Guidelines for researchers on dual use and misuse of research

Institutions and funding bodies aim to raise researchers' awareness of the issues relating to dual use and misuse of research and help them to handle this appropriately. Researchers indeed have a legal and ethical obligation to prevent or mitigate as much as possible the risks and potential damage which may be caused by malicious use of their research results.

1 Responsibility

Handling research responsibly requires the active commitment from research institutions, funding bodies, and others. However, the researchers concerned also play a key role and must take their responsibility. The researcher is indeed best placed to assess the nature and seriousness of potential misuse relating to the intended knowledge, products or technologies and must, if the occasion arises, report this within the research institution and to the funding body (see point 3).

2 Definition of dual use and misuse of research results

In the ethics self-assessment table within the framework of Horizon 2020 the European Commission distinguishes between two concepts: on the one hand, the concept of use for **civil versus military purposes** (described below as dual use), and on the other hand the concept of **good versus bad** use (described below as misuse).

2.1 Dual use of research

In Article 2 of Council Regulation (EC) No 428/2009 'dual-use items' are defined as *items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices*.

European legislation on the **export of dual-use items** (EU export control Regulation No 428/2009) requires that the EU countries take appropriate control measures to counter the undesirable and uncontrolled proliferation of dual-use items, software and knowledge specified on the dual-use control list to non-EU countries. This means that the export of such dual-use items to non-EU countries is **subject to authorisation**. In European legislation dual-use items are defined as items which are primarily used for civil (academic or industrial) purposes, but can also be used for military purposes. In accordance with Article 4 of Council Regulation (EC) No 428/2009 (the so-called **catch-all** provision), an authorisation is also required for items which do not feature on the dual-use list, if the country of destination is subject to an arms embargo and the items may be intended, in their entirety or in part, for a military end-use, or if the items may be intended, in their entirety or in part, for the production and proliferation of chemical, biological or nuclear weapons of mass destruction and their means of delivery (e.g. missiles capable of delivering such weapons) (see point c).

The three pillars of the control of the trade in dual-use items to non-EU countries (and for a limited

number of highly sensitive items specified in Annex IV of the dual-use control list to another EU country) are[1]:

a Item screening:

The first and most important step concerns the answer to the question whether the scientific output pertains to 1 of the 10 categories of the **dual-use control list** (Annex I of EU export control Regulation No 428/2009).

The list is broken down into 10 broad categories:

0. Nuclear materials, facilities and equipment
1. Special materials and related equipment
2. Materials processing
3. Electronics
4. Computers
5. Telecommunications and "information security"
6. Sensors and lasers
7. Navigation and avionics
8. Marine
9. Aerospace and propulsion

Each category is further broken down into five groups:

A. Systems, equipment and components
B. Test, inspection and production equipment
C. Materials
D. Software
E. Technology (strategic knowledge)

Technology means specific information 'required' for the development, production or use of the goods specified in categories 0 through 9. This refers to only that part of "technology" which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions from the dual-use control list.

Research in e.g. metal alloys, composites, semi-conductor electronic devices, thermal imaging cameras, encryption and internet surveillance equipment, intrusion software, pathogens and toxins potentially pertains to listed (and therefore subject to authorisation) physical items (groups A, B, C), software (group D) or strategic knowledge (group E) (see also https://www.ecochecker.trade.gov.uk/spirefox5live/fox/spire/).

When the scientific output (e.g. materials, but also software or know-how) can be found on the dual-use control list, an authorisation will have to be applied for before export[2].

b Trajectory screening:

During this step it must be examined whether the country of destination and the country of end use are subject to an embargo or sanction. Some countries or entities are **more sensitive destinations** (as intermediate stop and/or final destination) than others. That is why the export of certain items is prohibited and no authorisation can be acquired for these items. This list includes, amongst others, Iran, Syria, Russia, Sudan, South Sudan and North Korea, but also Belarus,

1 See also the brochure of the Flanders Department of Foreign Affairs (in Dutch): http://fdfa.be/nl/export-van-kennistechnologie

2 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R0428-20161116: "'export' shall mean transmission of software or technology by electronic media, including by fax, telephone, electronic mail or any other electronic means to a destination outside the European Community; it includes making available in an electronic form such software and technology to legal and natural persons and partnerships outside the Community. Export also applies to oral transmission of technology when the technology is described over the telephone".

Zimbabwe, Afghanistan, Yemen, Libya and Ivory Coast (consolidated list of sanctions - restrictive measures in force: https://eeas.europa.eu/topics/common-foreign-security-policy-cfsp/8442/consolidated-list-of-sanctions_en, consulted on 23 May 2017).

On the other hand, a **simplified registration** for export authorisations is in place for certain countries and dual-use items (http://www.fdfa.be/nl/uniale-vergunning), for instance for the export of most dual-use items to Australia, Canada, Japan, New Zealand, Norway, Switzerland, including Liechtenstein, and the United States.

c End use and end-user screening:

Finally, information must be provided through public sources about **who the customer is, what they do and what the items will be used for**. In accordance with **Article 4 of Council Regulation (EC) No 428/2009** an authorisation is also required for items that are not listed on the dual-use list. This is called the **catch-all** control (or ad hoc authorisation requirement). This is the case if the country of destination is subject to an arms embargo[3] and the items may be intended, in their entirety or in part, for a military end-use, or if the items may be intended, in their entirety or in part, for the production and dissemination of chemical, biological or nuclear weapons of mass destruction and their means of delivery (e.g. missiles capable of delivering such weapons).

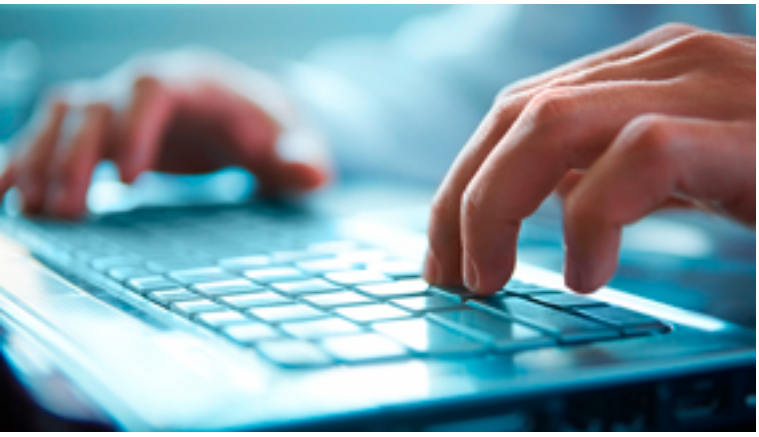
Exceptions to the authorisation requirement (decontrol):

- For software: No authorisation is required for software (licences) which meets one of the descriptions from the dual-use control list, if the software is a commercial mass-market product which the buyer can start to use on the basis of the DIY principle. The minimum necessary "object code[4]" for the installation, operation, maintenance (checking) or repair of those items whose export

3 The arms embargo must have been decided by an action adopted by the Council or a decision of the Organisation for Security and Cooperation in Europe (OSCE) or a binding resolution of the UN Security Council. For a (non-official) overview of the countries subject to an arms embargo, please refer to: https://www.sipri.org/databases/embargoes.

4 The object code is the code which is generated after the translation of a source code and is necessary to convert a set of object files into an operational software programme or library. For the precise definition, reference is made to the dual-use control list Council Regulation (EC) No 428/2009, as recast.

has been authorised shall be exempted from the authorisation requirement. This exemption does not apply to information security software which is subject to an authorisation requirement.
In concrete terms the rules from the Regulation



state in the general software note that an exemption applies to software which is:

A. **"Generally available to the public"** by being:
   1. Sold from stock at retail selling points, without restriction, by means of:
      a. Over-the-counter transactions;
      b. Mail order transactions;
      c. Electronic transactions; or
      d. Telephone call transactions; and
   2. Designed for installation by the user without further substantial support by the supplier;

B. **"In the public domain"**: Software which has been made available without restrictions upon its further dissemination (copyright restrictions do not remove "software" from being "in the public domain").

- For transmission of knowledge ("technology"):
  Possible exemptions from the transmission of technology which is otherwise subject to authorisation apply to "basic scientific research", "in the public domain" and the minimum necessary information for patent applications as specified in the general technology note.
  - "Basic scientific research": Experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.
    Whether the exemption for basic scientific research can apply may depend on several factors which are to be considered on a case-by-case basis. Indicators which may play a role include the research funding source (e.g. public grants or private sector funding), the research programme (e.g. VLAIO, Horizon 2020, ERC, etc.), the regulation regarding the ownership of results (e.g. will the ownership be transferred to the financier, is shared ownership in place, does the research institute retain the ownership rights), the type of results expected (e.g. new knowledge or rather existing knowledge that is built on). Other aspects of the relevant research may be important as well, which will necessitate an individual assessment of each separate case.
  - "In the public domain": Technology which has been made available without restrictions upon its further dissemination (copyright restrictions do not remove "technology" from being "in the public domain").

  Therefore, no authorisation is required if the research output is in the public domain (through an open access publication, a scientific publishing company, a commercial bookshop or because the presentation through programmes (such as SlideShare.net®) is available without restrictions to a broad public, or because it shows from the funding, the consortium partners or the project description that it involves "basic scientific research"[5].
  Note to the interpretation of "knowledge in the public domain" within the framework of training initiatives, whereby the technology/knowledge in itself is subject to authorisation:
  - No authorisation is required for merely transferring knowledge "from head to head".

5 Please note: The publication itself of the research output may still be subject to the guidelines regarding the misuse of research (see point 2.2).

- If the knowledge institute provides information (slides, papers, course) about technology/knowledge that is subject to authorisation within its own premises, to its own collaborators within the EU, this is not regarded as an export, which is why no authorisation is required for that specific transaction.
- If the knowledge institute provides information (slides, papers, course) about technology/knowledge that is subject to authorisation, within its own premises, to non-EU participants, this is not regarded as an export and no authorisation is required for that specific transaction (Flanders does not follow the principle of deemed exports, contrary to the US). However, knowledge institutes must point out to the participants that if they take documents outside of the EU, irrespective of the medium containing information that is subject to authorisation, they will be regarded as exporters and will therefore require an authorisation.
- If, after completion of a training course, the knowledge institute transmits information about technology/knowledge which is subject to authorisation to non-EU participants, this is regarded as an export and requires an authorisation (slides, papers, course, USB, by e-mail, available on server via password).
- If the knowledge institute provides information (slides, papers, course) abroad (outside of EU) about technology/knowledge that is subject to authorisation, to anyone whatsoever, an authorisation is required.

Points of focus:

- Research that is funded under **Horizon 2020** has an **exclusive focus on civil applications**. This does not exclude the participation of military partners or the development of generic technologies, products or knowledge.

In addition, a pilot project was already carried out within the **European Defence Agency** for the funding of **military research** in Europe and calls will be opened within the framework of the **EU's Preparatory Action on Defence Research**[6] (PADR) (period 2017-2019). As a result, attention is drawn not only to the dual-use control list, but also to the military control list.
For items that are specially designed or modified **for military use** (production listed on the Common Military List of the European Union) it must be checked whether the regulation concerning the import, export, transit and transfer of defence-related products and other material for military use applies. For Flanders this regulation is set out in the Arms Trade Decree and the Arms Trade Order. Examples of military items include fire control and thermal imaging equipment, weapons, ammunition, war vehicles, manned and unmanned war aircraft, vessels of war (surface and underwater), weapon sights, some chemicals like CW nerve agents, armoured or protective equipment, explosives and propellants.

Steps to be taken and/or obligations:

- A **reporting obligation** exists within the institute with regard to dual-use items within the framework of research (see also point 3).
- Via the centrally designated services of their research institutes and knowledge centres researchers must also contact the Strategic Goods Control Unit of the Government of Flanders

6 https://www.eda.europa.eu/what-we-do/activities/activities-search/preparatory-action-for-csdp-related-research

to apply for an authorisation for the export of dual-use items under Categories 0 to 9 of the dual-use list to non-EU countries and for highly sensitive items in Annex IV (e.g. ricin and saxitoxin), also to other EU countries.

- The **US Export Administration Regulations** apply to US-funded research. This legislation must also be respected when partner institutions from the US are collaborating with or use is made of materials or technologies originating from the US. This may entail that people of a certain nationality are not allowed to take part in the research, or that the further dissemination of the results is subject to authorisation from the US government.
- It is the responsibility of the researchers and knowledge institutes to take appropriate internal security measures (e.g. entry of an export clause in partnership agreements, design of a system for restricting access to sensitive information on network drives, development of a protocol on how sensitive information on data media is to be handled by users, etc.), in order to prevent technologies which are subject to authorisation from leaving the European Union through the passage of temporary **non-EU students, employees or researchers**.

2.2 Misuse of research[7]

"Misuse of research" is to be understood as "research that could be misused for unethical purposes".

Some research can generate knowledge, materials, methods or technologies that could also be used in unethical ways. Although such research is carried out with benign intentions, people with bad intentions may potentially harm humans, animals or the environment with the acquired research results.

Although anything can potentially be misused for unethical purposes, this mainly includes research that could be used by terrorists or criminals or technologies which may have a direct substantial impact on the safety of individuals, groups or countries.

The research most vulnerable to misuse is research that:

- provides knowledge, materials, methods and technologies that could be channelled into crime or terrorism;
- could result in chemical, biological, radiological or nuclear weapons and the means for their delivery;
- involves developing surveillance technologies that could curtail human rights and civil liberties;
- involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.

When designing a proposal, it is important to not only consider the immediate aims and intended applications, but also whether the research could serve unethical purposes.

7 This paragraph on misuse is mostly a translation of the European Commission's Guidance note – Potential misuse of research.

Steps to be taken and/or obligations:

- Carrying out a **risk assessment** for the intended research. The following questions could be asked in this context:
  - What would happen if the research results ended up in the wrong hands?
  - Could the research results (materials/methods/technologies and knowledge) harm people, animals or the environment if modified or enhanced?
  - Could the research results serve any purposes other than the intended ones? If so, would that be unethical?
- Proposing **adjusted safety and security measures** to cover the safety risks (during and after the project period):
  - taking additional security measures, e.g. physical security measures, classification of certain deliverables, compulsory security clearance for those involved in the project (if requested by the government, the government shall be responsible for this clearance);
  - taking additional safety measures, e.g. compulsory safety training for research staff;
  - adjusting the research design, e.g. using dummy data;
  - limiting the dissemination of research results, e.g. by publishing only part of the research results, regulating export, etc.
- Researchers may also consider appointing an **independent ethics advisor** or an ethics board with relevant expertise.
- A **reporting obligation** of the intended research applies within the institute (see point 3).

3 Obligations within the institute

Researchers have a **reporting obligation** to the proper internal channels (Dual Use Ethics Committee and/or the Dual Use Contact Point) within the institution in the context of the following types of applications:

- Project applications for the EU or other agencies that require an Ethics Review, e.g. Horizon 2020, FWO, internal funds (IOF, BOF).
- Project applications for funding by programmes of military authorities, e.g. US Department of Defense, AFOSR, etc.
- Bilateral cooperation with companies that also produce military systems.
- Partnerships or dissemination activities that require an export authorisation.

Advice can also be granted on the initiative of the individual researcher.

In cooperation projects with partners it can be mentioned in the cooperation agreement that the project coordinator will submit an application as "project applicant" for all the partners for the authorisation of the export of dual use "technologies" to non-EU countries, with all the partners committing to delivering the necessary information in time to the project coordinator. Another possibility is for the cooperation agreement to mention that all partners commit individually to abide the dual-use legislation and apply for the necessary authorisations themselves (especially when physical items are exported which should be declared to Customs).

4 Some examples/cases

To determine whether a product is a dual-use item, the technical specifications of the items must be verified against the descriptions in the list of dual-use items.

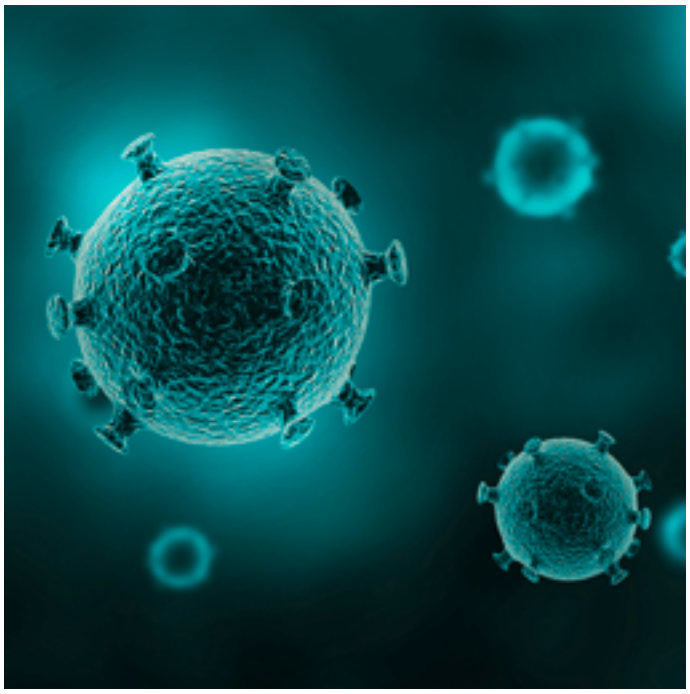
- Examples of **items on the dual-use list** (http://fdfa.be/sites/default/files/atoms/files/Outreach%20to%20academia%20presentatie_20171120_0.pdf):
  - Materials, chemicals, microorganisms and toxins (structural, chemical, biological) - EU Dual Use List Category 1:
    Aluminum, filamentary materials, graphite, zirconium, phosphorus compounds, human pathogens, zoonoses and toxins (Viruses: Dengue fever, Ebola, Variola (smallpox) - Rickettsiae: Coxiella burnetti (Q fever) - Bacteria: Bacillus anthracis (anthrax), Yersinia pestis (plague) - Toxins: Botulinum toxins, Ricin, Cholera)
  - Materials processing – EU Dual Use List Category 2:
    Filament winding machines, machine tools, isostatic presses, remote manipulators, furnaces, pressure transducers, chemical reaction vessels, heat exchangers, multi-walled piping, fermenters
  - Electronics, sensors and lasers - EU Dual-Use List Categories 3 and 6:
    Integrated circuits, A/D converters, capacitors, frequency changers, detonators, mass spectrometers, electronic cameras, lasers
- Example of a conventional **dual-use item** (example copied from the *Handboek strategische goederen en diensten* in the Netherlands).
  Image intensifier tubes are used both in military night-vision equipment and in security or (specific) television cameras. Depending on the design the tubes are designated as military items, dual-use items or items not subject to authorisation. Because the design and not the use is of decisive importance, it can happen that military tubes are being used for civil purposes and tubes falling within the scope of the dual-use list (and which will in reality be of lesser quality) being built into night-vision equipment for military personnel. In many cases this is not a problem, but sometimes it is not desirable that foreign armed forces receive equipment with Dutch dual-use components, e.g. armed forces of countries which are subject to an arms embargo. Through the export authorisation requirement foreign buyers can be compelled to only process the tubes in equipment for countries where the Netherlands would also grant an authorisation for direct supply.
- Example of a non-conventional **dual-use item** which is related to the development and production of weapons of mass destruction (WMD) (example copied from the *Handboek strategische goederen en diensten* in the Netherlands[8]).
  Certain flame retardants which are generally used in construction or the plastics industry can, when being combined or reacting with other chemicals, be used for the production of poison gases. The Netherlands do not object to the civil use of flame retardants. However, with the export authorisation requirement, the Ministry of Foreign Affairs wants to be assured that the flame retardants are used exclusively for the stated civil purpose. The more sensitive the country,

8 https://www.rijksoverheid.nl/documenten/rapporten/2006/10/23/handboek-strategische-goederen, consulted on 6 June 2017

the stricter the required guarantees. This ranges from a simple end-user declaration to agreements on inspections of the factory where the flame retardant concerned is being processed. If the Ministry of Foreign Affairs believes insufficient guarantees are given for the civil end-use, the export authorisation application will be refused.

- Examples of experiments with high misuse potential in **biology and biomedicine** include those that increase capacity[9]:
  - to manipulate the pathogenicity, virulence, host-specificity, transmissibility, resistance to drugs, or ability to overcome host immunity to pathogens;
  - to synthesize pathogens and toxins without cultivation of microorganisms or using other natural sources;
  - to identify new mechanisms to disrupt the healthy functioning of humans, animals and plants; and
  - to develop new means of delivering biological agents and toxins.

On-line educational materials:
http://www.fas.org/biosecurity/education/dualuse/index.html: Case Studies in Dual-use Biological Research, an 8-module resource that has been developed by the Federation of American Scientists.



5 Interesting links

- http://www.fdfa.be/csg
- http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls/
- EC Guidance note – Research involving dual-use items
- EC Guidance note – Potential misuse of research
- EC Guidance note – Research with an exclusive focus on civil applications
- https://www.sanctionsmap.eu/

Web links to US regulations:

- EAR (Export Administration Regulations): https://www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear
- ITAR (International Traffic in Arms Regulations) https://www.pmddtc.state.gov/regulations_laws/itar.html
- Office of Foreign Assets Controls: https://www.treasury.gov/resource-center/sanctions/Pages/default.aspx

9 http://nuffieldbioethics.org/wp-content/uploads/Background-paper-2016-Dual-use.pdf

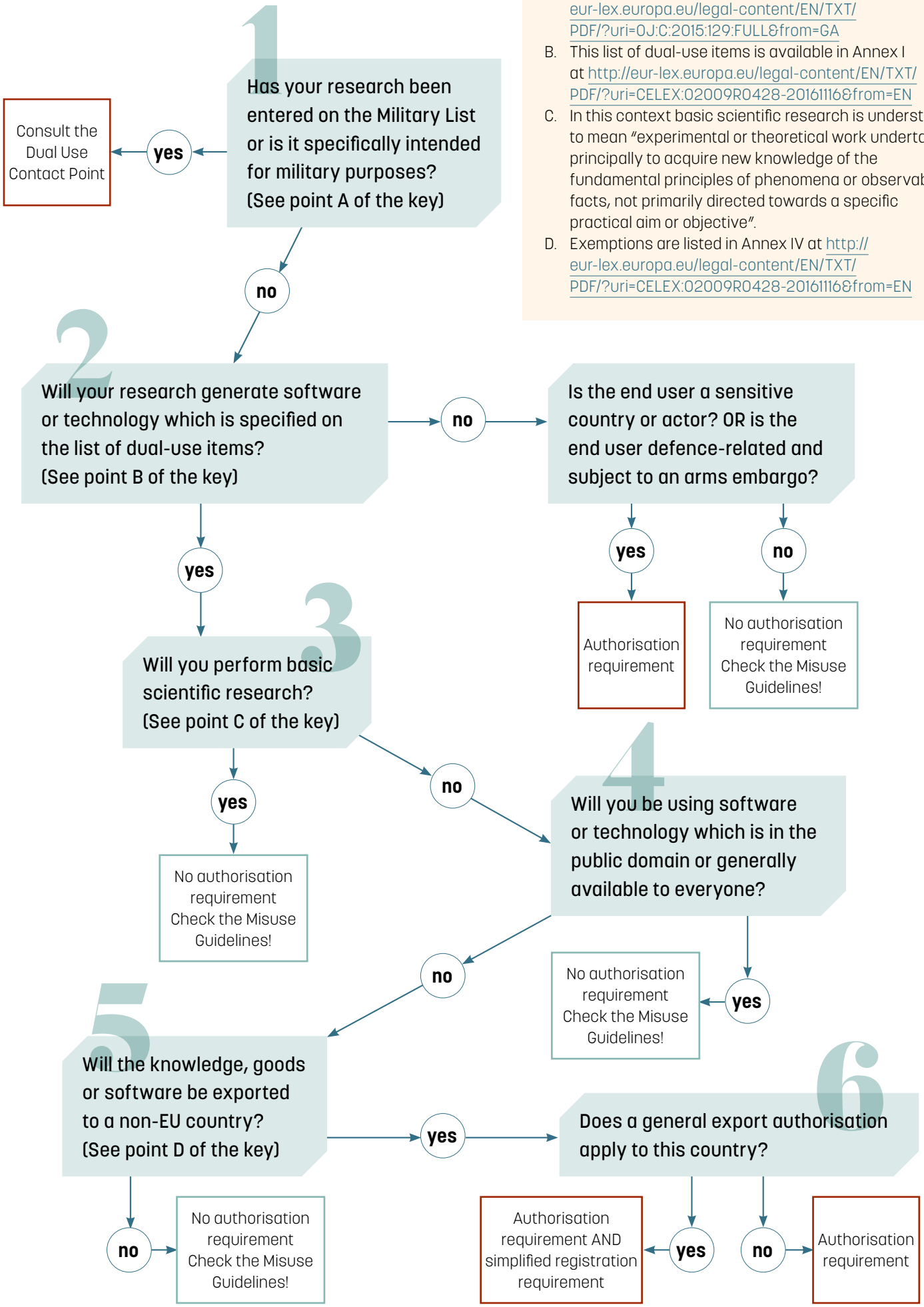
Key

A. This Military List is available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2015:129:FULL&from=GA

B. This list of dual-use items is available in Annex I at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R0428-20161116&from=EN

C. In this context basic scientific research is understood to mean "experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective".

D. Exemptions are listed in Annex IV at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R0428-20161116&from=EN



This brochure is the result of a collaboration between the 5 Flemish universities within the ad hoc Working Group Dual Use of the Flemish Interuniversity Council, with active participation of imec and the Flanders Institute for Biotechnology (VIB).

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