Global Harmonised Submission Transport Standard

(GHSTS)

OECD Project on Harmonisation of Electronic Submissions of Pesticide Dossiers

OECD

Benefits of the Global Harmonised Submission Transport Standard (GHSTS) | The OECD Harmonisation Project

The Global Harmonised Submission Transport Standard (GHSTS) is a standardised set of technical specifications for assembling electronic files prepared by pesticide companies for submission to governments for regulatory approval of pesticide products. The GHSTS has been published by the Organisation for Economic Co-operation and Development (OECD) and is available at www.oecd.org/chemicalsafety/submission-transport-standard/

GOAL

The overall goal of the GHSTS is to promote harmonisation and increase the efficiency of regulatory processes. The development of this standard allows for easier submission and exchange of electronic data packages between industry and regulatory authorities as well as across all participating regulatory authorities.

BENEFITS

- Promotes harmonisation through the establishment of a single worldwide technical standard for all types of pesticide submissions.

- Supports the submission of a single dossier to multiple recipients, even if they have different business requirements.

- Increases efficiency for preparing and processing Multi-National Reviews – currently multinational submissions are both resource intensive for industry to assemble and awkward for regulatory authorities to review. The GHSTS improves communication and simplifies work sharing between Regulatory Authorities by providing the information on a standard platform.

- Increases efficiency of regulatory processes and approvals – better quality electronic submissions can potentially lead to shorter and less variable regulatory timelines, since applicants have better tools and guidance on preparing complete dossiers.

- Version management for submissions and documents – in a regulatory action, it reduces the need to send duplicate documents across multiple submissions, since they are contained within a single revisable dossier.

- Delivers structured data about the submission in XML format. Multiple document types can be submitted including the structured OECD Harmonised Templates. Harmonised content allows the data to be more structured and readable for man and machine.

- The GHSTS includes elements that are common among existing electronic standards for pesticide submission. The OECD focused on the metadata used in each of the electronic standards already in place to submit information to regulatory authorities and developed a single set of metadata that could be used by all authorities. For example, there are plans to incorporate GHSTS requirements into future IUCLID releases, an electronic submission system for registering chemicals in Europe, which is increasingly used by other countries.

- Provides some information management capabilities for smaller companies, since the GHSTS tracks the lifecycle of a dossier.

- Due to the generalised nature of the components, fields, and lifecycles of the GHSTS, it can be adapted for use in other business lines, and is not only limited to pesticides.

- Promotes identification and tracking of entities using a unique coding system for companies, regulatory authorities, substances, documents, and other entities. This unique coding system helps companies and regulatory authorities work together in identifying and managing such information.

Current submission process:
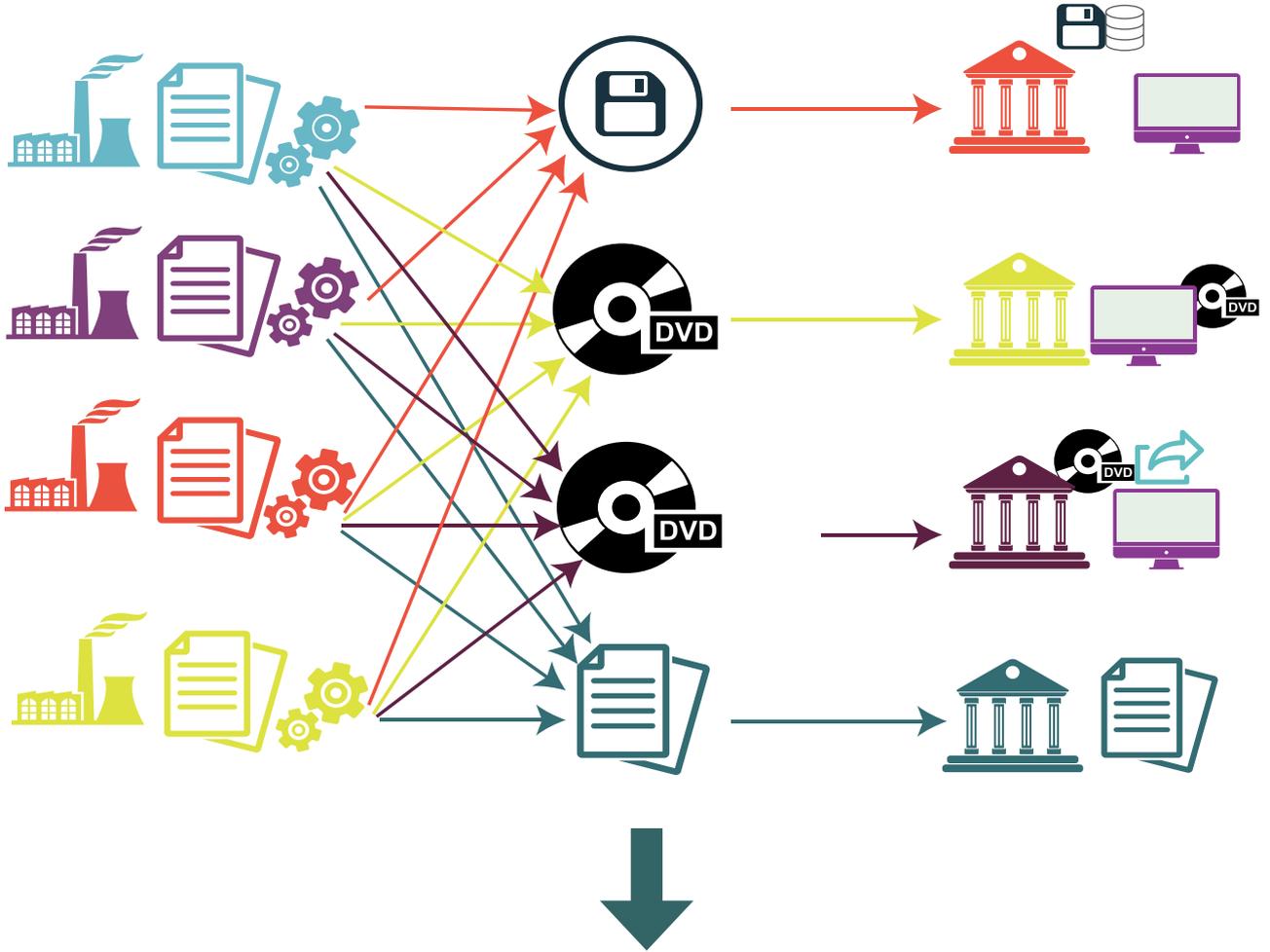
GHSTS develops one new standard acceptable for all based on and replacing the existing standards.
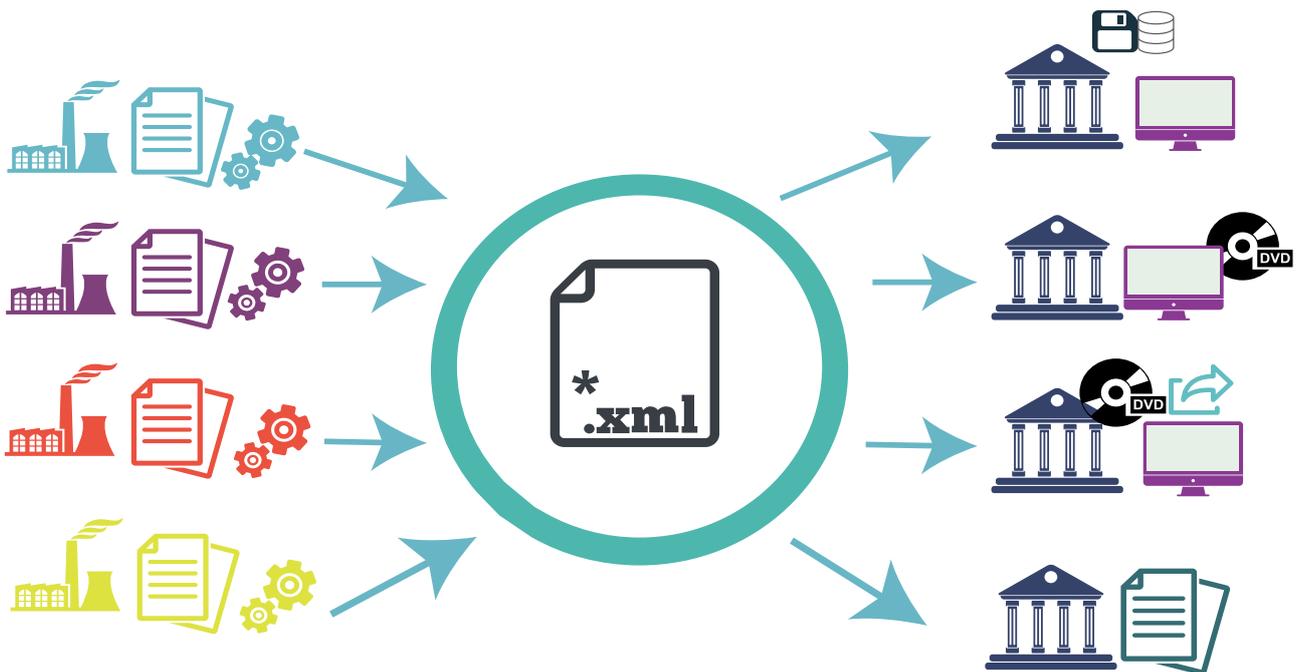
ECOSYSTEM

Composition:

In order to help both industry and regulatory authorities implement this standard, a GHSTS 'ecosystem' has been developed. The GHSTS ecosystem is comprised of elements that define the Standard maintained at the OECD, and tools developed by governments and private industry and made freely available that support the use of the Standard.

Standard Details:

- Specification Document – Guidance document for developers and business analysts.

- XSD (XML Technical Information) - Code that defines the GHSTS, and includes the OECD Table of Contents.

- Pick Lists – allows for a standard terminology to be used within the submission package and across packages. New items can be added to the pick list by the user.

- Validation Rules – Set of rules that can be integrated into a separate validator tool or an internal document management system. Used to validate the quality and completeness of the submission package.

Tools:

- Builder – used to create a GHSTS submission package based on information entered directly into the tool. Outputs are in structured XML format, along with associated submission documents.

- Viewer - software that allows for user-friendly viewing of a submission package, the XML structured data and associated submission documents.

FACING THE CHALLENGE

Bringing new standards and technology into an organisation has the potential to increase productivity, and help make better, faster decisions. However, getting buy-in from users is often a challenge when that technology is perceived as disruptive. From organisations that have no systems in place, to ones that already have well established systems, we all have unique challenges in adopting new standards and technologies.

To overcome this challenge, the OECD offers free online resources to help promote adoption of the GHSTS.

Documentation and training materials have been made available in the link below, and include an overview presentation along with a sample Dossier and a GHSTS desktop viewer: www.oecd.org/chemicalsafety/submission-transport-standard/documentation-training-materials.htm

Organisations can use these resources to create a compelling vision of the GHSTS, and to demonstrate the many tangible benefits associated with using the new technology.

Individuals or/and organisations that are willing to share lessons learned and/or offer support for any new country seeking to implement the GHSTS are currently being identified, as well as additional training materials needed to facilitate the adoption of the GHSTS.

Any questions regarding the GHSTS project may be addressed to ehscont@oecd.org.

GHSTS BENEFITS : How can GHSTS benefits me?

GHSTS offers advantages for Industry, Regulatory Authorities and the Public.

How can GHSTS benefit *smaller companies* with limited technical ressources?

GHSTS provides some information management solutions for smaller companies that may not already have a system in place. Metadata and lifecycle information associated with legal entities, substances, products, documents, dossiers and submissions can be managed within the GHSTS. Additionally, the builder and validation rules will help companies build better quality and complete submissions. By creating and storing submissions electronically, significant reduction on paper printing and document storage can be achieved.

How can GHSTS benefit *larger companies* with establied electronic systems?

The existence of multiple standards means that the applicant must duplicate their submission preparation effort which can be a time consuming and sometimes error-prone process. GHSTS will help reduce the administrative burden associated with preparing multiple submissions across individual regulatory authorities.
Developing a GHSTS standard can benefit larger companies by improving communication and simplifying work sharing between Regulatory Authorities on a national and multi-national level. Increased collaboration between regulatory authorities on all levels may help promote work sharing and increase the number of countries in which a product can be approved. As well, simplified information sharing between regulatory authorities can help broaden the use pattern of the label.

How can GHSTS benefit *Regulatory Authorities without* an electronic dossier system in place?

By adopting the GHSTS, regulatory authorities receive electronic submissions that contain version management for submissions and documents, which will help reduce administrative burden associated with processing redundant documents across multiple submissions. Additionally, GHSTS provides regulatory authorities with the necessary tools to review electronic dossiers, such as the viewer, which will be available free of charge.

How can GHSTS benefit *Regulatory Authorities with* an electronic dossier system already in place?

It is understood that many regulatory authorities may not be able to quickly and easily adopt new standards due to legislative, process and technology hurdles. However, it is suggested that the GHSTS be considered in any ongoing and future developments to your system.

As a first step in the development of GHSTS, the OECD focused on the metadata (in XML format) used in various electronic standards already in place by regulatory authorities, and developed a single set of structured metadata that could be used by all authorities.

This set of metadata includes elements common to many existing systems, along with additional elements required for specific systems. This will allow integration of GHSTS into already established systems with minimal disruption to business practices.

Viewer software, which will allow for user-friendly viewing of a submission package in a web-browser, functions independently of in-house document management systems. This provides co-operating regulatory authorities the assurance of knowing that they are working from a common set of material throughout the review process, regardless of the systems in use by the various regulatory authorities.

How can GHSTS benefit *Regulatory Authorities* developing an on-line submission portal?

GHSTS can provide a useful standard to follow regarding meta-data and life cycle management concepts and facilitation of an exchange of information amongst regulatory authorities even if a regulatory authority plans to receive submissions via data entry in an on-line portal.

How can the GHSTS benefit *citizens*?

Multi-national reviews of pesticide submissions facilitate a more efficient and cost effective regulatory process. Duplication of evaluative work is avoided. In fact, the joint evaluation of dossiers brings together experts from several countries who provide peer review evaluations which allow the public to have greater confidence in the scientific conclusions used as the basis for the regulatory decisions.

Further to this, GHSTS facilitates the exchange of information amongst regulatory authorities which could allow for approval of safer and more efficacious pesticides into the global market more rapidly than if each country were working completely independently.