

Deuterium Export Controls in Research

A Summary of the Current State and Impacts

Disclaimer - This is not legal advice

This is an overview of the current situation as we currently understand

It is based on a review of various legislation, regulatory guides and collated feedback from clients and regulators.

We accept no liability for errors or omissions

What is Deuterium and its uses

A stable (non-radioactive) isotope of Hydrogen - 'D'

155 parts per million in sea water (1:6400 ratio)

Used in "Heavy Water" which is mainly used in nuclear reactors and can also be used in nuclear weapon development

Numerous scientific applications including:-

NMR Spectroscopy:

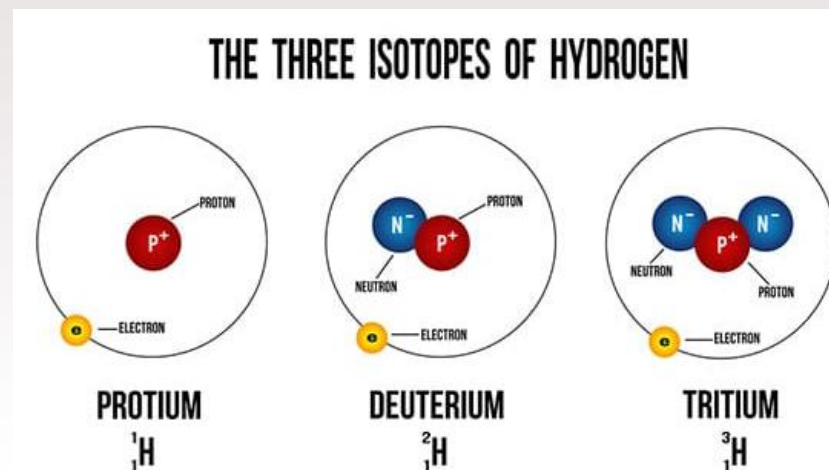
Deuterated solvents are used in NMR spectroscopy to analyze the structure and dynamics of molecules, as deuterium provides a distinct signal from hydrogen.

Isotopic Labeling:

Deuterium is used to track chemical and metabolic pathways in various scientific fields, including chemistry, biochemistry, and environmental science.

Deuterated Drugs:

Deuterium can be incorporated into drug molecules to enhance their properties, such as metabolic stability and duration of action (deutetrabenazine & deucravacitinib).



The OG / “One ring to rule them all” regulation



IAEA

International Atomic Energy Agency

Foreword

This document is a model Additional Protocol designed for States having a Safeguards Agreement with the Agency, in order to strengthen the effectiveness and improve the efficiency of the safeguards system as a contribution to global nuclear non-proliferation objectives.

The Board of Governors has requested the Director General to use this Model Protocol as the standard for additional protocols that are to be concluded by States and other parties to comprehensive safeguards agreements with the Agency. Such protocols shall contain all of the measures in this Model Protocol.

The Board of Governors has also requested the Director General to negotiate additional protocols or other legally binding agreements with nuclear-weapon States incorporating those measures provided for in the Model Protocol that each nuclear-weapon State has identified as capable of contributing to the non-proliferation and

(ix) The manufacture or upgrading of *heavy water or deuterium*.

Heavy water or deuterium means deuterium, heavy water (deuterium oxide) and any other deuterium compound in which the ratio of deuterium to hydrogen atoms exceeds 1:5000.

In conformity with the requirements of the Statute, each individual Protocol or other legally binding agreement will require the approval of the Board and its authorization to the Director General to conclude and subsequently implement the Protocol so approved.

Only a slight enrichment over sea water (1:6400) !!!

In 1997 the International Atomic Energy Agency (IAEA) proposed ‘model regulations’ for safeguards in the nuclear industry to contribute to the non-proliferation of nuclear weapons.

It does not just apply to nuclear materials, but also equipment, processes, technology etc.

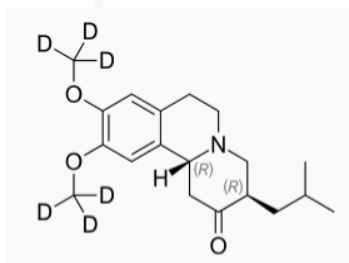
Members must implement these safeguards in their national legislation, the wording can be changed, but all the measures must be included.

Annex I deals with activities and includes enriching deuterium above 1:5000 D to H (manufacture of deuterium / deuterium compounds)

Annex II is a List of specified equipment and non-nuclear material for the reporting of exports and imports. It also includes Deuterium

The 1:5000 problem

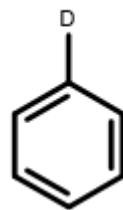
The problem comes when labelling a chemical with deuterium.
It will almost certainly always break the 1:5000 rule
Likely this was set without such use cases being considered.



6 Deuterium
to 14
Hydrogen
atoms

Deutetrabenazine

(treatment for effects of Huntington's
disease and tardive dyskinesia)



Even labelled benzene has a 1:5 ratio

Annex II

- Is Annex II maybe the cause of our licencing and reporting requirements
- Quantities >200kg at the national level (import or export) annually must be reported to the IAEA (hence tracked)
- But this states for use in reactors
- Maybe it provides some wiggle room for national regulators to exclude very small amounts / labelled medicines in future?

ANNEX II

LIST OF SPECIFIED EQUIPMENT AND NON-NUCLEAR MATERIAL FOR THE REPORTING OF EXPORTS AND IMPORTS ACCORDING TO ARTICLE 2.a.(ix)^{2/}

- d. shall provide to the Agency on a quarterly basis the information identified in Article 2.a.(ix)(a). This information shall be provided within sixty days of the end of each quarter.

2. Non-nuclear materials for reactors

2.1. Deuterium and heavy water

Deuterium, heavy water (deuterium oxide) and any other deuterium compound in which the ratio of deuterium to hydrogen atoms exceeds 1:5000 for use in a nuclear reactor as defined in paragraph 1.1. above in quantities exceeding 200 kg of deuterium atoms for any one recipient country in any period of 12 months.

What do national level regulations say

EU
UK
USA



United Kingdom

UK Strategic Export Control List

The consolidated list of strategic military and dual-use items that require export authorization from the United Kingdom

0C003
[T2.1*]
[IV*]
Deuterium, heavy water (deuterium oxide) and other compounds of deuterium, and mixtures and solutions containing deuterium, in which the isotopic ratio of deuterium to hydrogen exceeds 1:5 000.

Is this an exemption
in Annex 4?

Items of the NSG technology

All Category 0 of **Annex I** is included in **Annex IV**, subject to the following:

- 0C001: this item is not included in Annex IV.
- 0C002: this item is not included in Annex IV, with the exception of special fissile materials as follows:
 - (a) separated plutonium;
 - (b) "uranium enriched in the isotopes 235 or 233" to more than 20 %.
- **0C003** only if for use in a "nuclear reactor" (within 0A001.a.).
- 0D001 (software) is included in Annex IV except insofar as it relates to 0C001 or to those items of 0C002 that are excluded from Annex IV.
- 0E001 (technology) is included in Annex IV except insofar as these related to 0C001 or to those items of 0C002 that are excluded from Annex IV.

Sadly no

- The definition of Annex I and IV (and almost all UK strategic export control regulations) are from “retained” EU regulations
- Specifically COUNCIL REGULATION (EC) No 428/2009 (UK RETAINED LAW AFTER BREXIT)

Annex I – requires general export authorisation to a third country (but free movement within a country)

Annex IV - lists specific dual-use items for which authorisation is required for their transfer within a country, not just for export to a third country.

So, if for use in a nuclear reactor it requires permission even to move within a country.

UK – when is a licence required

A quick geography and Brexit recap...

- Great Britain = England, Wales and Scotland
- United Kingdom = England, Wales, Scotland and Northern Ireland
- Northern Ireland = Part of UK, but subject to EU rules in many areas to prevent a hard border with Ireland

Within Great Britain

Deuterium can be freely transported without a license, as long as it's not for use in a nuclear reactor.

Great Britain to Northern Ireland – no license required²

Great Britain to EU - license required (open General license)¹

Great Britain and Northern Ireland (UK) to anywhere else- license required¹

Northern Ireland to Great Britain – no license required²

Northern Ireland to EU - no license required¹

Great Britain to Northern Ireland to EU – likely license required (open general). End destination would be seen as the EU (with NI as transit country).

Dual-use licenses

You need a licence to:

- export controlled dual-use items from Great Britain
- export controlled dual-use items from Northern Ireland to outside the EU

You do not need a licence to export controlled dual-use items from Northern Ireland to the EU.

[Open general export licence \(export of dual-use items to EU member states\)](#) allows the export of dual-use items (with both a civilian and military application) from Great Britain to EU member states and the Channel Islands.

You need a new licence, issued by an EU member state for exporting dual-use items from the EU to Great Britain.

The EU has added the UK as a permitted destination to their General Export Authorisation (GEA) EU001 to minimise any additional licensing burden for those exporting dual-use items from EU to the UK.

¹ <https://www.gov.uk/guidance/export-controls-dual-use-items-software-and-technology-goods-for-torture-and-radioactive-sources>

From Great Britain to Northern Ireland

There is no licensing requirement to move dual-use items from Great Britain to Northern Ireland.

² <https://www.gov.uk/guidance/exporting-controlled-goods-after-eu-exit>

EU regulations

Unsurprisingly it is largely the same wording as the UK (as the UK act is retained from the EU legislation)

0C003 Deuterium, heavy water (deuterium oxide) and other compounds of deuterium, and mixtures and solutions containing deuterium, in which the isotopic ratio of deuterium to hydrogen exceeds 1:5 000.

Annex I [\(EU\) 2024/2547 of 5 September 2024 amending Regulation \(EU\) 2021/821](#)

With Annex IV in [Council Regulation \(EC\) No 428/2009 of 5 May 2009](#)

Deuterium (not for nuclear reactor use) does not require a licence for inter-EU transfer
A licence is required for export outside of the EU including Great Britain.

Although the EU has added the UK as a permitted destination to their General Export Authorisation (GEA) EU001 to minimise any additional licensing burden for those exporting dual-use items from EU to UK

EU to Northern Ireland – no license required (UK government website)
(but check with the EU member state)

From the EU to Northern Ireland

Northern Ireland applies the EU Dual-Use Regulation under the terms of the Northern Ireland Protocol. This means that no licence is required to export dual-use items (other than those in Annex IV of the EU Dual-Use Regulation) from the EU to Northern Ireland. You should seek advice from the relevant EU member state licensing authority.

<https://www.gov.uk/guidance/exporting-controlled-goods-after-eu-exit#:~:text=Northern%20Ireland%20applies%20the%20EU,these%20goods%20has%20not%20changed>

USA

In 2021, US authorities transferred responsibility for licensing of deuterium for non-nuclear uses from the Nuclear Regulatory Commission (NRC) to the Department of Commerce's Bureau of Industry and Security (BIS)

“This final rule eliminates the licensing burden on exporters of deuterium for non-nuclear end use which, under current industry trends, constitutes the majority of deuterium being exported. Removing exports of deuterium for non-nuclear end use from [10 CFR part 110](#) also reduces recordkeeping and reporting requirements for those licensees who will no longer require specific licenses for exports of deuterium for non-nuclear end use.

(I believe it was partly this change that raised the wider awareness of this within the industry)



USA

This does not remove all licencing requirements. But removes or simplifies it for many.

However, care should be taken when relying on them as there are some surprising limits to these and they do change. Some notable US allies require licencing, for example Israel. China is also subject to licensing since August 2023 ([with enforcement](#) action taken immediately after changes – 22nd August).

The exemption can also be supplier / receiver / use context dependant – e.g check your circumstances are applicable. You can see the US country lists requiring a licence [here](#) under the NP2 listing

Norfolk CBP Intercepts Deuterium Destined to China

Release Date: Tue, 10/31/2023

The New Jersey shipment violated nuclear materials export controls.

NORFOLK, Va. – U.S. Customs and Border Protection officers seized a shipment of China-bound deuterium cylinders in Norfolk on October 18 for violating nuclear nonproliferation licensing laws.

Deuterium is a stable isotope of hydrogen. It is used in military, industrial, and scientific applications and requires a license to be exported to China. Exportation of deuterium is regulated by the U.S. Department of Commerce's Bureau of Industry and Security.



USA “Gotchas”

The final destination is important

You can't export to the EU without license and then use the EU rules to export onto China – that requires a license.

This was explicitly asked of BIS who said its not permissible and is inline with the DEA and Controlled Drug rules

(This is inline with more general strategic export / arms control regulations for electronics, jet engines, weapons etc)

Number of stops.

With Controlled Drugs, the DEA will allow one stop over of a controlled substance.

USA to UK to Germany. - OK

USA to UK to Germany to Austria – Not ok.

So far (to our knowledge), BIS has not stated the maximum number of stops in the chain so in theory it could be re-exported a number of times as long as it did not end up in a proscribed country.

USA “Gotchas”

The same chemical for export to a country requiring a licence (e.g China) may be approved for one export and denied for another

- Both the distributor and end user details maybe required to get a licence
- This maybe due to end user / supply chain checks
- These checks and licence decisions can take months (if granted at all)

In theory BIS will assess an item the first time it is exported.

They will issue you an export license and over time they will build up a list of assessed items that they will exempt from the process.

But not much evidence that this exempted list is increasing or being applied.

Does this really apply to us?

This all seems a bit crazy for what are tiny amounts of deuterium with no weapons proliferation use?

It cannot really apply to us, can it?

What have the regulators said?

Can we have an exemption?

- The Export Control Joint Unit (ECJU) is responsible for licencing.
- Scitegrity have tried contacting them several times for clarification. We were told to take legal advice or apply for an Export licence of a dual use item for it to be evaluated.
- One of our clients with EU and UK sites had previously enquired with the ECJU and ended up simply applying for a general export licence (as it was quicker, safer and easier)
- A second client also said they got no meaningful response from the ECJU on the issues raised, who just issued a general export licence.

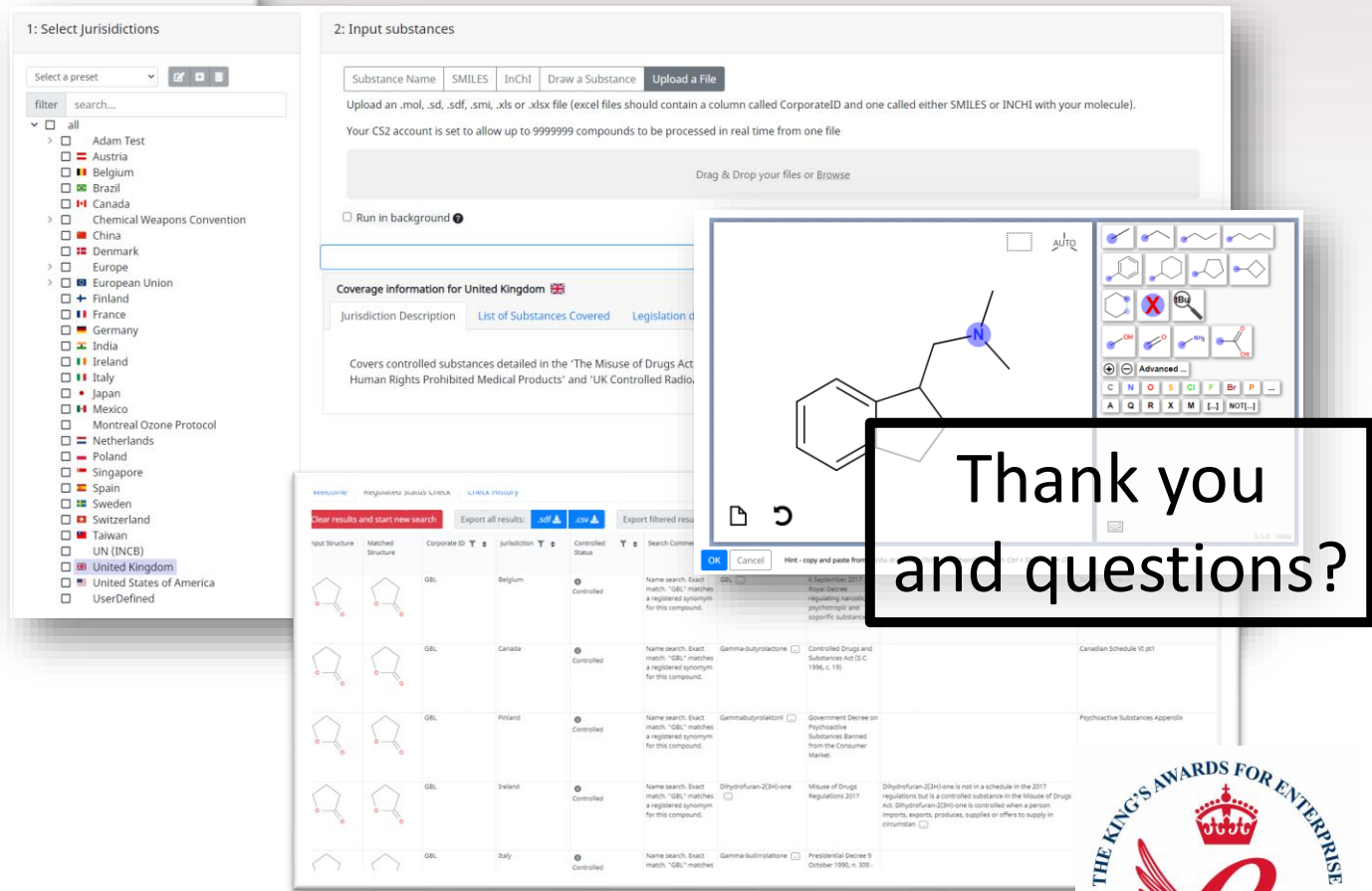
- Response from customs officials in Belgium to one of our clients was that the pharmaceutical usage of deuterium would likely not have been intended to be covered by the dual-use legislation, but the current phrasing does not allow for its exclusion
- They also offered to raise this with EU customs colleagues (to encourage a position similar too that of the US) and issued an export licence

Summary

- Export of deuterated chemicals for non-nuclear use from the EU or UK requires an export licence (usually a general licence)
- A licence is required for movements between the EU and UK (with NI exemptions)
- Movement of those chemicals within the EU do not require a licence
- Movement of those chemicals within the UK do not require a licence (including Northern Ireland)
- Export from the USA to many countries (but excluding China or Israel) do not require licences, or have a lower licencing requirement
 - However, even in these cases, you should be careful about re-export to places such as China and Israel (amongst others)
- The USA have exempted most licencing requirements for non-nuclear use.

Compliance Hub

Controlled Substances Squared, Expedichem, DG Assessor



1: Select Jurisdictions

Select a preset:

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

2: Input substances

Substance Name SMILES InChI Draw a Substance Upload a File

Upload an .mol, .sd, .sdf, .smi, .xls or .xlsx file (excel files should contain a column called CorporateID and one called either SMILES or INCHI with your molecule).

Your CS2 account is set to allow up to 9999999 compounds to be processed in real time from one file

Drag & Drop your files or Browse

☐ Run in background

Coverage information for United Kingdom

Jurisdiction Description List of Substances Covered Legislation

Covers controlled substances detailed in the 'The Misuse of Drugs Act', 'Human Rights Prohibited Medical Products' and 'UK Controlled Radiopharmaceuticals'.

Search results and start new search

Input Structure	Matched Structure	Corporate ID	Jurisdiction	Controlled Status	Search Comment
		GSL	Belgium	Controlled	Name search: Exact match. "GSL" matches a registered synonym for this compound.
		GSL	Canada	Controlled	Name search: Exact match. "GSL" matches a registered synonym for this compound.
		GSL	Finland	Controlled	Name search: Exact match. "GSL" matches a registered synonym for this compound.
		GSL	Ireland	Controlled	Name search: Exact match. "GSL" matches a registered synonym for this compound.
		GSL	Italy	Controlled	Name search: Exact match. "GSL" matches a registered synonym for this compound.

Thank you and questions?

- Controlled and regulated chemicals in 36 jurisdictions.
- Generate HS codes
- Dangerous Goods information

Laws covered include:-

- Controlled Drugs & precursors
- Dual use / export-controlled chemicals
- Chemical Weapons convention
- Ozone depleting
- PIC Rotterdam and more...

- ✓ Search by name or structure
- ✓ Handles novel and proprietary chemicals
- ✓ Automatically check millions of your chemicals
 - ✓ Weekly legislation updates
 - ✓ legislation support and advice