as a result of easy, standardized access of electronic documents including product labels. For the states that only require registrants to notify them of an amended label, a single posting to ALSTAR will, for most states, result in an automated posting of the revised label to the state's public repository. Automated data validation will ensure publicly posted labels are in fact registered in that state.

2. State Regulatory Agencies
   Agencies responsible for pesticide product registration will be able to retrieve an electronic version of a product label from a single source, in a common exchange format. The costly and time-consuming tasks currently required to handle and scan paper versions of product labels will be eliminated. States will be able to access and review product labels with confidence that security is provided. State inspectors will also benefit from an automated, timely posting of approved labels to their state's public repository. In addition, those agencies that wish to conduct electronic comparison between versions of labels will save resources and potentially increase accuracy of label review.

3. User Community
   A broad user community of dealers, growers, cooperative extension specialists, applicators, and the public currently "browse & search" a myriad of paper and Internet-based media in order to locate, retrieve and review the most current pesticide product label. More rapid access to approved "searchable" labels will benefit users of the NPIRS ALSTAR product. It is important to note, however, that the repository is not a substitute for the label affixed to the container (40 CFR 156 10(a)(4)). Product use and any resulting enforcement are dictated by the container label.

Historical Perspective

Multiple websites and databases have existed for a number of years that provide subsets of pesticide product information (labels or data). Some of these include the Crop Data Management System (CDMS), Agrian, Kelly Solutions, Greenbook, USEPA/OPP, and the National Pesticide Information Retrieval System (NPIRS). Each of these systems falls short, in some way, of providing either a complete repository of currently approved pesticide labels or the means to reduce regulatory burden.

A historical impediment, from the regulatory perspective, has been that many state lead agencies simply have not had the resources that are required to build, or have built, electronic document or data management systems. These resources might include hardware, software, staff expertise and budget.

Several state regulatory agencies, possessing sufficient resources, have been able to provide, either on their own websites or websites maintained by others, pesticide product databases, electronic labels images and related documents. These states include New York, Hawaii, North Dakota, and others. These solutions have been beneficial to the individual states, but generally have not addressed the need to reduce the expense, time, and complexity of the current regulatory process.

Goals and Objectives

The principal development goals of the ALSTAR project are (1) to provide a secure standardized process for the submission of electronic documents including product labels from registrants to the state regulatory agencies, (2) to create a process for regulatory agencies to easily manage a repository of state-specific approved or accepted labels and (3) to design an application that is dynamic enough in nature to allow for growth as future goals are defined. To achieve these goals, the following objectives have been identified:

a) Create format requirements for electronic labels and documents that meet acknowledged standards for security and portability.
b) Create a standard schema for unique identification of labels that meets the approval of both registrant companies and state regulatory agencies.
c) Provide a state-of-the-art application for electronic document submission, retrieval, label approval or acceptance, and automated posting to a public repository.
d) Create a secure and trusted environment for both registrant companies and state regulatory agencies to interface with the ALSTAR application.
e) Meet unique needs of both registrants and regulators by creating self-managed "profiles" that will allow companies and states to tailor the project to fit their specific business objectives or regulatory requirements, respectively.
f) Create error management processes to enable participants to correct submission and processing problems.
g) Provide these objectives in a cost effective manner and encourage the participation of all state regulatory agencies and registrants.
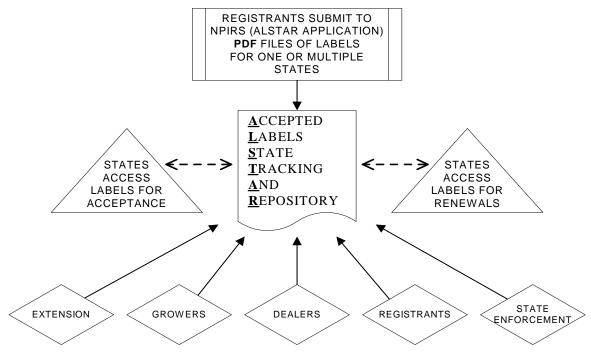h) Provide public access to state approved or accepted labels to the user community.

The Accepted Labels State Tracking and Repository – ALSTAR

The ALSTAR concept is the result of meetings over the course of the last two years that involved many participants from states, USEPA, the pesticide registrant community, and other stakeholders. The ALSTAR software is a secure data management application that facilitates the exchange of electronic documents including product label images between pesticide registrants and state regulators. The end product of ALSTAR is a repository of state-specific approved pesticide labels. The application will allow pesticide registrants to submit product labels and other required documents to multiple states, simultaneously. State pesticide regulators will be automatically notified and able to retrieve these labels for processing. After review and approval or acceptance, these state-specific labels will be posted to the public repository. These label "images" will be submitted and stored in a standard format, uniquely identified, and accessible via the Internet to stakeholders. This portable format may contain layers of data, state-specific electronic stamps, and may undergo automated processing that will provide agreed upon security to the document.

The ALSTAR application will be designed, implemented, and managed by the National Pesticide Information Retrieval System (NPIRS) at Purdue University in West Lafayette, Indiana. NPIRS is a center of excellence project within the Entomology Department under the auspices of the Center for Environmental and Regulatory Information Systems (CERIS) and is a not-for-profit organization. The NPIRS project has served the needs of both the regulated and regulator communities for over a quarter of a century. NPIRS has developed application software and publicly accessible websites that currently receive over 3 million hits per year. In addition, CERIS was responsible for the technical development of national data repositories for the National Agricultural Pest Information System (NAPIS), the Export Certification Project (EXCERPT), and the National Plant Diagnostic Network (NPDN) and continues to maintain these systems.

End Result Concept

Future Visions

A successful ALSTAR project lays the foundation for future collaboration between USEPA, states, registrants, and other stakeholders, that could include the development of data format standards for standardized registration submissions and processing along the lines of current Canadian (ERMA) and USEPA/OPP efforts. Additional standards and regulatory change could promote the reality of "true" electronic product labeling using the ALSTAR application as groundwork for collaboration. Other potential phases could include:

a) Establishment of data exchange standards between USEPA, registrants, and regulators to allow XML importing and exporting of data.
b) Development of customized data interfaces for registrant companies, state and federal regulatory agencies, and segments of the user community to allow dynamic linking to electronic document information housed in the public repository.
c) Interfacing ALSTAR unique document identifiers with label barcodes to aid with warehousing electronic inventory control.
d) Integration of USEPA data submission requirements to facilitate indexing of state specific pesticide label information.

Conclusions

There are several keys to success for the ALSTAR project:

1) The project must demonstrate that a cost effective methodology for conducting regulatory activities can be achieved using a solution that exhibits <u>real</u> benefits to all parties involved. The addition of just another extra layer of regulatory burden on the pesticide registrants will ensure failure. Likewise, a cumbersome, costly solution that creates an end product of modest value will ensure failure with the state regulators. All parties must benefit to a degree that matches or exceeds the effort.
2) The ALSTAR project must fit with a company's business objectives in order to make it feasible for a company to participate. Likewise, the project must not unwittingly alter or interfere with a state regulatory agency's registration process.
3) It is critical to start the project by defining a clear and achievable scope from an organizational, functional and stakeholder perspective. The scoping activity launches three parallel streams – technology, strategy/process and stakeholder engagement.
4) Sources of monetary support will have to be established. While NPIRS is a not-for-profit organization; hardware, software, application development and ongoing support do require substantial resources. Creative solutions are welcome!

Most importantly, there must be effective collaboration and commitment among all partners. Partners work to solve important business problems and tell you what you need to hear, not simply what you want to hear. The NPIRS ALSTAR project forms a partnership between pesticide registrants and pesticide regulators. All partners must be committed and willing to compromise when necessary. With collaboration and commitment the ALSTAR project will succeed and everyone will benefit.