

CSC & Shipping Expert communities

Improving the understanding of controlled substances and shipping legislation around the world

Jessie Bin Song, CSC Expert Community Lead, Merck

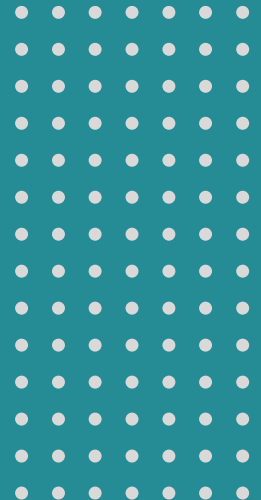
Jack DeCicco, Shipping Expert Community Lead, GSK

Birthe Nielsen, Expert Community Manager, Pistoia Alliance

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Joe Bradley, CSCS SC, Scitegrity

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Controlled Substance Compliance & Shipping Expert Communities (CSCS)

Project manager
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Problem Statement:

Legislation relating to pharma R&D is changing rapidly; each change adds complexity and widened controls. Remaining compliant in this complex environment is an ever-growing challenge and consequences for breaches are severe.

Compliance is also important in shipping. Customs, cold chains, dangerous goods and infectious material legislation all make R&D shipping complex.

Value Proposition:

High levels of compliance are vital to the credibility of and public trust in life science R&D. To assist its members, the CSCS Expert Communities provide a forum for compliance professionals, researchers, compound and shipping managers to share best practices and update their awareness of new legislation.

Project member:

The expert communities are made up of major pharmaceutical companies and specialist software providers. It is voluntary for the member companies to share their knowledge and experience.

Project champions:

- [Jack DeCicco](#), GSK (Shipping Expert community)
- [Jessie Bin Song](#), Merck (Controlled Substance Compliance Expert community)

Steering Committee:



\$7K per year ensures a seat on the Steering Committee



Project deliverables:

- Round table discussions
- Seminars
- Discussion and collaboration with expert external speakers and with independent and quasi-judicial monitoring bodies



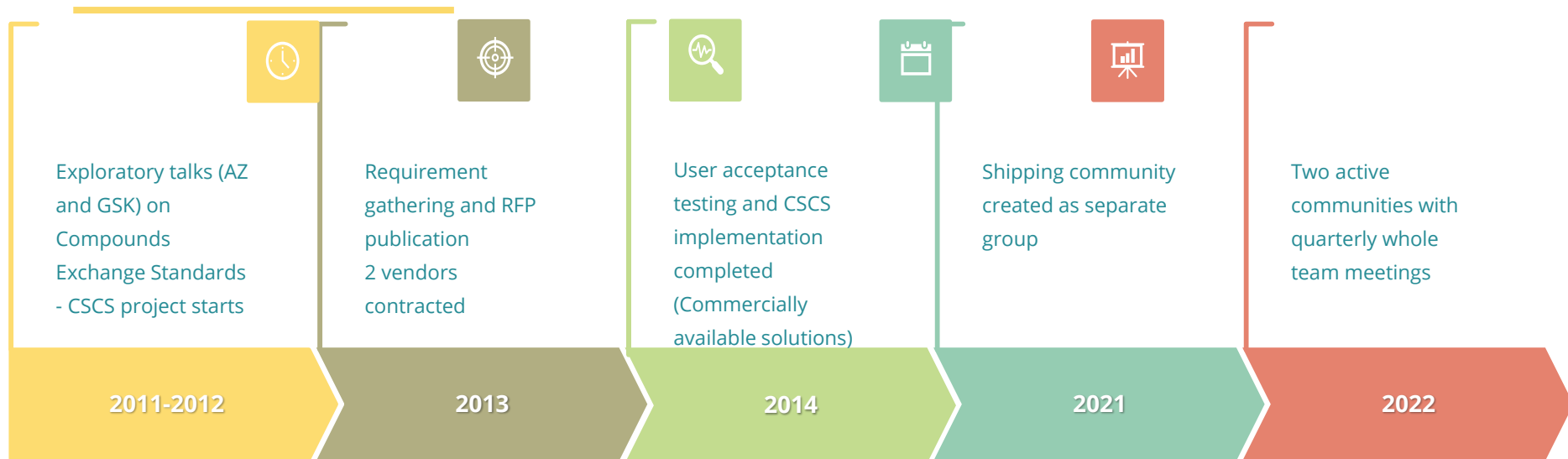


Collaborate to Innovate Conference Boston 2022

Agenda

- How does the communities operate
- CSC involvement, mission, and activity highlights
- CSC activities: communicating with regulators
- Controlled substance screening tools
 - CS2 and Compliance Checker
- Compliance requirements for shipping
- Shipping Expert Community Activities
- CSCS Outcomes/Tools
- How to join the communities

CSC & Shipping History



Pre-project

An Expert System combined with a Controlled Substance Knowledgebase to determine if a substance is controlled

Project Process

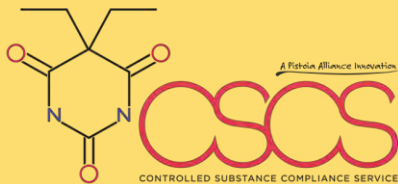
Chemaxon and Patcore: Compliance Checker
Scitegrity: CS2

2 Expert Communities

>20 members from different pharma companies

CSC - Mission

The Community focuses on tackling the challenges we face, developing solutions, communicating with regulators, and learning from each other to stay current and compliant with legislations governing controlled substance activities.



The Controlled Substance Landscape

... challenges we face



Landscape

- Complex and rapid changing legislation
- Super generic scheduling decision captures significantly more compounds in pharma libraries and more difficult to interpret
- Increasing externalization
- Cultural barrier
- Small number of internal experts to monitor and interpret the legislation
- High stakes for non-compliance

Complex legislation

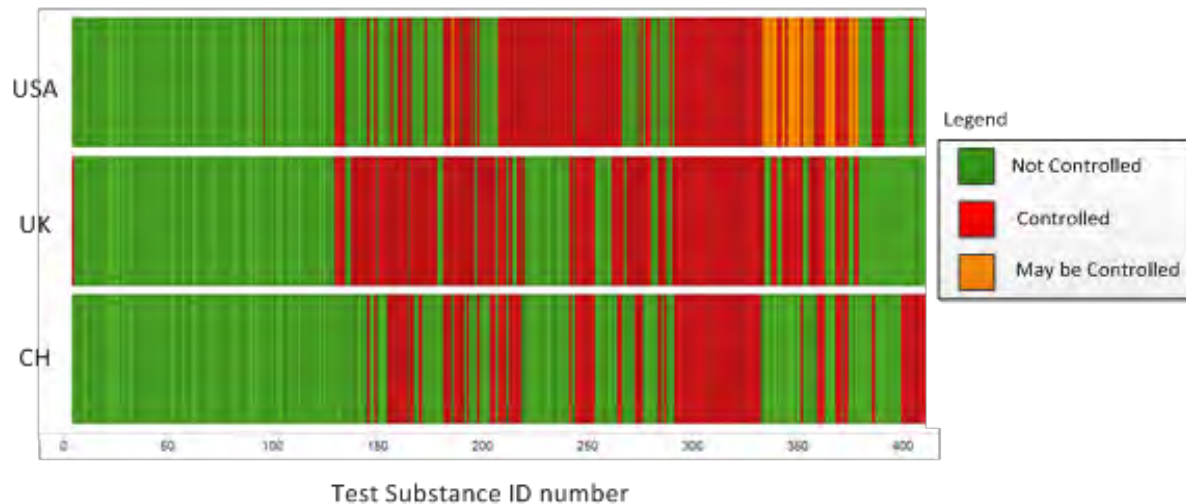
United Nations - Single Convention on Narcotic Drugs 1961
United Nations - Convention on Psychotropic Substances 1971
United Nations - Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988
United Kingdom - Misuse of Drugs Act 1971
United States - Controlled Substances Act 1970
United States - Chemical Diversion And Trafficking Act of 1988
Canada - Controlled Drugs and Substances Act 1996
India - Narcotic Drugs and Psychotropic Substances Act, 1985
Singapore – Misuse of Drugs Act
New Zealand – Misuse of Drugs Act 1975
Thailand - Psychotropic Substances Act
Pakistan - Narcotic Drugs and Psychotropic Substances Act, 1985
Australia - Standard for the Uniform Scheduling of Medicines and Poisons
Philippines - Comprehensive Dangerous Drugs Act of 2002
Russia - Regulations on the State Committee of Russian Federation for the control of narcotic drugs and psychotropic substances
United Arab Emirates - UAE Federal Law 14 of 1995
Japan - Narcotics & Psychotropics Control Law, Stimulants Control Law, Narcotics Special Law
South Africa - Drugs and Drug Trafficking Act No. 140 of 1992
Iceland - Regulation on habit-forming and narcotic substances and other controlled substances No. 233/2001
Gibraltar - Drugs (Misuse) Act 1973
Indonesia – law on narcotics (Law No. 22/1997), law on psychotropics (Law No. 5/1997)
European Union - Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances
European Union - REGULATION (EC) No 273/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2004 on drug precursors
European Union - COUNCIL REGULATION (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

Belgium - Royal Decree of 1930 on narcotic substances and Royal Decree of 1998 on psychotropic substances
Czech Republic - Law no. 167/1998, On Narcotic Drugs and Psychotropic Substances
Denmark - Executive Order 698 of 1993 on Euphoric Substances
Germany - Narcotics Act (BtMG)
Spain - Order of 8th July 1967 and the Royal Decree 2829/1977
Ireland - Misuse of Drugs Regulations 1988
France – Decree Law of 22 February 1990
Netherlands - Opium Act
Portugal - Decree-Law 15/93
Norway - Regulation of 1978
Poland - 1997 Act on Counteracting Drug Addiction
Greece - Law 3459/2006 (Codification of the Drug Legislation)
Estonia - Regulation No 39 of the Minister of Social Affairs of 4 November 1997
Austria - 'Narcotic Substances Act' (Suchtmittelgesetz, abbr. SMG)
Italy - Decree 4 March 1992
Sweden - Narcotic Drugs Punishments Act (1968:64).
Portugal - Decree Law 15/93, of 22 January 1993
Slovenia - Production and Trade in Illicit Drugs Act
Slovakia - Act No. 139/1998
Romania - Law no. 143/2000
Malta - Medical and Kindred Professions Ordinance (Cap. 31), Dangerous Drugs Ordinance (Cap. 101)
Luxembourg - Grand Ducal decrees, 4 March 1974, 20 March 1974, 26 March 1974, 8 May 1993 and 30 January 2004
Lithuania - Law on Narcotic and Psychotropic Substances Control (No.VIII-602; 1998)
Bulgaria - Drugs and Precursors Control Act 1999
Croatia - Law on Combating Narcotic Drugs Abuse 2001
Cyprus - Narcotic Drugs and Psychotropic Substances Law 1977
Finland - Narcotics Act (1289/1993)
Hungary - 1/1968. (V. 12., Government Decree No. 272/2001.(XII.21.), 4/1980. (VI. 24.)
Latvia - Law on Procedures for the Legal Trade of the Narcotic and Psychotropic Substances, Law on Precursors
Lithuania - Law on Narcotic and Psychotropic Substances Control (No.VIII-602; 1998)



Interpretation

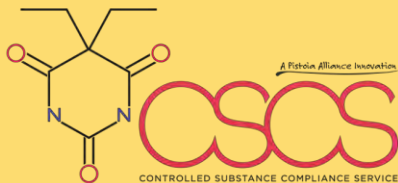
It is not always easy to know the right answer



Non-compliance is a Business Risk

You really, really don't want to get wrong

- DEA issues Two Year Suspension for Wholesale Distributor's Ability to Sell Controlled Substances.
- Large Logistics Carrier Pays \$40 Million Fine
- The wholesale drug distributor To Pay \$1 Million To Resolve Allegations of CSA Recordkeeping Violations by Subsidiary
- A pharmaceutical company Settles State's Opioid Claims, Avoids Trial; Settlement May Reach \$263 Million
- A pharmaceutical company settled with DOJ \$8 Billion Global Settlement
- A university agrees to pay \$308K to resolve allegations of violations of Controlled Substances Act
- Manufacturer Self-Discloses Listed Chemical Violations to DEA, Agrees to Pay \$25,000 Settlement
- Former Drug Distributor CEO Found Guilty of Conspiracy To Distribute Narcotics and To Defraud DEA



Controlled Substance Compliance Community

... what we do



CSC Community Activities

Regulation Monitoring, Enhancing Best Practice

Examples of last 2 years discussions and speaker program

The International
Narcotics Control
Board: Precursor
Controls

The Evolving
Landscape of
US Controlled
Substance
Regulation -
PhRMA

Defending
analogue cases
-James Felman

Chinese
Controlled
Substance
Legislation –
Millipore-
Sigma

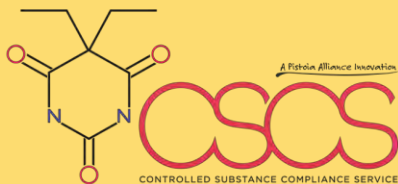
Suspicious
Order
Monitoring
- IQVIA

Regulatory
Inspections in
Italy, Ireland
and UK – The
Compliance
Group

International
Sample
Logistics
-Avantor

Inventory
Management
System –
Biovia

China to ban
all synthetic
cannabinoids



Examples of activities

..... communicating with regulators

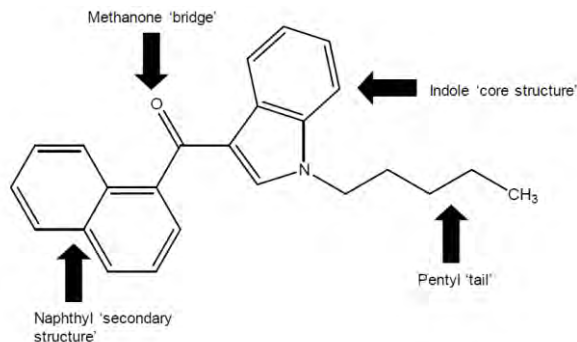
UK 3rd Generation Cannabinoids



2016 - The UK took a new approach to defining chemical space in UK

Not just a defined core + defined chemical attachments

Many possible cores + almost any type of attachments

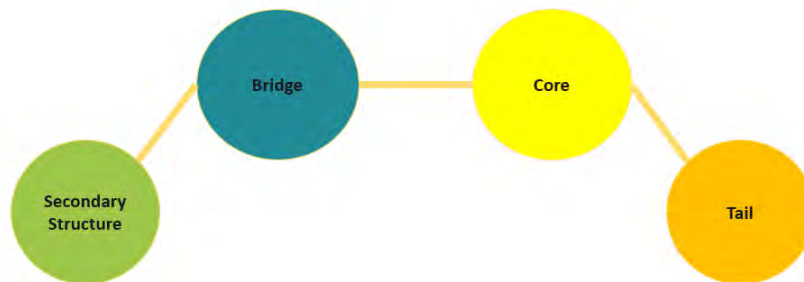


“any compound (not being **clonitazene, etonitazene, acetamin, atorvastatin, bazedoxifene, indometacin, losartan, olmesartan, proglumetacin, telmisartan, viminol, zafirlukast** or a compound for the time being specified in sub-paragraph (c) above) structurally related to 1-pentyl-3-(1-naphthoyl)indole (JWH-018), in that the four substructures, that is to say the indole ring, the pentyl substituent, the methanone linking group and the naphthyl ring, are linked together in a similar manner, whether or not any of the sub-structures have been modified, **and whether or not substituted in any of the linked sub-structures with one or more univalent substituents** and, where any of the sub-structures have been modified, the modifications of the sub-structures are limited to any of the following, that is to say—

(i) replacement of the indole ring with **indane, indene, indazole, pyrrole, pyrazole, imidazole, benzimidazole, pyrrolo[2,3-b]pyridine, pyrrolo[3,2-c]pyridine or pyrazolo[3,4-b]pyridine;**

(ii) replacement of the pentyl substituent with **alkyl**, alkenyl, benzyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl, 2-(4-morpholinyl)ethyl or (tetrahydropyran-4-yl)methyl;

(iii) replacement of the methanone linking group with an ethanone, carboxamide, carboxylate, methylene bridge or methine group;



- Unfortunately, this led to a large amounts of chemical space inadvertently becoming controlled
- Including significant numbers of chemicals in DD screening collections
- Plus clinical trial candidates with no cannabinoid activity (including cancer drugs)
- When advised of this the UK regulators response was that the law clearly says these are controlled, so they are!
- Regulators had no power to change this, only licence certain activities (only parliament can change laws)

The CSCS working group analysed and fed back possible new wording...

...which was subsequently accepted and enacted in law

Old

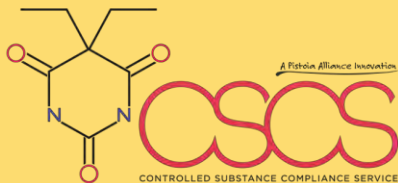
'and whether or not substituted in any of the linked sub-structures with one or more univalent substituents'

New

'and whether or not substituted in any of the linked sub-structures with a benzyl or phenyl group and whether or not such compound is further substituted to any extent with alkyl, alkenyl, alkoxy, halide, haloalkyl or cyano substituents'

*https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/670663/AC_MD_Letter_-_Legitimate_use_of_controlled_drugs_research_and_healthcare_22_Dec_17.pdf

- Within R&D chemical collections, this typically reduced the chemical space controlled as Cannabinoids by around 90%.
- Also meant several clinical candidates (including cancer drugs) unintentionally caught by the original wording (and required licences!) were no longer considered controlled
- Chemical space covered now much more focussed on likely cannabinoid activity
- Increased awareness amongst UK regulators as to the potential impact on R&D of Controlled Drug regulations and Pistoia's role
- But.... took over 2.5 years (partly due to Brexit). Better to engage early and before the regulations come out.



Examples of activities

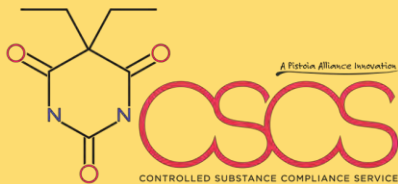
... communicating with regulators

Research Exemptions and de-minimus limits in the UK



Leading on from the 3rd Generation cannabinoids lessons learned

- UK government commissioned a report on possible research exemptions and reduced licencing requirements in research "Consideration of barriers to Research, part 1"
- The Pistoia CSCS group and our member companies, plus the ABPI and others worked together to submit evidence and opinions from across industry and academia
- We're not going to get a general research exemption, but maybe reduced requirements for smaller volumes or simpler licencing
- UK Advisory Council for the Misuse of Drugs has now published its report, which is now under consideration by the UK government
- https://www.gov.uk/government/publications/consideration-of-barriers-to-research-part-1?utm_medium=email&utm_campaign=govuk-notifications&utm_source=74727d67-1331-4361-944b-eeb9dfc87836&utm_content=daily
- Initially focussed on synthetic cannabinoids, but the hope is it could be a blue-print for all controlled drugs in future in the UK



Examples of activities

... communicating with regulators

U.S. Government Accountability Office (GAO) report into Fentanyl Class wide controls



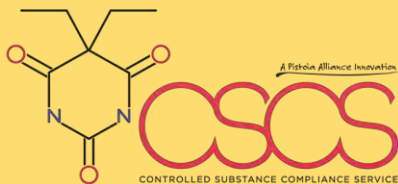
The GAO report specially highlighted and used the Pistoia CSCS groups evidence on the use of class wide controls (e.g controlling areas of chemical space)

"We selected 11 organizations that represent a range of perspectives in the research community, including those representing professional associations, research institutions, and the pharmaceutical industry, as well as researchers. The organizations were:

- Professional associations and associated researchers: American Society of Addiction Medicine, The College of Problems on Drug Dependence, and the American Society of Pharmacology and Experimental Therapeutics
- Research institutions and associated researchers: NMS Labs, RAND, University of California San Francisco, and Scripps Foundation

- Pharmaceutical industry research organizations: **Pistoia Alliance** and PhRMA
- Research-related interest groups: Friends of NIDA and Council on Government Relations





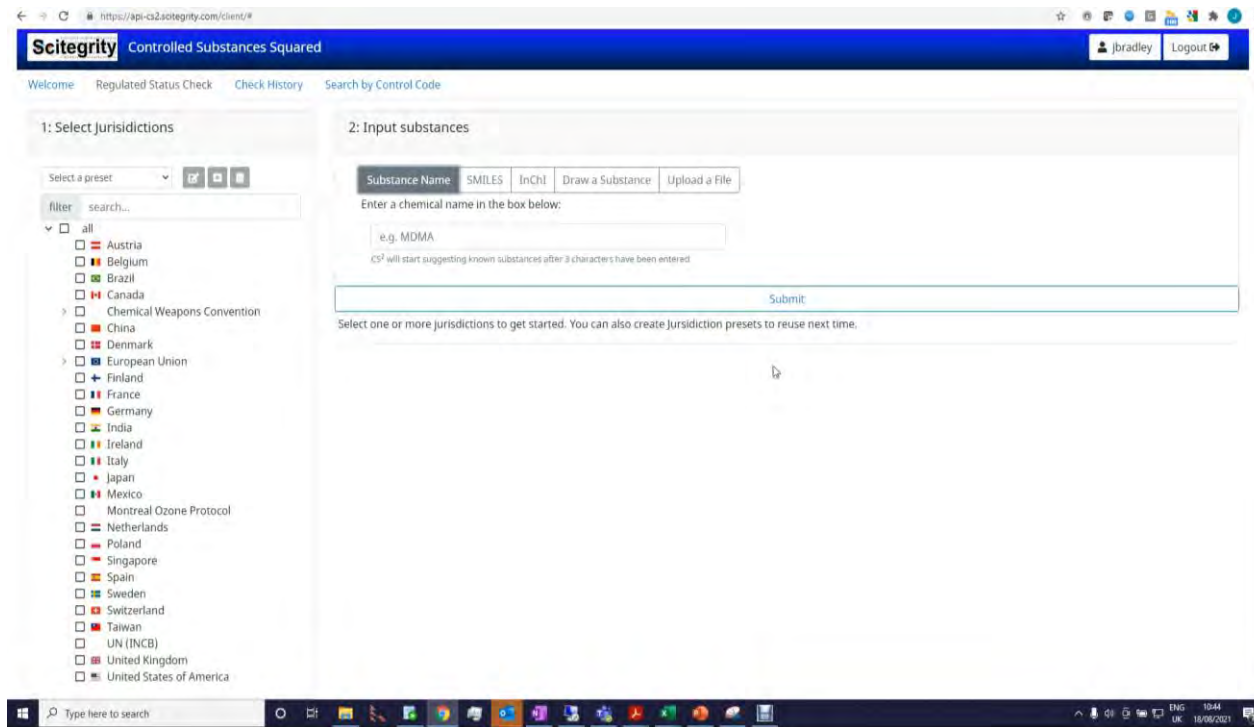
CSCS commercial tools

2 commercially available tools developed
Controlled Substances Squared (Scitegrity)
Compliance Checker (ChemAxon)



Controlled Substances Squared

Part of Compliance Hub for Drug Discovery



The screenshot shows the Scitegrity Controlled Substances Squared web application. The interface is divided into two main sections: "1: Select jurisdictions" and "2: Input substances".

1: Select jurisdictions

Under "1: Select jurisdictions", there is a "Select a preset" dropdown menu and a "filter search..." input field. Below these is a list of jurisdictions with checkboxes:

- ☐ all
- ☐ Austria
- ☐ Belgium
- ☐ Brazil
- ☐ Canada
- ☐ Chemical Weapons Convention
- ☐ China
- ☐ Denmark
- ☐ European Union
- ☐ Finland
- ☐ France
- ☐ Germany
- ☐ India
- ☐ Ireland
- ☐ Italy
- ☐ Japan
- ☐ Mexico
- ☐ Montreal Ozone Protocol
- ☐ Netherlands
- ☐ Poland
- ☐ Singapore
- ☐ Spain
- ☐ Sweden
- ☐ Switzerland
- ☐ Taiwan
- ☐ UN (INCB)
- ☐ United Kingdom
- ☐ United States of America

2: Input substances

Under "2: Input substances", there are tabs for "Substance Name", "SMILES", "InChI", "Draw a Substance", and "Upload a File". The "Substance Name" tab is active, showing a text input field with the placeholder "e.g. MDMA" and a note: "(S) will start suggesting known substances after 3 characters have been entered". Below the input field is a "Submit" button. At the bottom of this section, it says: "Select one or more jurisdictions to get started. You can also create jurisdiction presets to reuse next time."

Controlled Substances Squared

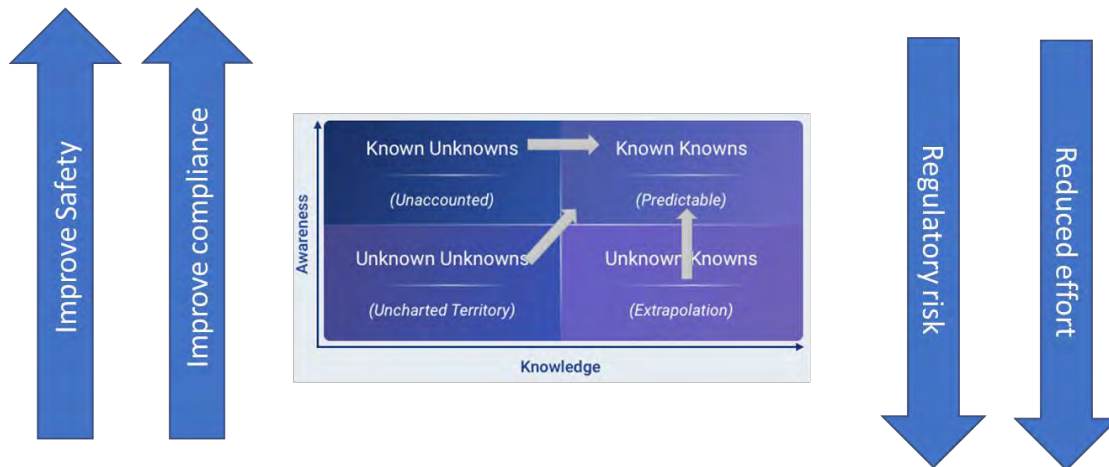
Part of Compliance Hub for Drug Discovery

- Covers over 32 jurisdictions / country's globally
- Not just Controlled Drugs, other research relevant regulations such as strategic export controlled, PIC Rotterdam, CWC (with Dangerous Goods coming soon)
- APIs - Automatically check all chemicals you have at the Enterprise level
- Detailed legislation guidance. Not just if, but also how, why, what to do next..
- Search using your own internal chemical IDs
- Place your own controls or context sensitive overrides
- Track the controlled status of all your chemicals over time
- Weekly legislation checks and updates
- E-mail support and advice on 'hits'

Controlled Substances Squared

Part of Compliance Hub for Drug Discovery

“A good compliance solution doesn’t require people to look and check, it should be automatic and provide alerts with relevant information”



Use Compliance Hubs APIs so your scientists know if chemicals are regulated or dangerous
A good implementation is where people don’t even know Compliance Hub exists

Compliance Checker

Compliance Checker

INPUT



Any text

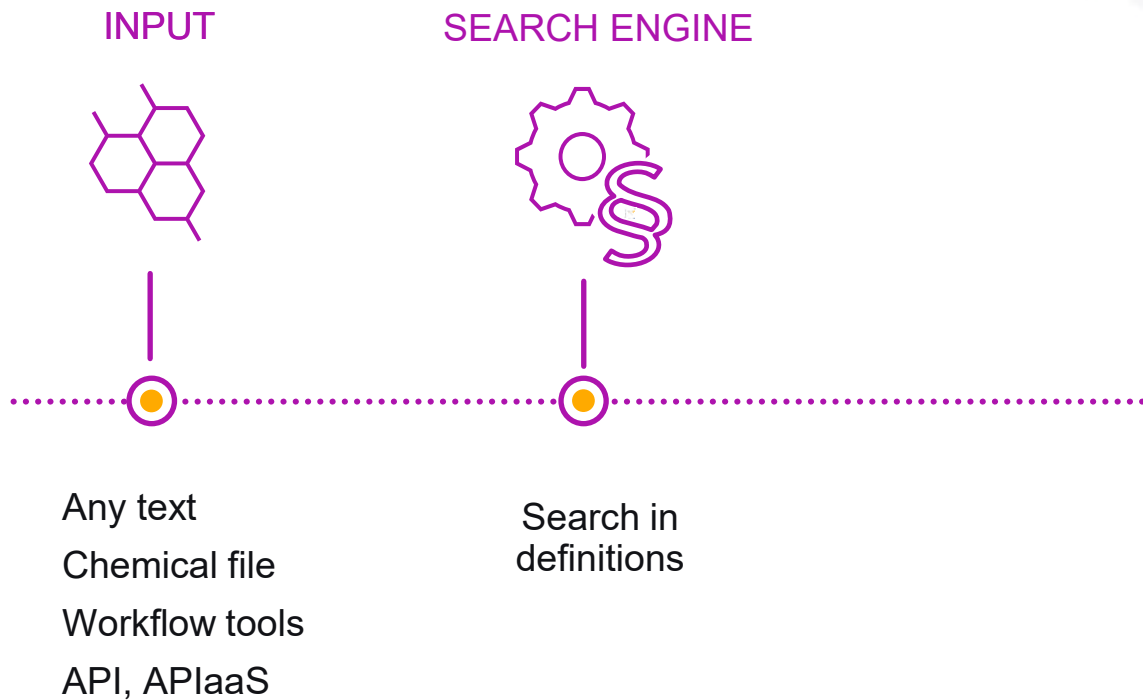
Chemical file

Workflow tools

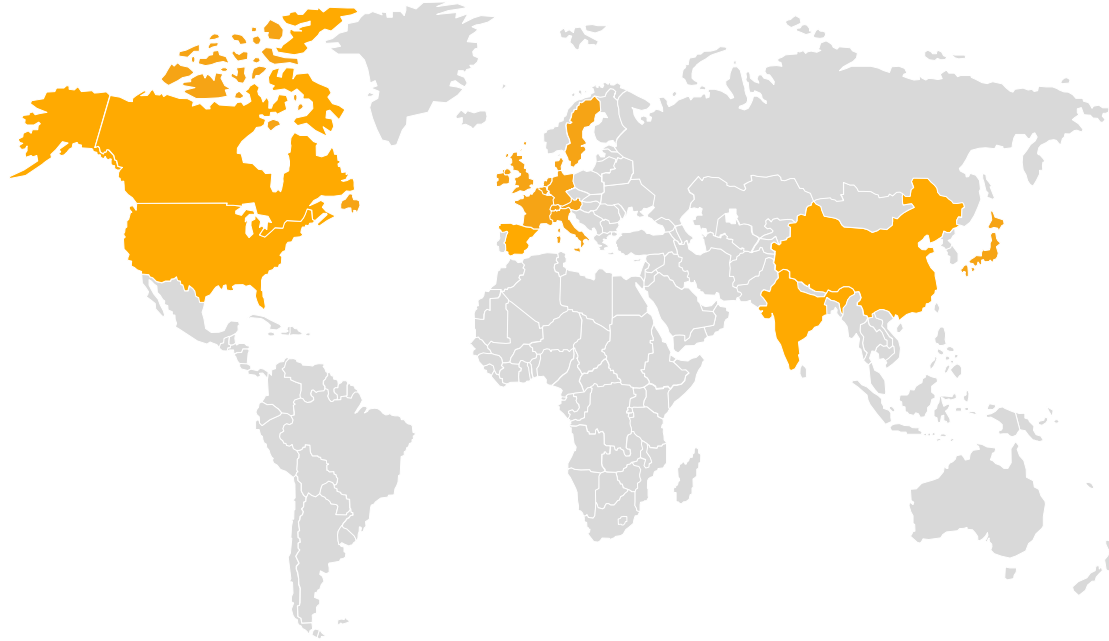
API, APIaaS



Compliance Checker



Countries



	Austria
	Belgium
	Canada
	China
	Denmark
	France
	Germany
	India
	Ireland
	Italy
	Japan
	Netherlands
	Singapore
	Spain
	Sweden
	Switzerland
	United Kingdom
	United States of America



EU



Rotterdam
Convention



Montreal
Protocol



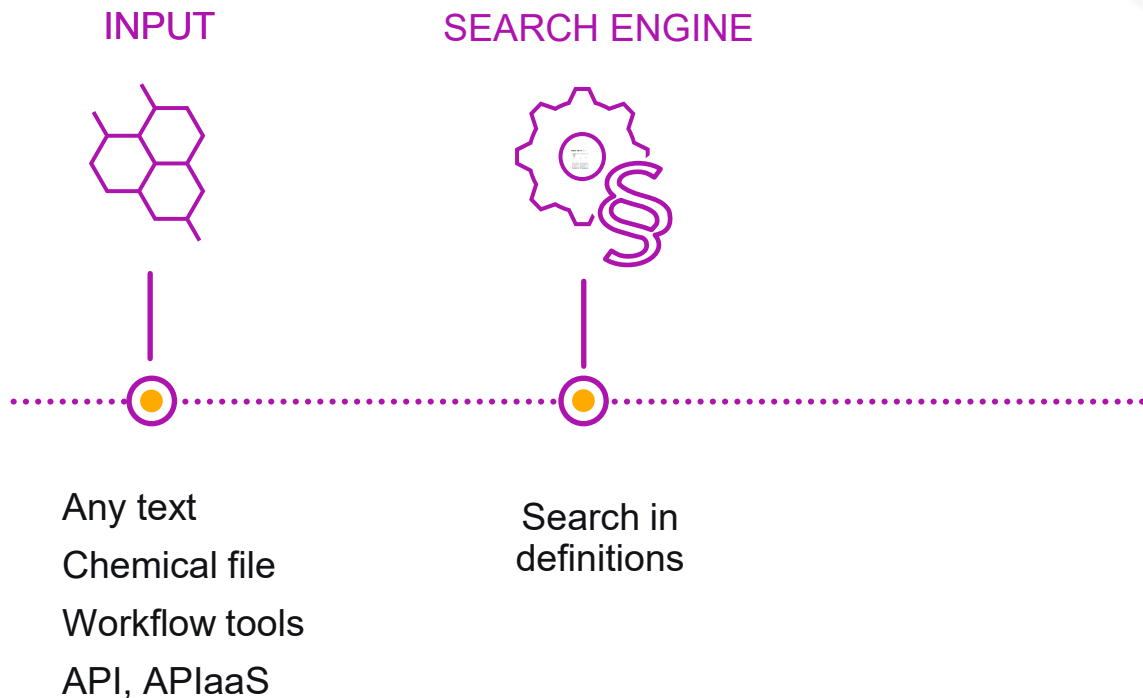
OPCW

Convention on the
Use of Chemical Weapons



UN

Compliance Checker



Search engine - JChem Engine by Chemaxon

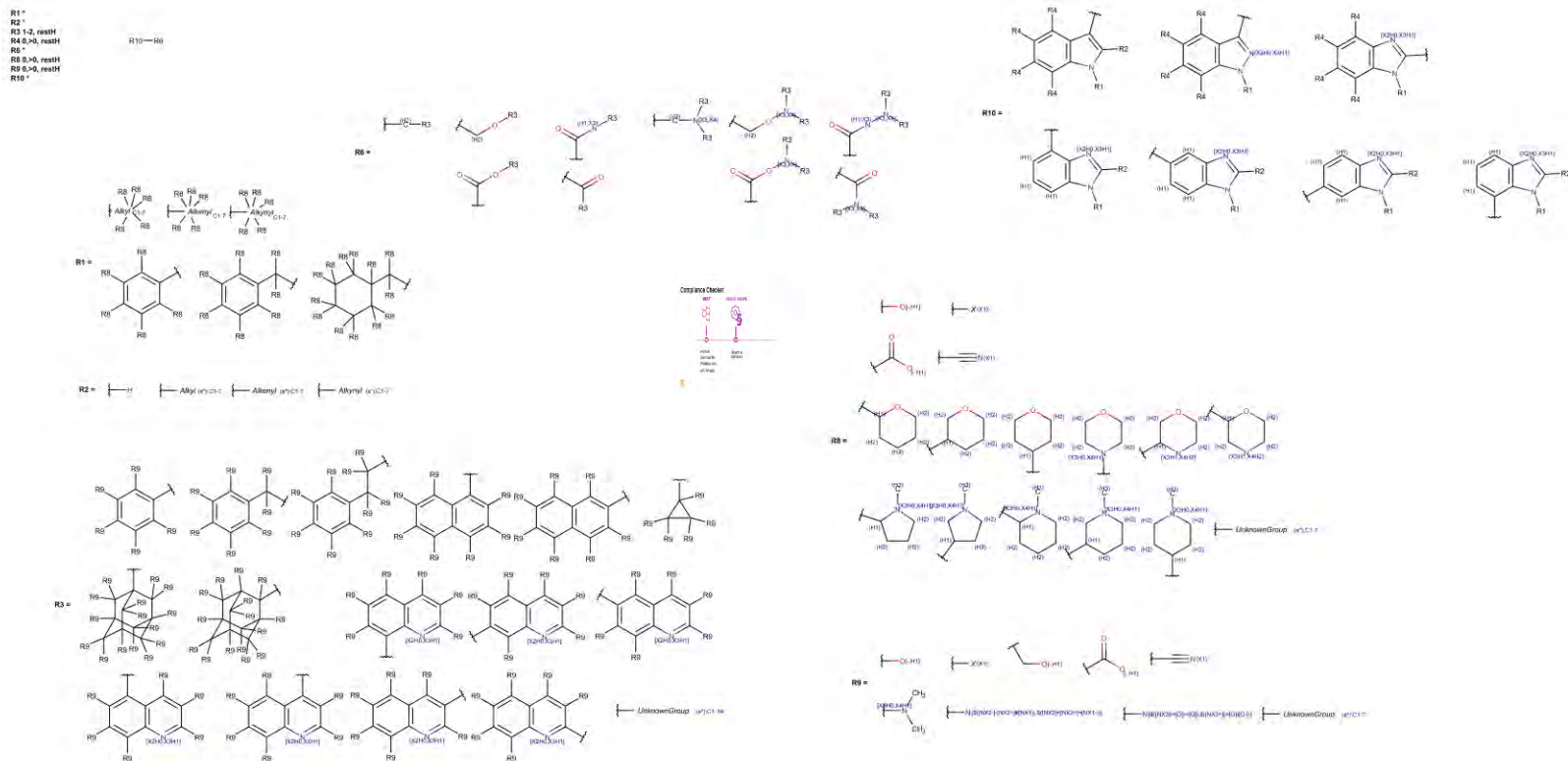
generic group definitions

4. SYNTHETISCHE CANNABINOÏDEN: stoffen die derivaten zijn van	4. CANNABINOÏDES SYNTHÉTIQUES : substances qui sont dérivées de :
<ul style="list-style-type: none"> - indoles (Fig. 4a en 4d) - indazoles (Fig. 4b en 4e) - benzodiazoles (Fig. 4c, 4f, 4g en 4h) - pyrroles (Fig. 4i) <div data-bbox="197 464 444 638"> </div> <p data-bbox="197 644 270 671">Fig. 4a</p>	<div data-bbox="782 453 1004 627"> </div> <p data-bbox="782 644 859 671">Fig. 4b</p> <div data-bbox="1226 469 1487 595"> </div> <p data-bbox="1226 644 1304 671">Fig. 4c</p>
<p>X = -CH₂-, -C(=O)-, -CH₂O-, -C(=O)O- of -C(=O)NH-;</p>	<p>X = -CH₂-, -C(=O)-, -CH₂O-, -C(=O)O- ou -C(=O)NH-;</p>
<p>R₁: C_nH_{2n+1}, C_nH_{2n-1}, C_nH_{2n-3} (n=1-7), phenyl, benzyl, cyclohexylmethyl; al dan niet verder gesubstitueerd met een of meerdere van volgende functionele groepen of een combinatie hiervan: OH, C(=O)OH, halogeen, CN, tetrahydropyranyl, morfolinil, N-methylpyrrolidinyl, N-methylpiperidinyl of een andere functionele groep met maximaal 7 C-atomen.</p> <p>R₂: H, C_nH_{2n+1}, C_nH_{2n-1}, C_nH_{2n-3} (n=1-7)</p> <p>R₃: phenyl, benzyl, phenylethyl, naphthalenyl, adamantanyl, quinolinyl, tetracyclopropyl, of een functionele groep met maximaal 7 koolstofatomen; al dan niet verder gesubstitueerd met een of meerdere van volgende functionele groepen of een combinatie hiervan: halogeen, OH, CH₂OH, C(O)OH, azide, dimethylamino, CN,</p>	<p>R₁: C_nH_{2n+1}, C_nH_{2n-1}, C_nH_{2n-3} (n=1-7), phényl, benzyl, cyclohexylméthyl ; ce groupe peut être substitué oui ou non avec un ou plusieurs, ou une combinaison, des groupes fonctionnels suivants : OH, C(=O)OH, halogène, CN, tetrahydropyranyl, morpholinyl, N-méthylpyrrolidinyl, N-méthylpipéridinyl, ou un autre groupe fonctionnel contenant au maximum 7 atomes de carbone.</p> <p>R₂: H, C_nH_{2n+1}, C_nH_{2n-1}, C_nH_{2n-3} (n=1-7)</p> <p>R₃: phényl, benzyl, phénylethyl, naphthalenyl, adamantanyl, quinolinyl, tetracyclopropyl, ou un groupe fonctionnel contenant au maximum 7 atomes de carbone; ce groupe peut être substitué oui ou non avec un ou plusieurs, ou une combinaison, des groupes fonctionnels suivants : OH, halogène, CH₂OH, C(O)OH, azide, diméthylamino, CN, NO₂ ou un autre</p>

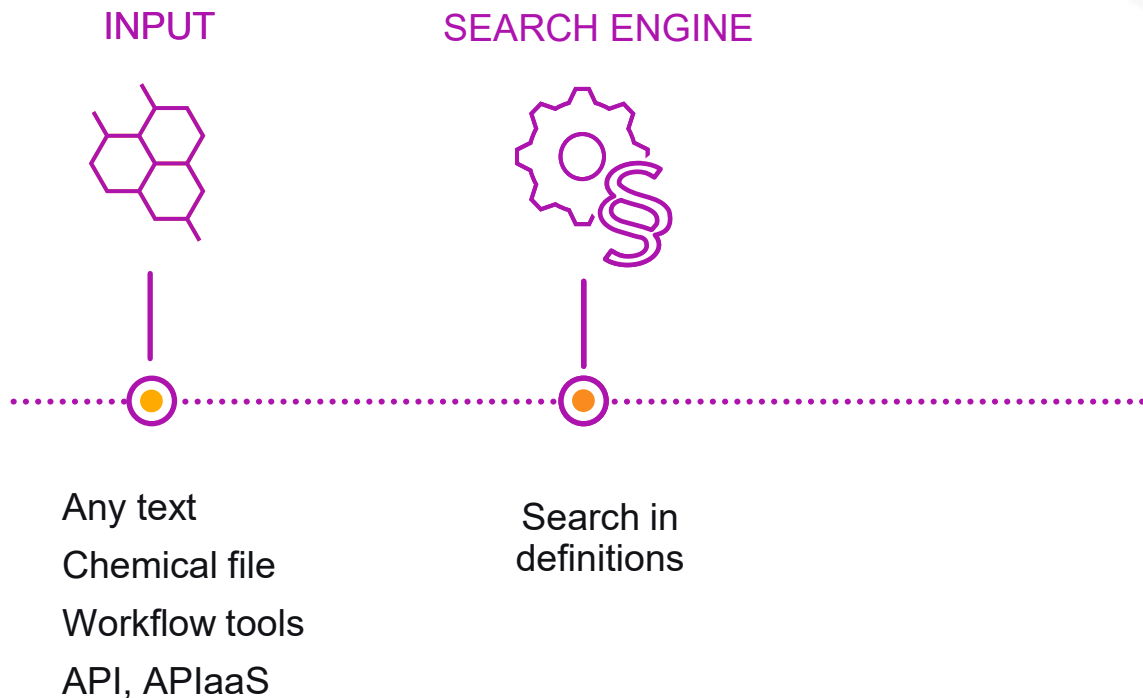


Search engine - JChem Engine by Chemaxon

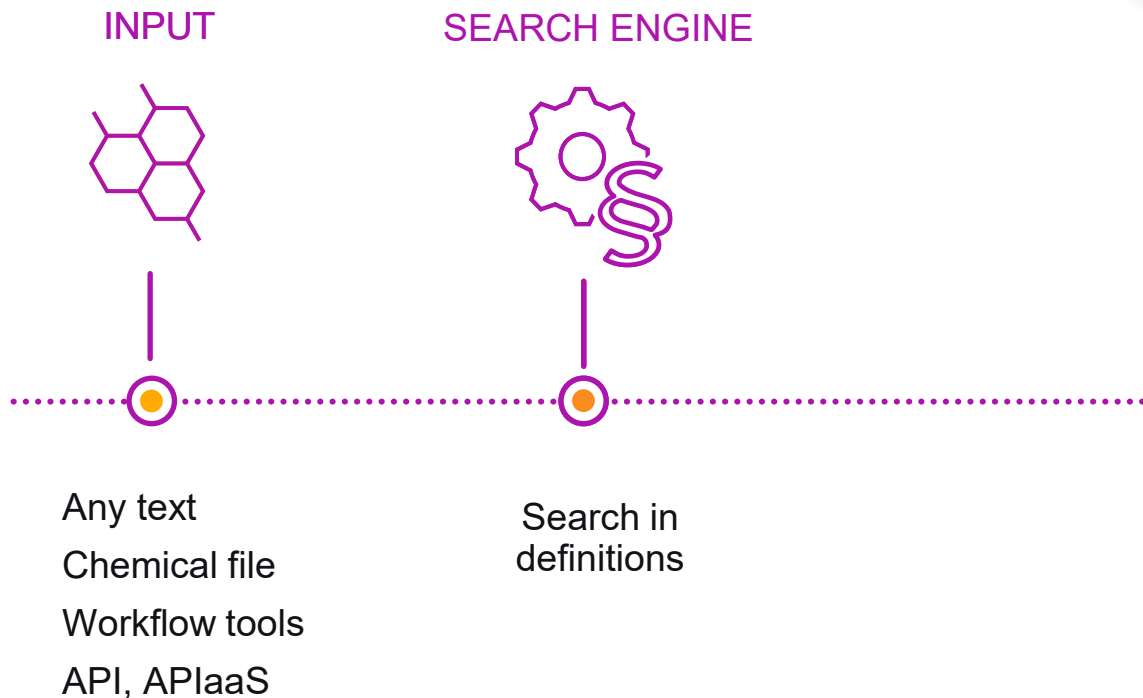
Markush structures



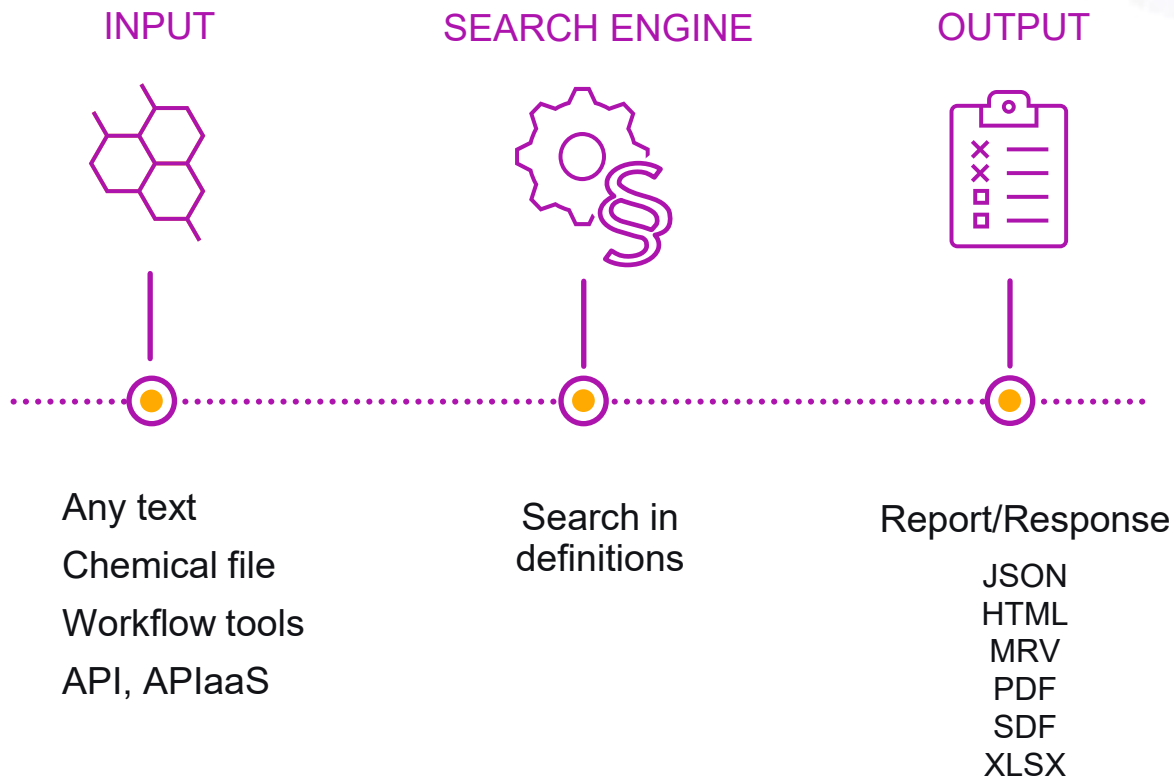
Compliance Checker



Compliance Checker



Compliance Checker



API integration



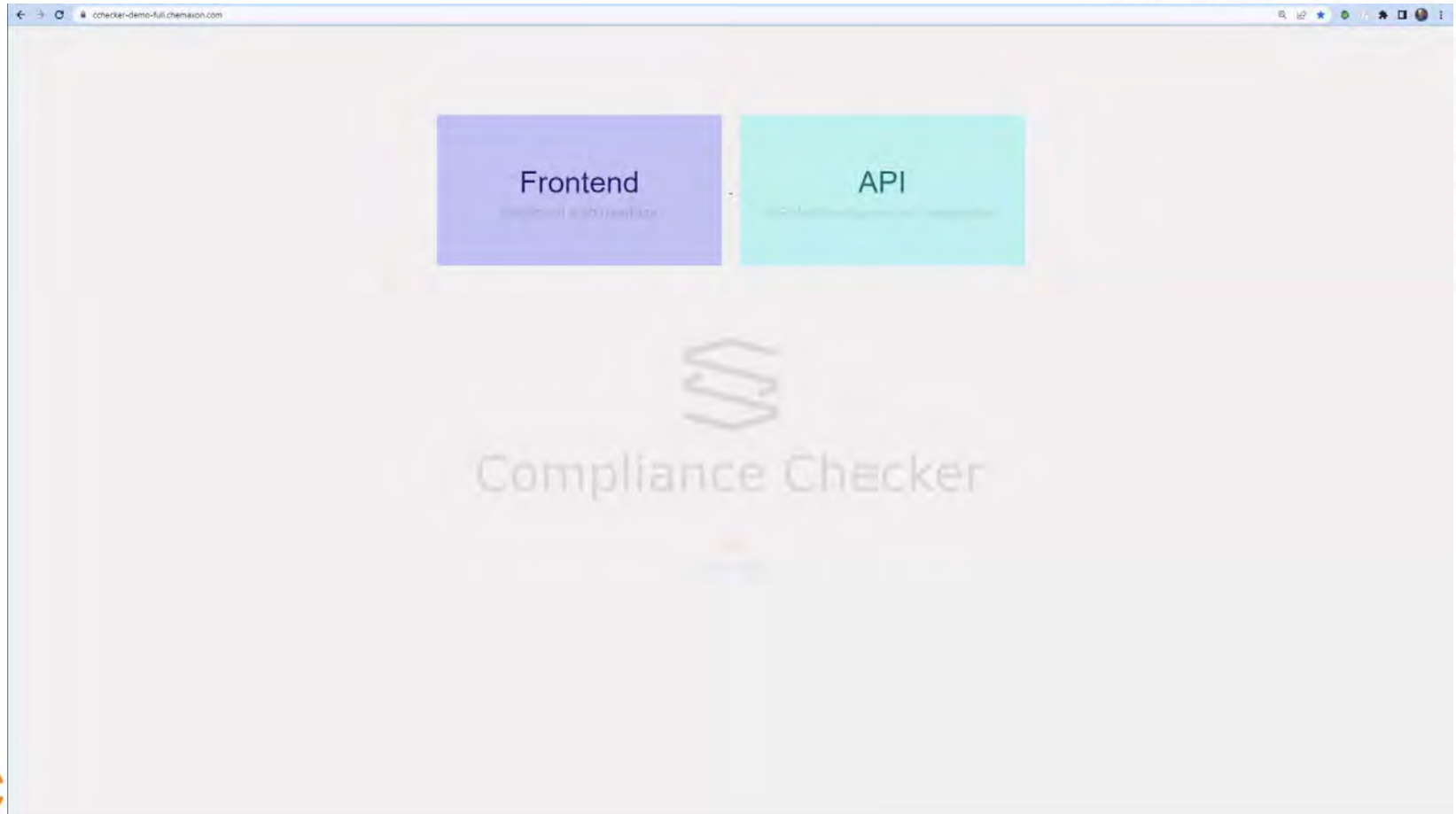
Compound
Database

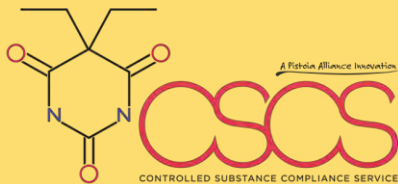


Computation
AWS



Compliance Checker








Shipping Expert Community



What's the Mutual Goal?

Materials arrive in a timely manner & same condition as when the shipment left site

Barriers to the GOAL:

- Temperature restrictions 
- Compliance aspects – Customs, FDA, HMRC, USDA, Fish and Wildlife, DEFRA, CDC
- Time to prepare the shipment 
- Time to transport the shipment
- Routing – Should/Must use preferred LSP
- Mistakes - Requestor, Shipper, Carrier 

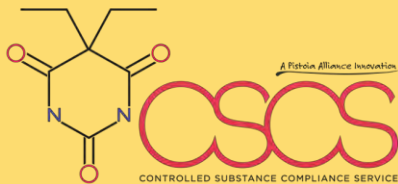


How do we reduce those Barriers?

Goal: Materials arrive in a timely manner and in the same condition as when the shipment left the site of departure

Reducing Barriers:

- Awareness to the Process
- Awareness to the People who Contribute to the Process
- Awareness to the Compliance Elements Critical to the Process



Compliance with regulators



Compliance Elements

What information is needed

All shipments have to be in compliance with local and international regulations. While these can vary there are typically 8 items that need to be considered.

- HS Code
- INCO Terms
- Valuation
- Permits and Licences
- Country of Origin
- Denied Party Screening
- Dangerous Goods
- Material Description (a catch all element)

HS code

- The Harmonized System (HS) of tariff nomenclature is a code that is internationally harmonized and describes the imported item to Customs.
- The HS code's first six digits are harmonized globally (with a few exceptions!)
- The HS code determines the amount of duty and tax that is to be charged on the import, it is also the trigger for other government agency's regulations, for example the FDA. It is also used for statistical purposes.
- The HS code should also be included on a shipping invoice.
- The HS code is also known as the HTS code, Commodity code and Tariff code
- HS codes are primarily used for imports, some countries also have export codes that may or may not be the same number as the HS code. In the USA this is known as the Schedule B number. The first 6 digits of the code are the same as the import code.

VI 29-6 Heading/ Subheading	Stat. Suf- fix	Article Description	Unit of Quantity	Rates of Duty		
				General	Special	2
2903 (con.)		Halogenated derivatives of hydrocarbons (con.): Saturated chlorinated derivatives of acyclic hydrocarbons (con.): Other:				
2903.19		1,2-Dichloropropane (Propylene dichloride)				
2903.19.05	00	and dichlorobutanes.	kg.	5.1%	Free (A,AU,BH, CA,CL,CO,E, IL,JO, KR,MA, MX,OM,P, PA,PE,SG)	33.3%
2903.19.10	00	Hexachloroethane and tetrachloroethane.....	kg.	3.7%	Free (A,AU,BH, CA,CL,CO,E, IL,JO, KR,MA, MX,OM,P, PA,PE,SG)	25%
2903.19.30	00	sec-Butyl chloride.	kg.	Free		114.5%
2903.19.60		Other.....		5.5%	Free (A,AU,BH, CA,CL,CO,E, IL,JO, KR,MA, MX,OM,P, PA,PE,SG)	114.5%

Valuation

- The accurate value of the goods must be listed on the shipping invoice
- Nominal values and zero values are NOT acceptable
- This is required globally by Customs
- False information is subject to fines and penalties.
 - Requestor can also be subject to fines and penalties in addition to your company
- For R&D material that is produced by your company the value should be determined by using an approved method.
- For material that is bought in then a purchase order value or market value should be used

Permits and Licenses

- Some shipments will require a permit or license
- The need for a permit is determined by the type of material that is being shipped and the country of export and/or import
- Items most likely to need a permit are animal material of livestock or endangered animal origin, controlled substances, certain equipment and chemicals that may require an export license and other items based on local government regulations
- The shipper preparing the material for shipment may determine any permit requirements and should work with a Compliance Manager to provide the permit or submit the application
- Some of the regulatory bodies that may require permits or licenses are;
 - United States Department of Agriculture (USDA)
 - Centers for Disease Control (CDC)
 - Convention on International Trade in Endangered Species (CITES)
 - Department for Environment, Food and Rural Affairs (DEFRA)
 - China Inspection and Quarantine Services (CIQ)

Species Regulated by USDA*

*(U.S. Department of Agriculture)

Materials derived from animals below will require a USDA permit

- Bovine (cattle)
- Ovine (sheep)
- Caprine (goats)
- Cervid (deer)
- Porcine (pigs)
- Equine (horses)
- Avian (birds)
- Aquatic farmed species (fish, shell fish)
- Pathogens that could impact poultry/livestock and would thus be a concern with regard to USDA:

https://www.aphis.usda.gov/animal_health/downloads/organisms_and_vectors/vsregulatedlivestockpoultrypathogens_partial%20list.pdf



Species Not Regulated by USDA*

*(U.S. Department of Agriculture)

Species not regulated under permit must travel with a USDA guideline statement that is completed on foreign shipper letterhead

- Dogs and cats
- Primates
- Marine mammals (except oils & meals)
- Wild animals other than ungulates and swine (i.e., bears, badgers, racoons)
- Rodents
- Amphibians and reptiles

Country of Origin

- Country of origin is the origin of the manufacture or growth of the materials being shipped which is determined based on the rules of the importing country.
- This is **not always** the country of export.
- This information is used to determine tariff rates, establish marking/labeling requirements, enforce quotas and compile trade statistics.
- Country of Origin is mandatory for all cross-border shipments and should be included on import and export documentation

Restricted Party Screening / Sanctions and Export Controls

- Export and Sanction controls covers all the export controls that may apply
- This can be a screening of the product for dual use or the need for an export license and also a screening of the individual or company the material is being received by
- The screening is conducted against a global lists of parties or individuals for which international trade is restricted for various reasons including being associated with terrorists or terrorist-supporting organizations, individuals and entities tied to international drug trafficking or proliferation of weapons of mass destruction; embargoed countries and nationals and their entities; individuals and businesses on country-specific lists and international organizations.
- The screening should be during initial contract set up with 3rd parties such as vendors or CROs, etc.

Dangerous Goods

- Many items shipped or received can be considered Dangerous Goods, the transport of dangerous goods is regulated by local and international regulations
- There is specific training that needs to be taken before a person can offer material that is a dangerous good for transportation
- Items must be packed, labeled and declared to the carrier according to the regulations
- Some common items could be considered a dangerous good for transport, such as lithium-ion batteries, aerosols, perfume etc.
- The classification of a dangerous good is located on Section 14 of the SDS

14. Transport Information

General	DOT Regulated Marine Pollutant. IMDG Regulated Marine Pollutant.
DOT	
Basic shipping requirements:	
UN number	UN3249
Proper shipping name	Medicine, solid, toxic, n.o.s. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE)), MARINE POLLUTANT
Hazard class	6.1
Packing group	III
Environmental hazards	
Marine pollutant	Yes
Additional information:	
Special provisions	T3, TP33
Packaging exceptions	153
Packaging non bulk	213
Packaging bulk	240
IATA	
UN number	UN3249

Dangerous Goods Incident 09Oct17



Shipping Activities

Regulators

Horizon scanning, encourage input to public consultations



Monitoring progress of bills such as SITSA

Challenges with Harmonized System Classifications

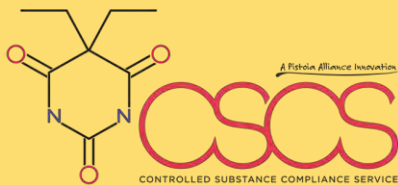
Shipping and logistics, Scitegrity



Monitoring legislative changes e.g. Belgium, Singapore



US Section 301

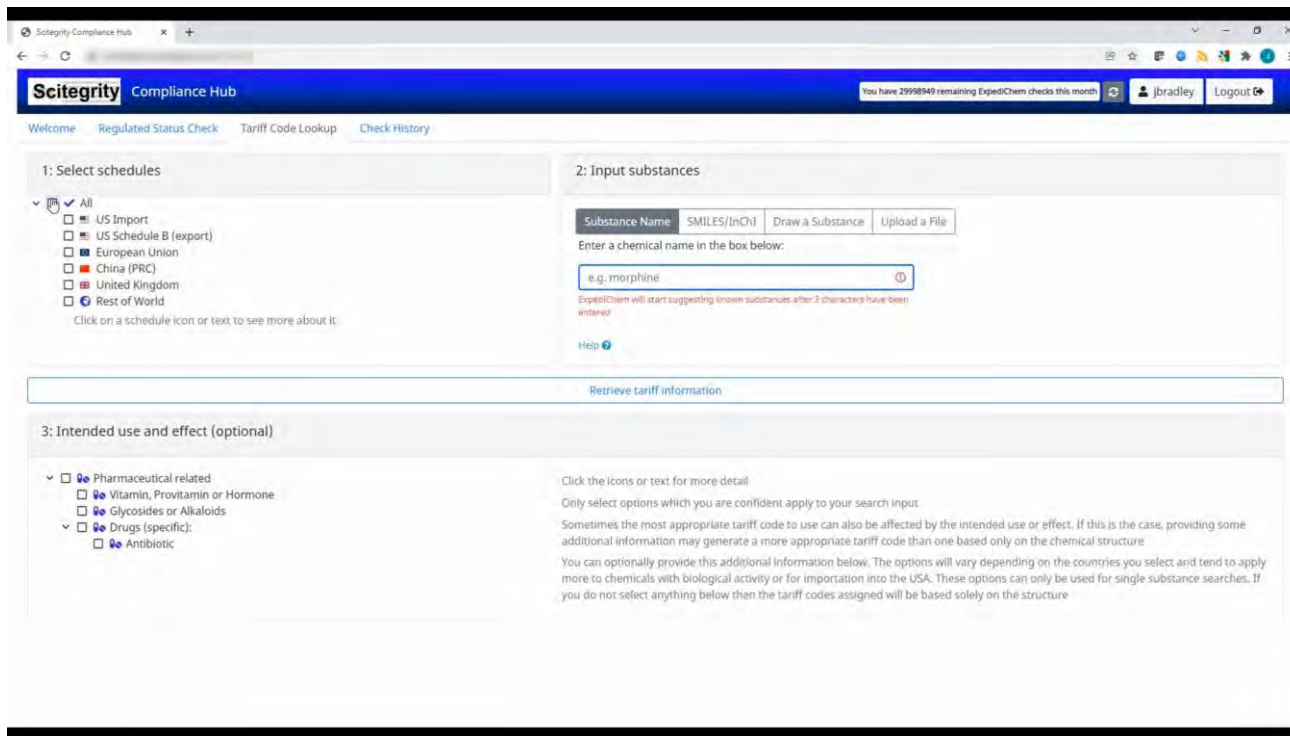


CSCS commercial tools



ExpediChem

Part of
Compliance Hub for Drug Discovery



Scitegrity Compliance Hub You have 2998949 remaining ExpediChem checks this month jbradley Logout

[Welcome](#) [Regulated Status Check](#) [Tariff Code Lookup](#) [Check History](#)

1: Select schedules

- ☒ All
 - ☐ US Import
 - ☐ US Schedule B (export)
 - ☐ European Union
 - ☐ China (PRC)
 - ☐ United Kingdom
 - ☐ Rest of World

Click on a schedule icon or text to see more about it.

2: Input substances

Substance Name

SMILES/InChI

Draw a Substance

Upload a File

Enter a chemical name in the box below:

ExpediChem will start suggesting known substances after 3 characters have been entered

[Help](#)

[Retrieve tariff information](#)

3: Intended use and effect (optional)

☒ Pharmaceutical related

- ☐ Vitamin, Provitamin or Hormone
- ☐ Glycosides or Alkaloids

☒ Drugs (specific):

- ☐ Antibiotic

Click the icons or text for more detail

Only select options which you are confident apply to your search input

Sometimes the most appropriate tariff code to use can also be affected by the intended use or effect. If this is the case, providing some additional information may generate a more appropriate tariff code than one based only on the chemical structure

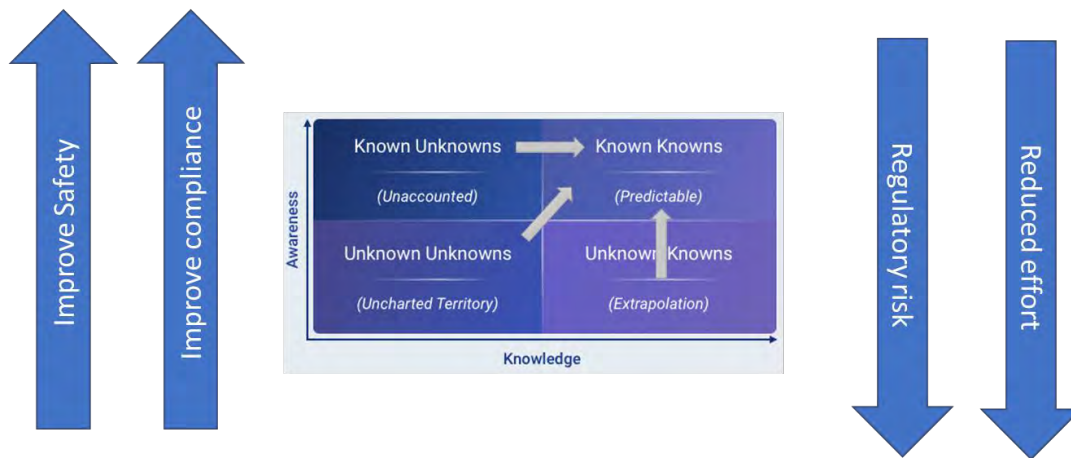
You can optionally provide this additional information below. The options will vary depending on the countries you select and tend to apply more to chemicals with biological activity or for importation into the USA. These options can only be used for single substance searches. If you do not select anything below then the tariff codes assigned will be based solely on the structure

- Covers UK, USA (incl schedule B), China, EU and Switzerland
- Chapters 28 & 29 (Inorganic & Organics chemicals) typically to the full 10-digit level
- Eliminate Tariff - Pharmaceutical and Chemical appendices covered
- APIs - Automatically code all chemicals you have at the enterprise level
- Search using your own internal chemical IDs
- Place your own context sensitive overrides
- Search by effect e.g “antibiotic” or “hormone”
- Provide optional use and biologic effect activity information for consideration (Drugs, Odiferous compounds, medicinal use etc)

ExpediChem

Part of
Compliance Hub for Drug Discovery

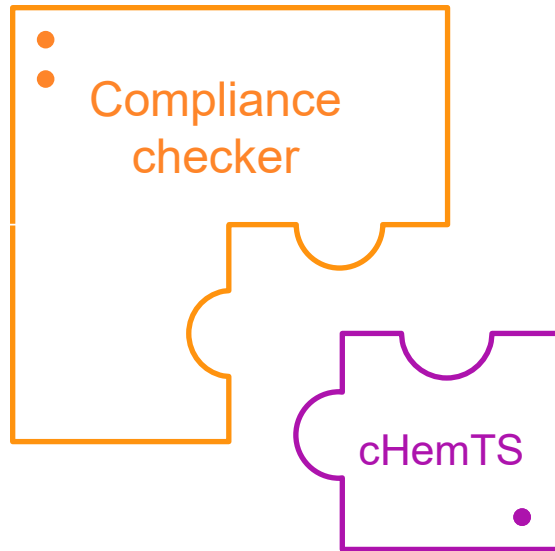
“A good compliance solution doesn’t require people to look and check, it should be automatic and provide alerts with relevant information”



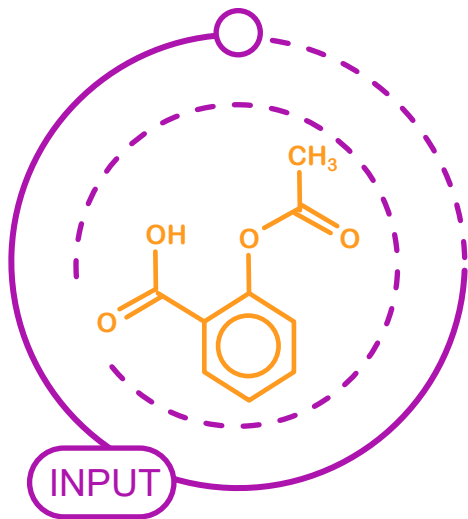
Use Compliance Hubs APIs so correct HS/commodity codes are incorporated into your workflows without your scientists even needing to know what one is

cHemTS

cHemTS is modular with Compliance Checker



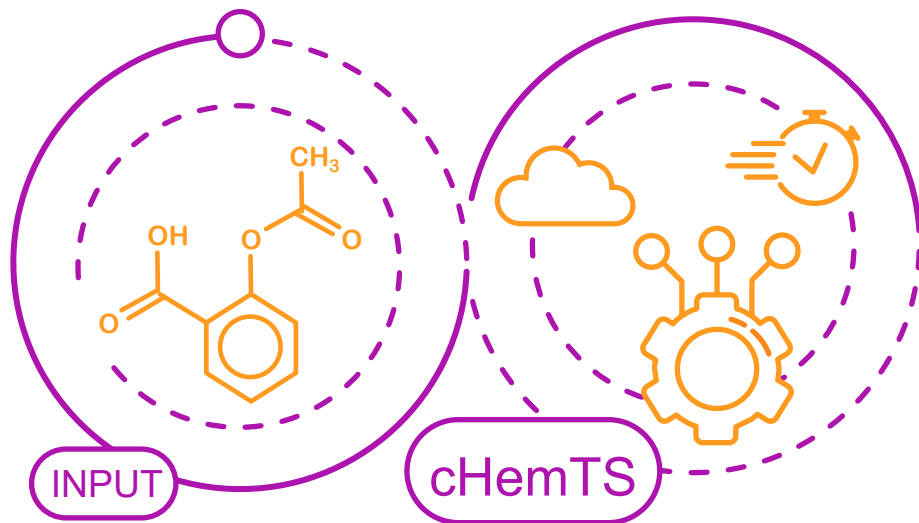
cHemTS



any chemical format
(SMILES, names, CAS#...)



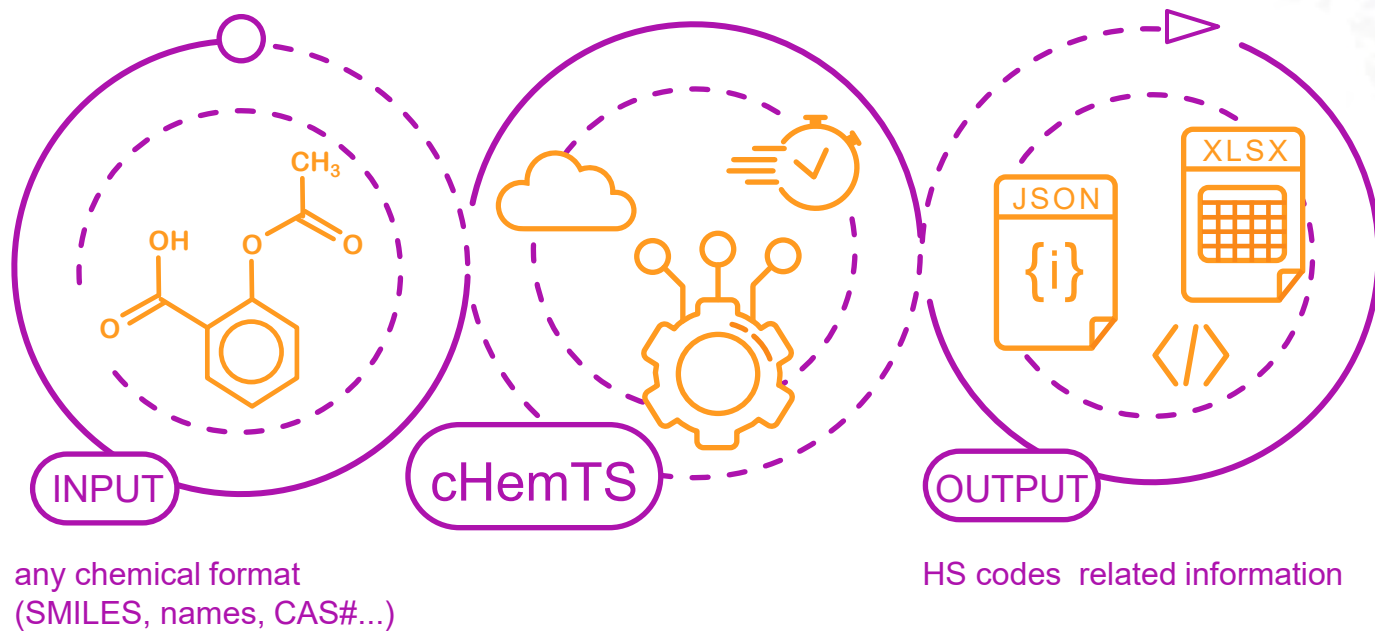
cHemTS



any chemical format
(SMILES, names, CAS#...)



cHemTS



cHemTS – Countries covered



China



European Union



India



Japan



Switzerland



United Kingdom



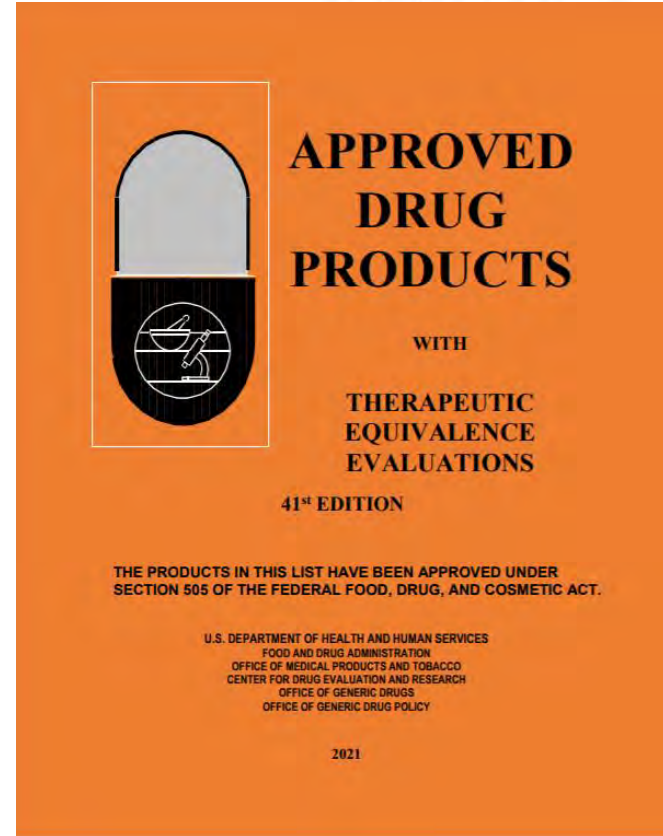
United States
including Schedule B



Drugs in the USA

Currently Identified by lookup in
FDA Orange Book and Green Book

Compendium of approved
human and animal drug products
and therapeutic equivalents



WTO Pharma Agreement



WORLD TRADE
ORGANIZATION

As a result of the 1994 Agreement and the subsequent reviews,
participating members committed to

eliminate customs duties and all other duties and charges
not only on all finished pharmaceutical products,
but also on over 7,000 pharmaceutical active ingredients
and chemical components used in pharmaceutical supply chains.



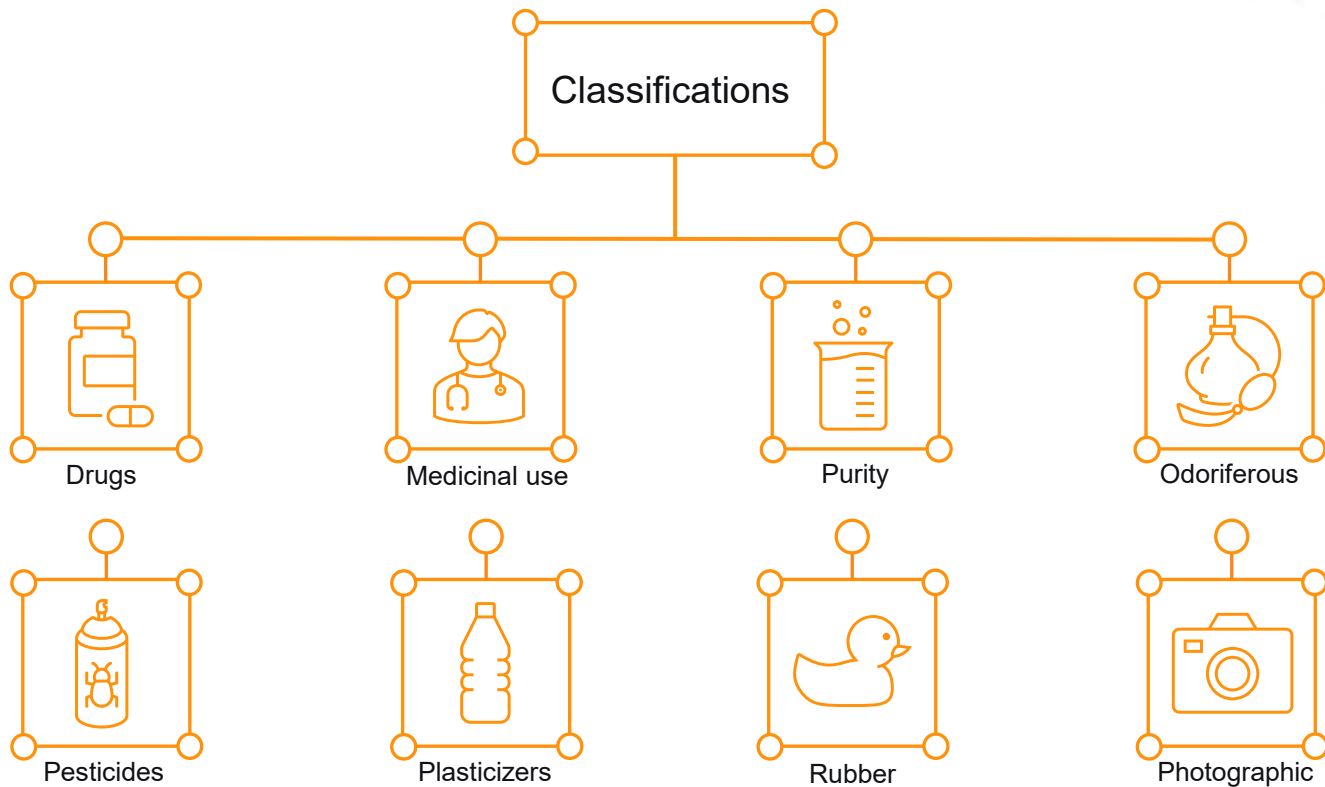
Exact structures

Salts/esters/hydrates

Intermediates




Compounds with extra info – Additional Classification





and more





cChemTS


 cChemTS

Administration  apapp [Help](#)

 Single check

 File check

 HS single check

 HS file check

HS single check

Draw molecule

Enter any text that represents a chemical structure
(SMILES, name, CAS Registry Number® or other identifier)

▼ Countries All countries

Selected countries:
All countries (click on the buttons to specify countries)

Available countries:
China European Union India Japan Switzerland
United Kingdom United States of America
US ScheduleB

► Output fields

► Classifications

► Categorize as

Check



How can I join?

- A company must be a member of the Pistoia Alliance
- Each company may send as many participants as they wish to the meetings
- You can join one or both expert communities
- Details on how to join: cscs@pistoiaalliance.org



Questions