# Memo M5/16

**Changes to CWC Licensing Arrangements**

Memo M7/15, asked departments to declare to the Safety Office any chemicals in their possession that were listed under Schedule 1 of the Chemical Weapons Convention (CWC), <https://www1.admin.ox.ac.uk/safety/memoranda/m715/>

The chemicals specifically listed by their Chemical Abstracts Service (CAS) registry numbers under Schedule 1 are subject to strict licensing arrangements, which limit the amount that can be held under different licensing conditions.

The list of Schedule 1 chemicals may be seen in [Appendix 1 to University Policy Statement S5/04.](https://www1.admin.ox.ac.uk/safety/policy-statements/s5-04/#d.en.9504) Departments holding, using or producing Schedule 1 chemicals, or intending to purchase or acquire them, must be covered by the appropriate license. In the past where a license has been required it has been held centrally.

The government department administering the CWC in the UK, the Department of Business, Energy and Industrial Strategy (BEIS), has recently written to the University regarding a new flexible approach towards the status of the CAS numbers, which will now lead to **more chemicals being considered licensable** under the Chemical Weapons Act, 1996.

The new licensing regime will not now be limited only to those particular chemicals which fall within the CAS list in Schedule 1, but rather that the CAS numbers should be used only as aids to identify the types of chemicals that should be considered as falling within Schedule 1, and therefore subject to the licensing regime.

The result is that the molecular structure of a chemical will determine whether it is covered by Schedule 1, and therefore isotopically labelled analogues, stereoisomers (both optical and geometric), and corresponding salts are also licensable. Annex A has been provided by BEIS as guidance.

In order to avoid over-burdensome and unnecessary licensing, to support medical research, and to allow the legitimate transfer, possession and/or use of, for example, diagnostic kits or some cancer treatments which contain very small amounts of particular versions of Schedule 1 chemicals, or contaminated items such environmental samples which might contain traces of Schedule 1 chemicals, some exemptions will be permitted.

The Safety Office is currently in discussion with BEIS to determine the exemptions that might apply and the type and number of licenses that may be required under the new regime.

Although there were only a few returns in response to Memo M7/15, and most were in relation to Schedule 1A06 (see annex A), it is anticipated that those departments may now have additional chemicals that fall within the extended scope of the Schedule 1 licensing, most probably the chemical salts.

If the Safety Office is to continue to hold licenses centrally Heads of Department must ensure that all relevant principal investigators / research group supervisors confirm whether or not work is being undertaken with such licensable chemicals, and provide the information set out in the attached **CWC S1 declaration form.** The return may be sent by Departmental Safety Officers or Administrators on their behalf. If reliable information is not forthcoming then it may be necessary for departments to obtain their own CWC S1 licenses going forward, and be subject to a stringent inspection regime.

This memo is being sent to all science and clinical departments. Even if these potentially licensable chemicals are not being used **a null return is required**.

In such a case please strike through the declaration form, tick the relevant box on page 2, sign and date the form.

The **changes to the licensing regime** **take effect from 2017.** BEIS are allowing the University additional time to collate this information but returns are time critical and a prompt response is required. A return is required by Monday 23 January 2017, **at the latest.**

Apologies for the tight turnaround.

Departments should use the attached form, which can be provided to departments electronically on request (email: julie.black@safety.ox.ac.uk).

19 December 2016 Julie Black

CIRC: C, S, Heads, DSOs1, DSOs2, Admins, List V

**CWC Schedule 1 Chemicals and CAS Numbers ANNEX A**

The number of additional chemicals which would require a Schedule 1 licence under the new regime is too large to be provided in a comprehensive list.

However, the additional chemicals fall into one of three distinct groups which can be described generically:

1. isotopically labelled analogues,
2. corresponding salts,
3. stereoisomers.

The summary table below outlines which additional groups of chemicals which are to be added to each section under Schedule 1:

|  |  |  |  |
| --- | --- | --- | --- |
| **Schedule** | **Isotopically labelled analogues** | **Corresponding salts** | **Stereoisomers** |
| **1A01** | x |  | x |
| **1A02** | x |  | x |
| **1A03** | x |  | x |
| **1A04** | x |  |  |
| **1A05** | x |  | x |
| **1A06** | x | x |  |
| **1A07** | x | x | x |
| **1A08** | x |  |  |
| **1B09** | x |  |  |
| **1B10** | x |  |  |
| **1B11** | x |  | x |
| **1B12** | x |  | x |

**Schedule 1A01 – Toxic chemicals**

In addition to the chemicals which are covered by the generic descriptors of scheduled ‘families’ in 1A01:

* Isotopically labelled and radiolabelled analogues of the chemical group described in 1A01 should be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and phosphorus-32.
* All stereoisomers, including mixtures of stereoisomers, of the chemical group described in 1A01 should also be declared.

**Schedule 1A02 – Toxic chemicals**

In addition to the chemicals which are covered by the generic descriptors of scheduled ‘families’ in 1A02:

* Isotopically labelled and radiolabelled analogues of the chemical group described in 1A02 should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and phosphorus-32.
* All stereoisomers, including mixtures of stereoisomers, of the chemical group described in 1A02 should also be declared.

**Schedule 1A03 – Toxic chemicals**

In addition to the chemicals which are covered by the generic descriptors of scheduled ‘families’ in 1A03:

* Isotopically labelled and radiolabelled analogues of the chemical group described in 1A03 should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, sulfur-35 and phosphorus-32.
* All stereoisomers, including mixtures of stereoisomers, of the chemical group described in 1A03 should also be declared.

**Schedule 1A04 – Sulfur mustards**

In addition to the chemicals which are explicitly listed in 1A04:

* Isotopically labelled and radiolabelled analogues of the sulfur mustards described in 1A04 should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and sulfur-35.

**Schedule 1A05 – Lewisites**

In addition to the chemicals which are explicitly listed in 1A05:

* Isotopically labelled and radiolabelled analogues of the Lewisites in 1A05 should be declared. This includes, but is not limited to, analogues containing deuterium and carbon-14.
* Any geometric isomers of the Lewisites should also be declared.

**Schedule 1A06 – Nitrogen mustards**

In addition to the chemicals which are explicitly listed in 1A06:

* The corresponding salts of the nitrogen mustards in Schedule 1A06 should be declared. This includes, but is not limited to, hydrochloride, hydrobromide, hydroiodide, sulfate and nitrate salts.

* Isotopically labelled and radiolabelled analogues of the nitrogen mustards and their corresponding salts should also be declared. This includes, but is not limited to, analogues containing deuterium, carbon-14 and carbon-13.

BEIS are aware that nitrogen mustard HN2 salt has been and can be used as a cancer treatment, and will consider how such legitimate uses of the chemical might best be dealt with by the licensing regime, including by means of a licencing exemption.

**Schedule 1A07 – Saxitoxin**

In addition to the single chemical which is explicitly listed in 1A07:

* All salts of saxitoxin should be covered under Schedule 1A07. This includes, but is not limited to, the dihydrochloride and diacetate salts.
* All stereoisomers of saxitoxin (both the free base and its salts) should be covered under Schedule 1A07.
* Isotopically labelled and radiolabelled analogues of all optical isomers of saxitoxin and its corresponding salts should also be declared. This includes, but is not limited to, analogues containing deuterium, tritium and carbon-14.

BEIS are aware that the most common salts are the dihydrochloride and diacetate salts, which are found in the diagnostic kits for paralytic shellfish poisoning, and will consider how such legitimate uses of the chemical might best be dealt with by the licensing regime, including by means of a licencing exemption.

**Schedule 1A08 – Ricin**

The following should be covered by the ricin descriptor in Schedule 1A08:

* All forms of ricin originating from *Ricinus communis*, including any variations in the structure of the molecule arising from natural processes, or man-made modification designed to maintain or enhance toxicity. This includes isotopically labelled and radiolabelled ricin. The A- and B-chain sub-units of the toxin must be linked only by a disulfide bond for the molecule to be considered ricin.

In addition:

* All ricin toxoids, hybrids and ricin A- and B-chains (both naturally occurring and recombinant), including any variations in the structure of the molecules arising from natural processes, or man-made modification designed to maintain or enhance toxicity. This includes any isotopically labelled and radiolabelled analogues and toxoided ricin hybrids.

**Schedule 1B09 – Alkyl (Me, Et, n-Pr or i-Pr) phosphonyldifluorides**

In addition to the chemicals which are covered by the generic descriptors of scheduled ‘families’ in 1B09:

* Isotopically labelled and radiolabelled analogues of the chemical group described in 1B09 should be declared. This includes, but is not limited to, analogues containing deuterium, carbon-14, oxygen-18 and phosphorus-32.

**Schedule 1B10 – O-Alkyl O-2-dialkylaminoethyl alkylphosphonites and corresponding salts**

In addition to the chemicals which are covered by the generic descriptors of scheduled ‘families’ in 1B10:

* Isotopically labelled and radiolabelled analogues of the chemicals described in 1B10 should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and phosphorus-32.

**Schedule 1B11 - Chlorosarin**

In addition to the single chemical which is explicitly listed in 1B11:

* Isotopically labelled and radiolabelled analogues of chlorosarin should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and phosphorus-32.
* All stereoisomers, including mixtures of stereoisomers, of chlorosarin (and its isotopically labelled analogues) should also be declared.

**Schedule 1B12 - Chlorosoman**

In addition to the single chemical which is explicitly listed in 1B12:

* Isotopically labelled and radiolabelled analogues of chlorosoman should also be declared. This includes, but is not limited to, chemicals containing deuterium, carbon-14, and phosphorus-32.
* All stereoisomers, including mixtures of stereoisomers, of chlorosoman (and its isotopically labelled analogues) should also be declared.

**CWC Schedule 1 Declaration Form Page 1 of 2**

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| --- | --- | --- | --- |
| **Department/Unit:** |  | **Date:** |  |
| **Description of activity**  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Location of material****(Building, room number)** | **Name of PI / supervisor** | **Chemical Name** | **CAS number** | **Quantity held** | **Possession & Use** **YES / NO*****See note 1*** | **Name of supplier** | **Production****YES / NO*****See notes 2&3*** |
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\*Append additional pages as required. \*\* Strike though this page if submitting a null return.

**CWC Schedule 1 Declaration Form Page 2 of 2**

|  |  |
| --- | --- |
| **DEPARTMENT/UNIT:** | …………………………………………………………………… |
| **PRINT NAME:** | …………………………………………………………………… |
| **SIGNATURE:** | …………………………………………………………………… |
| **POSITION:** | …………………………………………………………………… |
|  |  |

 **NULL RETURN**

**This department does NOT hold, use, or produce potentially licensable chemicals under Schedule 1 of the CWC**

**Additional notes:**

1. A Schedule1 **Possession and Use license** is required even if the material is only being stored or being held for disposal.
2. Schedule 1 chemical transient intermediates are excluded from the CWC declaration requirements and are therefore NOT licensable, providing they are reacted in their entirety and not isolated.
3. If a Schedule 1 chemical intermediate is isolated, it is considered to be production, and a Schedule 1 **Production license** is required up to an aggregate of <100g per annum. A Schedule1 **Possession and Use license** will also be required, to an aggregate of <100g.
4. The aggregate limit is applied across the University.
5. Any **production** of Schedule 1 chemicals above the 100g aggregate is considered ‘significant’ production and in such a case the University will have to be approved by the UK National Authority, BEIS, and declared to the Organisation for the Prohibition of Chemical Weapons (OPCW) in advance of activity taking place. It will also be subject to a rigorous inspection regime.
6. One of the exemptions being considered is in relation to HN2 salts, which is only intended to exempt hospitals, pharmacies, production QC, vets and distribution companies from needing licenses to hold, administer, sell medical treatments:

 *‘Salts of bis(2-chloroethyl)methylamine (CAS 51-75-2) may be exempted if their product forms meet all of the following criteria:*

*- they are pharmaceutical formulations, or active pharmaceutical ingredients, designed for human or animal administration in the treatment of medical or veterinarian conditions, or are for the quality control of these products; and*

*- they are authorised by a state authority to be marketed as clinical, medical or veterinary products, or are prescribed by a physician or veterinarian.’*

7. Any HN1 or HN3 salts that are used for similar purposes (note 6) **may** be exempt. Departments should provide supporting information.