EU compliance guidance for research involving dual-use items

This guidance is developed to help researchers and research organisations to identify, manage and mitigate risks associated with dual-use export controls and to facilitate compliance with the relevant EU and national laws and regulations.

The guidance has 4 sections and is structured as follows:

- Section 1 summarizes how research organisations can be affected by EU and national dual-use export control regulations and how important top-level management commitment to compliance is to implement proportionate and effective internal compliance measures.
- Section 2 provides for awareness information to researchers, including the basics of dual-use export controls and the potential impact on research related activities.
- Section 3 provides for specific guidance to compliance staff on how to set up and review an Internal Compliance Programme.
- Section 4 gives an overview of the regulatory framework for dual-use export controls.

Sections 1 to 3 are drafted for the intended target audience mentioned above, so some overlap in the guidance could be provided.

This document applies to Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (the EU dual-use Regulation).

The content of the examples that refer to the control text in this guidance are to be understood as illustrative. They derived from Annex I to the EU dual-use Regulation that was in force in 2020. Please check the latest update of Annex I for classification according to the latest update.

The guidance will be updated, where necessary, in accordance to relevant revisions of the EU export control system.

Research organisations are invited to contact the national competent authority of the EU Member State where they are established in case they have enquiries linked to this guidance or to the development or implementation of an Internal Compliance Programme.

Glossary

This glossary explains or defines recurring terms used in this guidance. The items marked with an * refer to definitions from Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Term	Description or definition
Annex I, Annex II or Annex IV to the EU dual-use Regulation	Annex I, Annex II or Annex IV to Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. These annexes are updated periodically. For the latest updated version of Annex I, II and IV, see https://eur-lex.europa.eu/ .
Australia Group (AG)	Export control regime for controlling chemical and biological production equipment, materials and technology.
Biological Weapons Convention (BWC)	Convention on the prohibition of the development, production and stockpiling of bacteriological (biological) and toxin weapons and on their destruction.
Catch-all controls	Export controls for non-listed dual-use items according to the conditions referred to in Article 4 of the EU dual-use Regulation.
Chemical Weapons Convention (CWC)	Convention on the prohibition of the development, production, stockpiling and use of chemical weapons and on their destruction.
Consignee	First recipient abroad of the item(s) to be exported. This may be where the item remains in which case the consignee will be the end-user.
Dual-use items*	Items, including software and technology, which can be used for both civil and military purposes and including 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.
End-user	Final recipient abroad of the item(s) to be exported.
EU Common Military List	Common Military List of the European Union with equipment covered by Council Common Position 2008/944/CFSP defining common rules governing the control of exports of military technology and equipment. This list is updated periodically. For the latest updated version, see https://eur-lex.europa.eu/ .
EU Territory	Customs territory of the European Union
Export control regimes	Multilateral arrangements seeking to prevent the proliferation of nuclear, biological and chemical weapons and their means of delivery as well as to prevent the destabilizing accumulation of

	conventional arms and dual-use items, e.g. by establishing lists of items which should be under control. The export control regimes refer to Nuclear Suppliers Group, Zangger Committee, Missile Technology Control Regime, Australia Group and Wassenaar Arrangement.
Export*	 an export procedure within the meaning of Article 161 of Regulation (EEC) No 2913/92 (the Community Customs Code).
	 a re-export within the meaning of Article 182 of that Code but not including items in transit.
	 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.
Exporter*	Any natural or legal person or partnership:
	 on whose behalf an export declaration is made, that is to say the person who, at the time when the declaration is accepted, holds the contract with the consignee in the third country and has the power for determining the sending of the item out of the customs territory of the Community. If no export contract has been concluded or if the holder of the contract does not act on its own behalf, the exporter shall mean the person who has the power for determining the sending of the item out of the customs territory of the Community.
	 which decides to transmit or make available software or technology by electronic media including by fax, telephone, electronic mail or by any other electronic means to a destination outside the Community.
	Where the benefit of a right to dispose of the dual-use item belongs to a person established outside the Community pursuant to the contract on which the export is based, the exporter shall be considered to be the contracting party established in the Community
Internal Compliance Programme (ICP)	Effective, appropriate and proportionate policies and procedures, adopted by research organisations to facilitate compliance with the provisions and objectives of the EU dual-use Regulation and additional national measures.
	additional national incasures.

Intra-EU transfer (or transfer)	Movement or transmission of a dual-use item listed in Annex IV to the EU dual-use Regulation from a supplier in one EU Member State to a recipient in another EU Member State.
Listed dual-use items	Dual-use items that are listed in Annex I to the EU dual-use Regulation.
Missile Technology Control Regime (MTCR)	Export control regime for controlling delivery systems (unmanned aerial vehicles and missiles) for nuclear, chemical or biological weapons of mass destruction.
Non-listed dual-use items	Dual-use items that are not listed in Annex I to the EU dual-use Regulation. It includes items that are (just) below the technical thresholds in Annex I to the EU dual-use Regulation. Such items can become subject to export controls (catch-all controls).
Nuclear Nonproliferation Treaty (NPT)	Treaty on the non-proliferation of nuclear weapons
Nuclear Suppliers Group (NSG)	Export control regime for nuclear-related goods and technology.
Research organisations	Research-performing entities that are active in the academic or research sector, irrespective of their legal status (organised under public or private law) or way of financing, whose primary goal is to independently conduct fundamental research, industrial research or experimental development or to widely disseminate the results of such activities by way of teaching, publication or knowledge transfer. It includes universities, university colleges, academies of science applied research centres, and laboratories.
Technology Readiness Levels (TRL)	Technology Readiness Levels is a non-discipline specific measurement system with indicators of the maturity level of particular technologies.
United Nations Security Council Resolution (UNSCR) 1540	United Nations Resolution that aims at preventing non-state actors from acquiring nuclear, biological, and chemical weapons, their means of delivery, and related materials.
Wassenaar Arrangement (WA)	Multilateral export control regime for controlling conventional arms and dual use goods and technologies.
Weapons of Mass Destruction (WMD)	Chemical, biological, radiological or nuclear (CBRN) materials and their means of delivery with the capacity to kill large numbers of human beings.
Zangger Committee	The Zangger Committee maintains a Trigger List triggering International Atomic Energy Agency safeguards as a condition of the supply of nuclear-related goods.

Content

Glo	ssary	⁷	2
Sec	ction :	1 - Executive summary for management	6
Sec	ction 2	2 - Awareness for researchers	9
2	2.1	Introduction	9
2	2.2	Possible impact on academic research	9
2	2.3.	Basics of the EU dual-use export control system	11
	2.3.	1. The EU dual-use Regulation	11
	2.3.	2 How to read the control text?	14
	2.3.	3 Technology controls	15
	2.3.	4 Controlled activities	16
	2.3.	5 De-controls for "basic scientific research" and "in the public domain"	17
	2.3.	6 Red flags	19
	2.3.	7 Who is the exporter?	19
	2.3.	8 Frequently Asked Questions	20
		3 - Setting up or reviewing an internal compliance programme for research invo	_
3	3.1	Risk assessment	21
3	3.2	The core elements of an ICP	22
	3.2.	1 Top-level management commitment to compliance	23
	3.2.	Organisation structure, responsibilities and resources	24
	3.2.	3 Training and awareness raising	26
	3.2.	4 Export screening process and procedures	28
	3.2.	5 Performance review, audits, reporting and corrective actions	36
	3.2.	6 Recordkeeping and documentation	37
	3.2.	7 Physical and information security	38
Sec	ction 4	4 - Regulatory framework	40
2	l.1.	EU list of dual-use items	40
4	1.2.	De-control notes for "software" and "technology"	42
	4.2.	1 In the public domain	43
	4.2.	2 Basic scientific research	44
	4.2.	3 Minimum necessary information for patent applications	45
2	1.3	Controlled activities	45

4.4	Controls on export for non-listed dual-use items (catch-all controls)	46
4.5	Types of authorisations	46
4.6	Export controls and restrictive measures (sanctions)	48
4.7	Dual-use items versus military items	48
Appen	dices	49
	endix 1 - Research areas that are more likely to be impacted by dual-use export	49
App	endix 2 – Research scenarios of where export controls may come into place	52
App	endix 3 - List of red flags	55
App	endix 4 - Helpful questions when setting up a research organisation's ICP	57
	endix 5 - Flow chart of licence requirements for exports and intra-EU transfers of items	
	endix 6 - Examples of possible compliance organisation structure in a research inisation	62
App	endix 7 - Summary of licence requirements for dual-use items	64
App	endix 8 - Technology Readiness Levels	64
Ann	andiv Q - References and contacts	64

Section 1 - Executive summary for management

Research organisations have strong incentives to innovate and collaborate internationally as a basis to advancing research. A thriving European research and innovation sector attracts public and private investments from across the world. It is known that amidst many genuine and transparent collaborations to develop meaningful scientific and technological advancement, there are offers of collaboration, invitations and informal exchanges with covert motives, i.e. seeking access to research involving dual-use items for other purposes than those stated. Researchers and research organisations may then inadvertently violating export regulations.

Dual-use export controls exist to govern activities involving items (materials, equipment, software and technologies) which can be used for both civil and military purposes and possibly associated with the creation of conventional military items or the proliferation of nuclear, radiological, chemical or biological weapons, also known as Weapons of Mass Destruction, and their delivery systems such as missiles and drones.

Cooperation between researchers, research organisations and governments is essential to contribute to the European Union (EU) and Member States security goals, international security obligations and non-proliferation commitments such as the European Security Strategy, export control regimes, the Biological Weapons Convention, the Chemical Weapons

Convention, the Nuclear Non-proliferation Treaty and the United Nations Security Council Resolution 1540.

Dual-use export controls pose specific challenges for research organisations connected to the importance of sharing research results, together with the 'publish or perish' imperative in nowadays research ecosystem. Raising awareness about these controls is an important aspect of preventing and mitigating risks related to non-compliance. In the EU, the level of experience in implementing and managing such compliance measures within research organisations varies significantly. Competent authorities in the EU are committed to provide guidance for research organisations on how to strengthen internal compliance measures.

While it is recognised that it takes time for research organisations to set up and maintain such measures, a systematic and proportionate approach to internal compliance measures for dual-use export controls is vital to comply with the applicable EU regulation¹ and national complementary measures.

It is up to each research organisation to determine how internal compliance measures are best implemented and what internal operational procedures for individual researchers are to be followed. This could be accomplished by building new export control structures or incorporating these measures in (existing) structures, such as advisory bodies. An Internal Compliance Programme (ICP) for dual-use export controls is often only one part of the research organisation's overall compliance system.

Most of the activities performed by research organisations do not deal with dual-use items in the meaning of the EU dual-use Regulation and are thus not subject to dual-use export control scrutiny. Dual-use export controls are not meant to curb basic scientific research or scientific output already available in the public domain.

However, it is important that research organisations take proportionate and effective internal measures to minimise the risk of non-compliance. The absence of such measures may lead to legal liability being attached to the institution should non-compliance be detected. Top-level management commitment is needed to emphasise the importance and value placed on effective compliance and to provide sufficient resources to ensure the compliance commitments.

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¹ COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items - (Recast) - (OJ L 134 29.5.2009, p. 1) - http://data.europa.eu/eli/reg/2009/428/oj

EU Dual Use Research guidance-draft version for Targeted Consultation

This guidance builds on the EU guidance on Internal Compliance Programme for dual-use export controls published in August 2019², on existing guidance material for academia from EU Member States³ and on best practices provided by research organisations.

² COMMISSION RECOMMENDATION (EU) 2019/1318 of 30 July 2019 on internal compliance programmes for dual-use trade controls under Council Regulation (EC) No 428/2009 published on 5 August 2019 (OJ L 205) - http://data.europa.eu/eli/reco/2019/1318/oj

³ Consult your national authority for specific national guidance on this topic, if available. A list of national competent authorities is in Appendix 9.

Section 2 - Awareness for researchers

2.1 Introduction

Dual-use export controls exist to prevent the undesired accumulation of conventional military items and the proliferation of nuclear, radiological, chemical and biological weapons, also known as Weapons of Mass Destruction (WMD), and their delivery systems such as missiles and drones. Since dual-use items are predominantly used for civilian purposes, their potential for abuse is often not apparent at first glance. In the wrong hands, however, they pose a threat to international peace and the security interests of the European Union and its Member States.

Research organisations are often concerned about the public perception of research with military potential. 'Dual-use' in the context of research is often considered in a broad sense: what are the (un)desired civil and military applications of research, or what is potential misuse of research for unethical purposes.

With regards to the EU dual-use export control system, however, 'dual-use' is to be understood in a restricted meaning. It refers to items, including software and technology, which can be used for both civil and military purposes. For more information on the scope of listed and non-listed dual-use items, see sections 2.3 and 4.1.

Everyone, natural or legal persons, has the legal obligation when dealing with dual-use items to comply with the relevant laws and regulations. These legal obligations are not identical to (but may overlap with) ethical motivations or self-restriction that exist to prevent or mitigate the risks and potential damage which may be caused by malicious use of research involving dual-use items.

This guidance speaks of 'research involving dual-use items': dual-use items that are used during research or research that results in research output, in any possible form (e.g., hard-copy or electronic forms of dissemination, publication, presentation, communication and collaboration in which research results are made available to people other than the authors), meeting the technical specification of a dual-use item in the EU dual-use control list or in a complementary national dual-use list (if any). In a limited number of cases, it includes situations with military or WMD end-use(r) concerns for non-listed dual-use items.

2.2 Possible impact on academic research

Academic freedom is a fundamental right guaranteed by the Charter of fundamental rights of the European Union⁴. However, academic freedom does not exempt the researchers and research

⁴ Article 13 of the 'Charter of Fundamental Rights of the European Union' published on 7 June 2016 (*OJ C 202*) - http://data.europa.eu/eli/treaty/char_2016/oj

organisations from complying with regulations that are established to safeguard the security interests of the EU and of its Member States⁵.

Research disciplines within Science, Technology and Engineering are more likely to be affected by dual-use export controls than academic activities in Humanities, Social Sciences and Economics.

The following topics are **examples of research that could trigger dual-use export controls**:

- changing the host spectrum of Lumpy skin disease virus to include human reservoirs;
- multispectral imaging camera sensors for data collection of crops;
- laser-based next-generation uranium enrichment technology as a potential alternative for the industrial enrichment that involves gaseous uranium in centrifuges;
- 3D printing of energetic materials;
- prototype drone with spraying system for combatting Eastern equine encephalitis virus; and
- autonomous scientific underwater vessel that collects data automatically in deep sea regions.

Appendix 1 illustrates research areas that, among others, may be affected by dual-use export controls as the EU dual-use control list contains items in these technology domains.

Appendix 2 highlights some recurring research scenarios that may trigger export controls:

- Teaching^{6,7}, consulting, collaborating or working on research involving dual-use items with visiting foreign researchers inside EU Territory⁸;
- Teaching, consulting, collaborating or working on research involving dual-use items outside EU Territory;
- Organising a (virtual) conference/meeting/seminar/... or presenting at a (virtual) conference/meeting/seminar/... on EU Territory on research involving dual-use items inside or outside EU Territory;

⁵ National legislation on academic freedom and limits therein may exist as well.

⁶ Teaching generally does not address research involving dual-use items. Educational information used for teaching is generally already in the public domain and thus exempted from export controls. Exempting teaching by default from dual-use export control scrutiny is, however, not correct. By means of example: educational material that is not available in the public domain and which is important to the design, construction, operation, or maintenance of an uranium enrichment or nuclear fuel reprocessing facility may face export controls.

⁷ In many cases export controls do not apply to teaching activities. But teaching to third country nationals inside the EU Territory may fall under the notion of "technical assistance" as provided by restrictive measures (sanctions) regulations.

⁸ Visa screening is often performed distinct from export controls inside research organisations and by different competent authorities.

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- Publishing listed dual-use technology;
- Submitting information for patent application and patented information; and
- Exporting tangible dual-use items (goods).

In each of these scenarios, it is also important to determine if any EU or national sanctions apply for the involved items, for the type of activity, for the end-use or the entities and countries involved.

In these scenarios, it is irrelevant whether the research was supported exclusively by public national or EU funding programs. Hence, the origin of research funding or the nature of research partners does not determine whether the research involving dual-use items meets the control thresholds.

Dual-use export controls may arise at different levels during the research life cycle: at the stage of research funding, project application, contract development, disseminating research output, etcetera. Section 3 provides more information on how to set up a systematic export screening procedure at the different levels during the research life cycle.

2.3. Basics of the EU dual-use export control system

2.3.1. The EU dual-use Regulation

The EU dual-use export control system is governed by Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items ('the EU dual-use Regulation').

- Annex I to the EU dual-use Regulation contains the EU list of dual-use items.
- All items in Annex I to the EU dual-use Regulation require a licence for exporting outside the EU Territory.
- Annex IV to the EU dual-use Regulation is a small subset of Annex I which contains more sensitive items that require a licence also for intra-EU transfers.

Annex I is dynamic to account for technological advances over time and the EU export controls reflect commitments agreed upon in export control regimes. Therefore the list is regularly updated. It is important to always consult the latest version of Annex I to the EU dual-use Regulation⁹.

The classification of dual-use items is based on objective technical criteria, and the end-use and end-user do not play a role in the technical classification. Accordingly, it is irrelevant for the

⁹ See https://eur-lex.europa.eu/, the website of your competent export control authority or an internal source in your research organisation for the latest version of Annex I to the EU dual-use Regulation.

classification and for the existence of the licensing requirement whether the item is to be used exclusively for civilian purposes or whether a military use is intended. However, the end-use and involved parties play an essential role in the question of eligibility for licence approval. Consult sections 3.2.4 and Appendix 3 for more support on end-use and end-user checks.

Every dual-use item has a classification number. This is a combination of numbers and a letter (comprising the Category, the Subcategory and the individual control entry) and is crucial for the item classification and authorisation documents. The classification number is not random; it refers to the nature of the item and the origin of control by the corresponding export control regime (see Figure 1).

Figure 1 illustrates by means of example the meaning of the dual-use classification number.

The dual-use classification number 9A012.a. refers to controlled unmanned aerial vehicles (or drones) with technical specifications and certain technical and related equipment and components.

- '9' means that the item is listed in Category 9 (Aerospace and Propulsion)
- 'A' means that the item is listed in Subcategory A (Systems, equipment or components).
 Hence, a complete drone meeting the technical specifications under 9A012 will be listed under A.
- '012' means that the item originates from the control list of the Wassenaar Arrangement
- '.a.' is the individual sub-control entry for complete drones.

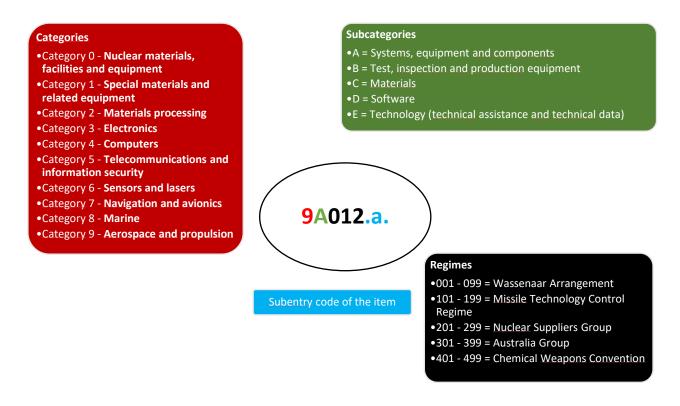


Figure 1 - Dual-use classification number for drones (9A012.a)

Concerning the list of dual-use items in Annex I to the EU dual-use Regulation, it is important to keep the following in mind:

- Dual-use items are distinct from military items. Military items are commodities (such as systems, equipment, components, materials, software or technology) that are specially designed or modified for military use, whereas dual-use items are controlled based on their technical specifications. See also subsection 4.7.
- The items specified in Annex I to the EU dual-use Regulation include both new and used (second-hand) items.
- The dual-use classification list number is not the same as the customs commodity code (Harmonised System or Combined Nomenclature). ¹⁰

¹⁰ A Correlation Table between dual-use control list numbers and customs commodity codes (CN codes) is provided by the European Commission and is available on DG TRADE dual-use webpage. Classification of commodities according to the EU dual-use checklist solely based on customs codes (so called Correlation Table) is however not sufficient, accordingly to the different correlation degree of each CN code to the corresponding dual-use classification number.

- The EU dual-use list contains tangible items (equipment, materials), but also intangible items such as software or technology in the form of technical data or technical assistance. Intangible items can be transferred in tangible format (e.g. hard-copy slides or physical data storage device) or transferred electronically, visually or orally (also known as intangible format).
- Controls on technology are of the utmost importance. If proliferators are able to obtain a tangible dual-use item, they may be able to copy parts of it, but they would not necessarily be able to produce additional items. However, if they acquire the technology to develop or produce the item, they can manufacture as many as they want. Additionally, while tangible items may be exported temporarily, the export of technology is almost impossible to recover and is to be considered as definitive.
- An authorisation issued for an item also covers the minimum technology necessary for the installation, operation, maintenance and repair of that item.

2.3.2 How to read the control text?

Annex I to the EU dual-use Regulation is long and there is no single best way to quickly find each and every listed dual-use item. During a novel classification exercise it is important to go through the latest version of Annex I thoroughly to find the most relevant and thus most specific control entry for the item at hand. In case of doubt or in case of multiple possible classification numbers, consult the compliance officer at your research organisation or, where appropriate, the competent authority.

In many control entries there are several notes (Note, Technical Note or *Nota Bene*) to assist in the exact item classification. These notes further clarify the control scope (including illustrations or de-control) or make a cross reference to other parts of Annex I or the EU Common Military List¹¹. These notes are integral part of the item classification and thus should not be considered as illustrative.

The list has a set of global definitions¹² indicated with " " and local definitions indicated with ' '. These definitions may differ from commercial of scientific jargon.

Example: The dual-use control number of the SARS-related coronavirus is 1C351.a.57.

1C351 Human and animal pathogens and "toxins", as follows:

¹¹ Common Military List of the European Union with equipment covered by Council Common Position 2008/944/CFSP defining common rules governing the control of exports of military technology and equipment. This Common Military List is updated every year in line with the amendments of the Munitions List of the Wassenaar Arrangement.

¹² This set of global definitions can be found in Annex I to the EU dual-use Regulation under the heading 'Definitions of terms used in this Annex'.

a. Viruses, whether natural, enhanced or modified, either in the form of "isolated live cultures" or as material including living material which has been deliberately inoculated or contaminated with such cultures, as follows:

...

57. Severe acute respiratory syndrome-related coronavirus (SARS-related coronavirus);

...

Note: 1C351 does not control "vaccines" or "immunotoxins".

2.3.3 Technology controls

For category 1 to 9, only that part of "technology"¹³ that is "required" for the "development", "production" or "use" of goods controlled in Categories 1 to 9, is controlled according to the provisions of Categories 1 to 9. "Required" is defined as that part of the information which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions from the dual-use control list.¹⁴

Hence, for category 1 to 9, only this specific information is to be considered as listed dual-use technology. The aim of the definition of "required" is to focus the technology controls on the specific technology that makes an item subject to license. Importantly, listed dual-use technology remains under control even when applicable to any uncontrolled item.

Example:

1E001 controls "technology" according to the General Technology Note for the "development" or "production" of equipment or materials specified in 1A002 to 1A005, 1A006.b., 1A007, 1B or 1C.

Let's apply this to 1C216.

1C216 specifies the controls for maraging steel. This item is controlled in Category 1 therefore the General Technology Note is applicable. Hence, the controlled dual-use technology under 1E001 is the one that is "required" for the "development" or "production" of maraging steel with the specifications of 1C216.

What is not controlled under 1E001?

Research output detailing

this type of maraging steel without providing detailed information on how to develop or produce this type of maraging steel;

¹³ "Technology" in the context of the EU dual-use Regulation means specific information necessary for the "development", "production" or "use" of goods. This information takes the form of 'technical data' or 'technical assistance'.

¹⁴ For category 0 (nuclear related items), the technology controls are broader. In only a few cases there are standalone technology controls in category 0 to 9.

- an historic overview of existing production methods (in the public domain) of this type of maraging steel;
- an innovative production process of maraging steel that does not meet the required thresholds in 1C216 (and 1C116).

What is controlled under 1E001?

Samples of maraging steel

Research output detailing

- existing development or production processes that are not yet in the public domain and are not basic scientific research.
- an innovative (not yet in the public domain) development of production process of maraging steel that does meet the required thresholds in 1C216 and that is not basic scientific research.

It is a good practice based on internal review mechanisms to detect early on in the research program or project which of the involved equipment or materials, or the anticipated results (such as publications) may need further dual-use export control scrutiny. If such (potential) dual-use export control issues are identified, follow-up is needed during and at the end of the research programs or projects.

Publications will rarely in entirety meet the controlled technology threshold. Some subsections of the publication may meet the threshold. Only these parts are licence required. The exporter is obliged to adequately assess the technology to determine if it meets the threshold for dual-use control. Due to their expertise and knowledge of their own research, the researchers is most suited to adequately classify their own research, possibly with the support of trained administrative staff that is familiar with the structure of the EU dual-use list. If the researcher or research organisation is in need of guidance they can contact their national competent authority. This enables the researcher or research organisation to make an informed choice regarding which parts should be submitted for export licence application before publication.

2.3.4 Controlled activities

There are four different types of activities that require an authorisation, two of which are constant (export authorisation for movement or transmission of items outside the EU Territory and transfer authorisation for movement or transmission of items inside the EU Territory) and two of which occur on a case-by-case basis (transit authorisation for items passing through the EU Territory and brokering authorisation to brokering of items between third countries from inside the EU Territory).

Some items do not meet the technical specifications of Annex I, but are nonetheless proliferation sensitive due to their technical possibilities or suspected end-use of concern. In some cases such items could also require an authorisation requirement for exports. Controls for non-listed dual-use items are called 'catch-all controls' (see also subsection 4.4).

See Appendix 5 for a flow chart on determining the licence requirements under the EU dual-use Regulation.

2.3.5 De-controls for "basic scientific research" and "in the public domain"

The role of dual-use export controls is not to regulate research as such. It is to regulate the export (and in some cases transfer, transit and brokering) of research involving dual-use items.

Determining whether research involves dual-use items can be challenging. Innovative research does not easily allow itself to be labelled according to the existing control entries. A good understanding of the definition of "technology", the technology notes and the de-control notes "basic scientific research" and "in the public domain" are essential to navigate through the control text. See subsection 4.1 for more information on the definition of technology and the technology notes.

Key take-aways for the definition of technology and the technology notes

- Technology is defined as the specific information necessary for the "development", "production" or "use" of listed dual-use items. This means that in order to be classified as listed dual-use technology, the technical data or technical assistance must contain specific information for the development, production or use of the goods specified in categories 0 through 9. The meaning of specific information is not defined in the EU dual-use Regulation. The meaning of development, production and use is defined.
- The definition of technology needs to be read in conjunction with the Nuclear Technology Note for category 0 and the General Technology Note (for categories 1 to 9).
- For category 0 (nuclear items), listed dual-use technology is the specific information that is 'directly associated with any goods controlled in Category 0'. This is a broad description; hence the range of controlled nuclear technology is bigger than compared to the controlled technology in category 1 to 9.
- For category 1 to 9, only that part of "technology" that is "required" for the "development", "production" or "use" of goods controlled in Categories 1 to 9, is controlled according to the provisions of Categories 1 to 9. "Required" is defined as that part of the information which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions from the dual-use control list. These controlled performance levels, characteristics or functions are generally very specific and high, hereby thus limiting the technology that meets the "required" threshold. And thus limiting the technology for which one may seek to apply the de-control notes "basic scientific research" and "in the public domain".

The de-control notes state under which conditions a certain listed item is excluded from control, which means that no license is required for export or transfer. In case of technology, the EU dual-

use Regulation states that there are exemptions for "basic scientific research" and technology that is already "in the public domain" ¹⁶.

See section 4 to this guidance for a more detailed explanation about these de-control notes.

Key take-aways for the de-control note "basic scientific research"

Basic scientific research is a de-control for listed dual-use technology only. It cannot be used for tangible items such as equipment and materials.

In essence, it de-controls research output and not the intention to produce research output (at the research funding stage). This is a crucial distinction when to consider applying this de-control note.

Technology Readiness Level (TRL) and prevalence of industry funding are two indicators to assist in assessing the applicability of the de-control note:

- See Appendix 8 for a description of the different TRL levels. For export control purposes, research output stemming from TRL 1 and 2 research are generally considered as basic scientific research. The eligibility of research output stemming from TRL 3 and 4 are to be assessed on a case-by-case basis. Research output stemming from research above TRL 4 is not anymore considered as basic scientific research.
- Research that is externally funded by an industry partner is likely to result in a commercial development, regardless of whether the project is initiated by industry itself or a public body. Furthermore, in many cases (via contractual arrangements) the industry funder (or sponsor) could be given the opportunity to review and comment on publications (or presentations) prior to their release and to request the (temporary) exclusive use of research results or pre-patent information. These types of collaboration can be indicative that the resulting research output will not be basic scientific research and thus may require a licence before publication or patenting.

Key take-aways for the de-control note "in the public domain"

The de-control note "in the public domain" only applies to controlled dual-use technology that is already in the public domain (has been made available).

¹⁵ The EU dual-use regulation defines "basic scientific research" as 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.

¹⁶ The EU dual-use regulation defines "in the public domain" as follows: "technology" or "software" which has been made available without restrictions upon its further dissemination (copyright restrictions do not remove "technology" or "software" from being "in the public domain").

In essence, it de-controls listed dual-use software and technology anyone can obtain.

The reference to 'without restrictions' has to be understood as not limiting the access to only a restricted group of persons. If information is only made accessible after an individual decision has been taken by the information carrier or owner, than not everyone has the possibility to access the information, and thus the information cannot be considered as being in the public domain.

Legal restrictions, for example copyright restrictions, without relevance under export control law do not affect eligibility for being de-controlled. Other similar restrictions could be requesting a fee for access or prior registration to access, as long as everybody is allowed to pay the fee or register.

The de-control note only applies to software and technology, whether in a tangible or intangible format.

2.3.6 Red flags

Being vigilant for signs of suspicious enquiries or collaborations is vital for countering the risks of WMD proliferation, their means of delivery, and the destabilising accumulations of conventional weapons. Sharing suspicious information with your internal compliance point of contact is highly recommended. In some cases information sharing with the competent export control authority may be mandatory under EU and national laws and regulations.

Appendix 3 provides a list of 'red flags' to assist researchers to make an initial assessment whether dual-use export controls may apply. This list groups the red flags according to the research, enduse and end-user, shipment, and funding, finance and contract condition. This list is particularly useful for non-listed dual-use items (to determine whether catch-all controls may apply). It is a good practice as well to use this list when gathering necessary information during the licence application process for listed dual-use items.

Based on your research organisation's internal policy, additions or amendments to the list below can be made. Researchers know best what is suspicious within their research area.

2.3.7 Who is the exporter?

Both natural persons and legal persons are covered by the definition of exporter. This means that a researcher on his or her own behalf or on behalf of the research organisation can be the exporter. The exporter definition applies not only to export operations, but to all controlled activities of the EU dual-use Regulation, including the intra-EU transfers for items listed in Annex IV. It is up to the research organisation to make internal arrangements concerning who will apply for a licence.

It should be noted that the identification of the exporter is different from the identification of an export. When a visiting third country researcher gets access to, for instance, controlled technology at a university campus inside EU Territory, then no export takes place. When this researchers returns home to his/her third country with this controlled technology, then an export takes place which requires an approved and valid licence. Hence, prior to this export, a licence

application needs to be filed. The last person inside the EU Territory deciding on the transmission of the controlled technology outside the EU, needs to apply for a licence. Who may apply for this licence application, is up to each EU Member State to decide. It may be the visiting third country researcher, but in many cases, this researcher will need to have a representative that is established inside the EU Territory. Despite who is the exporter, an export control violation takes place when this controlled technology leaves the EU Territory without an approved and valid licence.

2.3.8 Frequently Asked Questions

If a publication contains controlled technology, does the author, the university or the scientific publisher have to apply for a licence?

It is up to the research organisation to make internal arrangements concerning who will apply for a licence. The key point here is that a person needs to apply for a licence and thus act as the exporter. Who that is depends on the internal policy or the contractual arrangement between the author of the publication and the scientific publisher. If the publisher is established outside the EU, then the last person inside the EU deciding on the transmission of the controlled technology outside the EU, needs to apply for a licence.

Can an employee of a research organisation when traveling abroad on a professional visit remotely accessing controlled technology or software located on the server of an EU-based research organisation?

Employees accessing controlled technology or software abroad on a professional visit generally have to apply for a licence before traveling. Some EU Member States¹⁷ consider the key determinant here whether the controlled technology or software is accessed abroad by other persons (besides the employee(s)).

Who needs to apply for a licence in case of a research consortium with partners in multiple EU Member States and third country partners?

The exporter, and thus the one who has to apply for a licence, is the one that is the contractual partner of the consignee in the third country and has the power for determining the sending or transmission of the items from the customs territory of the EU (for Annex I items). In other words, the consortium partner itself or the consortium leader itself may have to request a licence before sending off the dual-use items. This depends on the contractual arrangements between the consortium partners and the consortium leader.

Page **20** of **64**

¹⁷ See Appendix 9 for the contact details of the competent authorities or contact the compliance officer inside your research organisation to determine what is the situation in your EU Member State.

Section 3 - Setting up or reviewing an internal compliance programme for research involving dual-use items

The role of every Internal Compliance Programme (ICP) is to systematically address and mitigate one or more types of risk in order to ensure compliance with obligations set in the law or undertaken voluntary by an organisation.

In a research environment, setting up compliance measures to conform to export control laws and regulations is a process that takes time and effort.

The section below lays out all the main elements that a research organisation should consider when it designs or reviews its internal dual-use export compliance system.

3.1 Risk assessment

While considering whether and to what extent it is concerned by dual-use export controls, a research organisation needs to conduct an initial risk assessment by examining the following parameters:

- 1. The subjects of its activities (e.g., disciplines and research areas where it is active). For an overview of research areas that are more likely to be affected by export controls see Appendix 1.
- 2. The type and scope of these activities (e.g., field research, online and distance learning and amount of international collaborations and foreign participation involved in its activities).
- 3. The current status of institutional policies and standardised procedures (e.g. type of organisation structure, existing mitigating measures for security risks and predominant attitudes of the staff).

These parameters have to be assessed against legal obligations set in the EU and national export control laws¹⁸. At the end of this initial risk assessment, a research organisation will be able to determine its specific dual-use risk profile. This will help the organisation to become aware of the parts of its research activities that need to be covered by the ICP (scope of its internal export compliance system) and target the ICP to the organisation's specific circumstances (e.g., structure, institutional procedures and available resources).

The initial risk assessment is instrumental in designing and implementing ICP measures which are efficient, proportionate and tailored to the specific profile of the organisation. It is often

¹⁸ An overview of the export control obligations at the EU level is offered in sections 2 and 4 of this guidance.

preferable to start by addressing activities/research areas that require immediate action and such areas which are easily identified as involving dual-use items. Following that, the ICP can be expanded to cover additional sources of risk and consolidate more robust mitigating procedures. Integrating dual-use internal compliance measures to existing institutional policies and procedures is often a key to creating efficiencies and synergies.

Research organisations should take into account a dynamic legal and research environment where risks should be determined or re-evaluated regularly and thus, internal compliance measures depend on the evolving control lists and the activities of a research organisation undertaken each time¹⁹. Indeed, a more thorough evaluation and rating of materials, equipment, software and technology involved or produced in a research takes place under the "export screening process and procedures" as explained in core element 4.

3.2 The core elements of an ICP

This section builds on Commission Recommendation (EU) 2019/1318 of 30 July 2019 on internal compliance programmes for dual-use trade controls under Council Regulation (EC) No 428/2009.

It presents an adaptation of the ICP core elements to make them more suitable for use in a research context. This adaptation is based on feedback received from the research community.

- 1. Top-level management commitment to compliance
- 2. Organisation structure, responsibilities and resources
- 3. Training and awareness raising
- 4. Export screening process and procedures
- 5. Performance review, audits, reporting and corrective actions
- 6. Recordkeeping and documentation
- 7. Physical and information security

In Appendix 4 a checklist for each core element is provided to support developing an ICP, or at a later stage reviewing an existing ICP.

¹⁹ C. Charatsis, "Interferences between non-proliferation and science: 'exporting' dual-use know-how and technology in conformity with security imperatives", Publications Office of the European Union (Joint Research Centre.-European Commission and Université de Liège), December 2017, p. 153.

3.2.1 Top-level management commitment to compliance

Top-level management commitment and support to an ICP is important for both symbolic and practical reasons. A proclaimed statement of commitment to compliance with export control law by the top management body/function of the organisation can raise the awareness of the staff, increase the importance attached to such compliance measures, and result to enhanced human and technical resources by other departments of the organisation.

What is expected from research organisations?

As in every organisation, top-level management commitment aims to increase legitimacy of compliance measures and create or enhance an organisational culture that is conducive to dual-use export control imperatives. In a research environment, top management commitment is all the more important in order to encourage and actively support the deployment of an ICP.

Given that research organisations and particularly universities often feature decentralised models of organisation structure, it might be useful to consider the expression of commitment also at a department, faculty or school level (e.g., the different deans of faculties/schools). Such an approach can be particularly relevant to organisations having just few departments potentially concerned by export controls.

This element is materialised by a written statement and support from top-level management which results in sufficient organisational, human and technical resources for the organisation's ICP. Such commitment statement calls all concerned staff to comply with the relevant EU and Member State laws and regulations and take the necessary precautions when using controlled inputs or producing research outputs that can be controlled.

What are the steps involved?

Develop a commitment statement stating that the scientific and administrative staff shall comply with all EU and national dual-use export control laws and regulations by applying the mitigating measures foreseen in the organisation's policies and procedures.

Clearly and regularly communicate the commitment statement to all potentially concerned staff (also staff with no role in dual-use export control) in order to raise awareness and promote a culture of compliance with the dual-use export control laws and regulations.

Consider using all available means (either electronic or print-outs) to publicise the statement and sources of information about the internal compliance procedures of the organisation²⁰.

²⁰ Research organisations could also consider to disseminate the statement in both public and internal websites, codes of conduct and staff regulations to inform staff about the importance of the trade controls and the cost of non-compliance for the research community and the university.

3.2.2 Organisation structure, responsibilities and resources

Each research organisation is unique and therefore, there is not only one way to organise compliance procedures and allocate respective responsibilities. However, having a well-defined set of procedures and responsibilities for export compliance can help the organisation to achieve its compliance objectives and improve its management model as a whole.

What is expected from research organisations?

In a research context, there are different types of responsibility to be considered. Typically, such responsibilities will be shared by both administrative and scientific staff.

The first type of responsibility concerns the overall responsibility for implementing the organisation's compliance policies, which lies with the management of the organisation. This responsibility might entail approval of license applications, oversight that sufficient resources are allocated to compliance as well as approval of regular reviews and updates of the compliance measures in place. In some Member States, this function must be assumed by a member of the top-level management.

The second type of responsibility requires the establishment of an export compliance function responsible for developing or implementing the compliance measures of the organisation. The tasks of this function may include: responding to export control enquiries, deciding whether a licence application is relevant and what mitigating measures are necessary for a given activity. The export control function may also help staff to understand license conditions, apply due diligence checks and maintain appropriate records.

This responsibility is typically assumed by a department having experience in complying with legal obligations and interacting with the organisation's staffs and external collaborators²¹. There should be at least one person in the organisation who is entrusted with export compliance (not necessarily exclusively). If possible, the export control function should be free from conflicts of interest. Also, it should have direct access and a reporting obligation to the top management.

In addition to this, it might be necessary to appoint points of contact in different departments of the organisation, who can raise awareness, guide the administrative and scientific staff whenever

Page **24** of **64**

²¹ Depending on the structure of an organisation, experience in dealing with such tasks will most probably reside in the 'compliance office', the 'legal department', the 'research office', the 'security department' or, in the 'technology transfer office'. The specific terms used are suggestive names used frequently by various research organisations. The list with examples of departments offered is not exhaustive.

a relevant issue arises and, if necessary, refer enquiries and requests to the export control function.

The third type of responsibility concerns the implementation of practical steps to be taken by scientific staff in order to ensure conformity with the organisation's compliance requirements. This function entails tasks such as identifying projects that might require a license, apply enduse/end-user checks and undertake the prescribed mitigating measures and approvals while performing research activities. While all concerned staff must adhere to the organisation's compliance procedures when performing their work, typically the responsibility to identify sensitive projects and apply the required checks lies with the project leader. Frequently, this is the person who secures the funding and coordinates the project within an organisation, known also in some research contexts, as the Principal Investigator.

Administrative staff (e.g. from the procurement and legal department) can be in charge of certain compliance tasks as foreseen by the compliance policies. Such staff can be part of the export compliance function or merely collaborate closely with it.

Administrative staff might be able to identify issues that have escaped the attention of the research staff. This way, trained administrative staff could act also as the "gate keepers" when other safeguards fail²².

What are the steps involved?

Determine which parts of your organisation are relevant for export control compliance. Identify and appoint the person(s) with the overall responsibility and attribute at least one person to the export compliance function. Depending on the organisation's needs this person may only have to handle tasks relating to dual-use export control on a part-time basis.

Consider all different types of responsibility and compliance related functions. Define clear processes and responsibilities for both administrative and scientific staff. Start by the departments conducting research in a critical area and expand to address other less sensitive departments as your compliance system evolves. Do not overlook to define the delegation of powers (e.g. in case of sickness or holidays) and back-up functions whenever possible.

Page **25** of **64**

²² For instance, while processing contracts and agreements, trained administrative staff can identify contractual requirements that potentially pose export control issues (e.g. restrictions to accessing the research results), allude to sensitive topics of applied research, and/or pose suspicions concerning end-users/end-uses and destinations/nationalities involved. Likewise, the administration can encounter and report to the export compliance function inconsistencies with terms of export licenses or other ICP requirements throughout the execution of projects and research activities.

Ensure that appropriate resources are allocated to the ICP and consider the knowledge and skillset needed in terms of both legal and technical expertise. Written job descriptions are recommended.

Be ready to fully exploit expertise and experience already available in different parts of the organisation. Consult with colleagues of different departments (e.g., procurement, security and legal department) on the ways that available policies and procedures could accommodate export compliance requirements. Consider setting up - along with your IT support - online tools and procedures to facilitate the implementation of internal compliance measures.

Codify the organisation's export compliance policies and procedures including the main chain of responsibility in manuals/handbooks and make them available to the organisation online or in hard copy. Try to use language that is as precise and clear as possible. Consider including examples and practical cases such as the ones offered in this guidance or in national sources.

Make sure that the scientific and administrative staff knows what procedure to follow and who is the contact point whenever an export control question arises.

Appendix 6 offers two examples of possible compliance organisation structure in research settings.

3.2.3 Training and awareness raising

Training and awareness raising is an important element of every ICP and it should be tailored to the specific situation of a research organisation. Awareness raising is considered the first step in enabling both scientific and administrative staff to understand security risks and fulfil their responsibilities under the export control law and the organisation's ICP. Training includes specialised courses tailored to the functions and staffs in the organisation that are affected by export controls.

What is expected from research organisations?

Research organisations need to consider awareness raising and training initiatives at different levels, through different means and with varying goals.

First, general introduction to export control issues for all potentially concerned research staff and students is important for raising awareness and promoting a culture of responsibility throughout the organisation. This can be accomplished through inclusion of references to export control

objectives and related internal measures in codes of conduct, webpages on ethics and research integrity, as well as general safety and security courses provided regularly²³.

Second, general training and awareness raising activities should be developed for those scientific staff coming from the organisation's departments identified as of relevance to export controls in the initial risk assessment and subsequent re-assessments. The aim of these trainings is to make staff familiar with export control requirements and ensure that they are able to take the necessary action when an issue or concern arises in the design, planning, and execution of their research.

Third, targeted training should be conducted towards administrative staff dealing with the implementation of the different internal control procedures such as those relating to security, procurement, technology transmission, contracts and research collaborations. Likewise, specialised training should be organised for research staff being regularly affected by the implementation of export controls due to their involvement in sensitive projects requiring particular attention and control measures.

A research organisation may perform very different types of research and dual-use export control lists relate to a wide spectrum of items and technologies. This implies a need to consider developing training material and approaches tailored to audiences coming from different departments, expertise and backgrounds.

Taking into account the dynamic character of the export control laws and developments in this area, training should be carried out on an annual basis while the staff having the main responsibility for the operation of the ICP should update available tools and information material regularly.

Please check with your national authority whether additional resources such as subscription to information sessions and newsletters, national guidance and trainings are available.

What are the steps involved?

Provide compulsory, periodic training for all staff potentially involved in export controlled dualuse activities in order to raise awareness of export control issues and infuse a culture of responsibility throughout the organisation.

²³ A research organisation and particularly a university could take further initiatives to include an awareness raising section concerning non-proliferation and export control issues in the curricula of most sensitive disciplines.

When possible, use existing training initiatives such as introductory courses for newly recruited staff to incorporate references to export compliance measures and requirements. Follow the same approach with staff regulations and didactic material being already in use.

Ensure via awareness raising tools (e.g., decision trees, intranet webpages, information and acknowledgement notes in export control relevant procedures) that all concerned staffs are aware of all internal policies and measures on export controls. Make use of material containing information on relevant EU dual-use export control laws and control lists and restrictive measures, as well as national measures and embargoes. Consider making user-friendly tools (developed in-house or provided by external resources) available to all concerned staff to facilitate easy navigation through these legal documents and their updates. If possible, consider customised trainings for both administrative and scientific staff.

Consider, whenever appropriate, to make use of opportunities to receive national or EU training for dual-use export controls.

Incorporate lessons learnt from performance reviews, audits, reporting and corrective actions, whenever possible, in your training or export awareness programmes. Conversely, take note of any findings alluding to an insufficient functioning of the compliance measures in place.

3.2.4 Export screening process and procedures

This element contains internal measures the organisation should implement to ensure that no "export" takes place without the required license or against any relevant export restriction or prohibition.

The export screening process collects and analyses relevant information concerning the following aspects: item classification, risk assessment of the activity, license determination and application, and post-licensing. While following the steps mentioned below, a research organisation needs to design and operate an export screening process taking into the specific types of activities undertaken, existing institutional policies and procedures and the specific challenges linked to the risk profile of the organisation.

What is expected from research organisations?

The export screening process is in the very heart of the organisation's internal compliance measures. The implementation of this element must be shared by administrative and scientific staff as their compliance roles have a mutually reinforcing impact on the operation of an ICP. The aim is to set up screening procedures that specify the steps involved for complying with the export control law and the organisation's internal control policies. Depending on the scope and the

sensitivity of the research undertaken, the export control screening process can be relevant to a number of activities:

- Exporting items (through tangible means of transfer);
- Contracting (primarily with international partners)²⁴;
- Patenting/licensing of research results;
- Publishing (e.g. articles, conference material, software);
- Electronic transmissions (including making items available online);
- Hiring staff and receiving visitors (mostly, sanctions related);
- Traveling abroad.

A research organisation can consider adjusting its institutional policies and procedures concerning all the activities mentioned above by inserting export control checks and verifications. Most of the time, non-university research institutes have centralised procedures in place, that can be adapted to accommodate such screening and mitigating procedures. Universities can choose to follow the same approach, tailored to their needs.

In a research organisation and particularly in a university, export controlled activities can take place in the context of both formal collaborations with external partners and informal exchanges. In the latter case, the exchanges can take place mostly at the level of individual researchers. Therefore, the export screening process shall address both possibilities and introduce screening procedures and checks for identifying whether a specific research activity entails the "export" of a controlled item.

Individual researchers must be able to identify and report export control issues while conducting their research. This can be materialised by using generic tools such as decision trees guiding researchers through the steps to be taken in identifying possible export control issues²⁵. In addition, targeted procedures and checks could be integrated into institutional processes authorising the aforementioned activities. For example, a research organisation could insert in its

²⁴ This includes agreements regarding funding and cooperation under contracts, Memoranda of Understanding etc.

²⁵ Such a tool could be posted online, in the organisation's internal website, for instance, in the section concerning research integrity or compliance with security and safety regulations. It can have some utility also in terms of awareness raising.

online system for approving travels abroad, an informatory note and a requirement for researchers to perform export control checks prior to submitting a request²⁶.

Furthermore, export screening procedures should be included in the phase of planning a research project and prior to entering into a formal agreement with other partner organisations. In this phase already, the definition of the project's objectives and the funding source might have implications from an export control point of view.

An export control issue can come into play in different phases of the project life. In some cases, an export control authorisation might become relevant only at the very final phase of a research project when the research organisation/researcher chooses to share an export controlled output with third parties, for instance through a license agreement. This showcases the importance of introducing export control verifications in different institutional procedures.

In other situations - particularly those involving collaborations with international partners - a research can entail the disclosure of sensitive technologies and the consignment of export controlled outputs in different phases of the project. Therefore, for projects flagged as sensitive, it is appropriate to add export controls checks and mitigating measures throughout the project's life. This is important to be specified in the agreement signed with other organisations.

In all instances discussed above, the export screening procedures to be set shall take into account the following aspects:

- Item classification, including software and technology;
- Risk assessment of the activity
 - Checks on embargoed, sanctioned or sensitive destinations and entities²⁷;
 - Stated end-use and involved parties screening;
 - Diversion risk screening;
 - Catch-all controls for non-listed dual-use items;

²⁶ It is acknowledged that not all research organisations have in place institutional policies for authorising all the activities potentially concerned by an export control risk. Also, this screening does not capture the case where informal exchanges and collaborations are not authorized through a formal mechanism.

²⁷ Sensitive destinations and entities are not embargoed or sanctioned, but the shipment or transmission of (certain) dual-use items thereto can be critical in individual cases, for example because of proliferation or human rights concerns. Member State governments can implement their own approach on this matter. Whenever in doubt, be sure to contact your competent authority.

If the result of the items classification and the risk assessment of the activity leads to the conclusion that the activity is controlled further aspects need to be addressed as below:

- Determination of which license (authorisation) is needed, i.e. for export, brokering, transfer and transit as well as application for such license²⁸, and
- Post-licencing, including shipment control and compliance with the conditions of the authorisation.

In a limited number of cases, it might be determined that the organisation or the individual researcher must refrain from a certain activity or that a project or engagement with a collaborating organisation cannot take place. For example, this can be the case where an involved party is included on a restricted list under sanctions or where the organisation deems the risk of a research output to be used for nefarious purposes in a third country as high. Likewise, it is possible that the competent authority denies (i.e. rejects) an application for an export authorisation if its assessment concludes a sensitivity.

In case of doubt or suspicion during the export screening process, in particular about the results of the stated end-use and involved parties or, diversion risk screening, consult with the competent authority in the EU Member State where your organisation is established.

What are the steps involved?

Set up export screening procedures allowing your organisation to perform a risk assessment that addresses all different potentially sensitive activities and sources of risk. These procedures shall enable individual researchers, students, project leaders and administrative staff to contribute to the assessment of the export control risks relating to the organisation's activities.

Where possible, adjust your institutional policies and procedures to accommodate export control checks for potentially sensitive activities (shipping, contracting, publishing, sharing online etc.) and, allow for mitigating measures concerning projects flagged as sensitive.

²⁸ Please note that section 4.5 lists the different types of the authorisations that might apply to a specific activity. Depending on the destinations and items linked to a controlled activity, a research organisation can make use of simplified license procedures such as those foreseen for EUGEAs.

Consider using generic risk assessment tools (e.g. flow charts²⁹) as well as data mining technics and other software for screening items, projects and linked activities against export control lists and lists of restricted entities and destinations³⁰.

Item classification

This aspect of the screening procedure seeks to understand whether an item used or produced in the framework of a research falls within the scope of the control list(s) or, whether a research project will be confronted with controlled items.

This is done by comparing the technical characteristics of an item against the EU and national dual-use control lists. If applicable, identify whether the item is subject to restrictive measures (including sanctions) imposed by the EU or the EU Member State in which your organisation is established³¹.

Please keep in mind that software and technology that meet the control specifications could be exempted if the "basic scientific research" and "public domain" exemptions apply (see section 4).

Try to determine whether an envisaged project will use controlled items and examine whether its contributions will meet the thresholds specified in the control list. For projects identified as of high risk, provide for export screening checks throughout the life cycle of the project.

Pay particular attention to the classification of dual-use components and spare parts, and to the classification of dual-use software and technology that can be transferred by e-mail or made available via a 'cloud' service abroad.

As a precautionary measure, consider verifying whether dual-use items falling within the scope of the control lists exist in the laboratories and repositories of the organisation. Their presence can be an indicator of export control sensitivities. Examine the possibility to register in your

²⁹ An example of a flow chart of licence requirements for exports and intra-EU transfers of dual-use items a decision tree is provided in Appendix 5. Organisations could consider to develop in-house other flowcharts and online tools that best fit their needs.

³⁰ The European Commission has developed a text mining tool that can help research organisations to identify sources of risk linked to their EU funded projects, publications and patents. For more information, please consult the TIM analytics webpage: https://ec.europa.eu/knowledge4policy/text-mining/topic/tim_analytics_en.

³¹ The EU sanctions map is a useful tool that can help a research organisation to identify applicable EU restrictions: https://www.sanctionsmap.eu/#/main.

inventories whether an item (either new, used or spare) is of dual-use relevance, and thus requires special handling in case of export.

Consult with the project leaders and available experts in order to collect information about the possible misuse of your dual-use items in the context of conventional military weapons or WMDs.

While collaborating with companies or other research organisations, it is a good practice to request additional information about the technical parameters and the control status and classification of materials, components, subsystems that are to be used by your organisation from them.

As required by Article 22(10) of the EU dual-use regulation concerning intra-EU transfers, mention³² in the relevant documents (contract, order confirmation, invoice or dispatch note) that the transaction involves listed dual-use items and are subject to controls if exported from the EU.

Risk assessment of the activity

The export screening process also takes into account the partners involved to a sensitive research project and all different recipients of controlled research outputs as well as the risk that these recipients will use such outputs for unlawful purposes. The list of the red flag questions offered in Appendix 3 of this Guidance is of help in assessing the risks linked to an activity.

Checks on embargoed, sanctioned or sensitive destinations and entities

Ensure that none of the parties involved in a project or sensitive activity are subject to restrictive measures (including sanctions) by consulting the EU consolidated list of sanctions³³ or national list.

Stated end-use and involved parties screening;

Know your partner(s) and consider how they intend to use your research involving dual-use items.

Be aware of the existence of research organisations acting as cover for military research or having strong ties with state-owned entities.

The consolidated list of EU sanctions is available in the following link: https://eeas.europa.eu/topics/sanctions-policy/8442/consolidated-list-of-sanctions en. Also, the EU sanctions map is a useful tool that can help a research organisation to identify applicable restrictions: https://www.sanctionsmap.eu/#/main.

Ask for an end-use statement if the activity involves listed dual-use items and when there are end-use(r) concerns in case of non-listed dual-use items³⁴. Consult the information provided by your competent authority for national rules and requirements concerning end-use statements³⁵. Please be aware that end-use statements can be requested also for sharing controlled software and technology.

Be vigilant for diversion risk indicators and signs about suspicious enquiries or orders.

Diversion risk screening

Be vigilant for diversion risk indicators and signs about suspicious enquiries for cooperation. There might be indications suggesting that a partner will use dual-use items shared or delivered by your organisation in the context of unauthorised military research or, in relation to WMDs and their means of delivery or, other unlawful purposes.

Please take into account that also non-listed dual-use items might require an export authorisation, if the stated end-use and involved parties screening or the diversion risk screening raises some concern in the sense of the catch-all provisions, in Article 4 of Council Regulation (EC) No 428/2009. Usually, this situation may concern items having technical parameters close to the controlled ones.

Catch-all controls for non-listed dual-use items

The export screening process should assess the possibility for a non-listed dual-use item to be used in connection to sensitive end-uses specified under Article 4 of the EU dual-use Regulation. If the researcher or research organisation is aware or suspects that an activity or project entails such a risk, it must abstain from engaging further to this research and immediately inform the competent authorities who will conclude whether a license application is necessary. For more information on the application of catch-all controls see section 4.

³⁴ In case your partner is unfamiliar with the request for an end-use statement, consider drafting a (one-page) accompanying letter explaining the very basics of dual-use export controls and indicating that the requested document speeds up applying for a licence or might even be necessary for receiving a license.

³⁵ Article 9(2) of Council Regulation (EC) No 428/2009 states that granting an authorisation may be subject to an obligation to provide an end-use statement. Therefore, inform yourself whether the competent export control authority requires (1) a correctly filled-out and signed end-use statement for one or more authorisations; and (2) whether the end-use statement shall contain the letterhead of the end-user/consignee in the country of final destination. Even without a national obligation to submit a correctly filled-out and signed end-use statement, an end-use statement is a useful means to check the reliability of the end-user/consignee and the information can be used to determine if an authorisation is required for non-listed dual-use items, where there are stated end-use concerns in the sense of the catch-all provisions in Article 4 of Council Regulation (EC) No 428/2009.

License determination and application, including for controlled brokering, transfer and transit activities

The result of the item classification and risk assessment of the activity might be that a licence requirement is relevant.

Gather and disseminate information about the range of license types (including individual, global and general licenses) and controlled operations (export, brokering, transfer and transit), and about the license application procedures relating to the applicable EU and national dual-use export controls. Be aware of national dual-use export control measures for other activities, such as technical assistance. See section 4 for more information on the possible authorisation requirements.

Consider to make use of simplified licence procedures (general licenses) for destinations mentioned in the EU dual-use Regulation or national measures.

Ensure that all concerned staff knows about the different types of licences and procedures to be followed internally and for submission to the authority (who will be able to apply and what steps to follow).

Post-licencing, including shipment control and compliance with the conditions of the authorisation

Before the actual shipment or transmission of a controlled item, there should be a final check if all steps regarding compliance were taken. This is a good moment to double check if items are correctly classified, if red flags have been checked, if the screening of entities was done and whether there is a valid licence for the shipment. Be aware that a change of relevant legislation could have taken place in the meantime. For example: the item is now a listed dual-use item or the end-user is now sanctioned.

Ensure that the terms and conditions of the licence have been complied with (including reporting). Please be aware that a licence may restrict the transfer of technology and software to only certain recipients and consider how partners involved in a sensitive research observe such requirements.

Be aware that any changes to the organisation's details (such as name, address and legal status), to the details of the end-user and/or intermediaries and to the details of the authorised items may affect the validity of your license.

3.2.5 Performance review, audits, reporting and corrective actions

Every management system needs to be subject to periodic review to identify omissions and operational failures as well as to adjust its policies and procedures on the basis of new information, legal requirements and newly identified best practices.

A well-functioning ICP has clear reporting procedures about the notification and escalation actions of staff when a suspected or known incident of non-compliance has occurred. As part of a sound compliance culture, scientific and administrative staff must feel confident and reassured when they raise questions or report concerns about compliance in good faith.

Performance reviews, audits and reporting procedures are designed to detect inconsistencies to clarify and revise routines if they (risk to) result in non-compliance and improve the efficiency of the controls in place.

What is expected from research organisations?

The role of this core element is to verify the day-to-day compliance work within the organisation, consider areas of improvement and revise the compliance procedures, if deemed necessary. Information retrieved during training and awareness raising and other reporting measures in place can feed into the performance review.

Another important component of this core element is audits to be performed internally or by an independent auditor to check whether the ICP is correctly implemented. If resources allow, it is a good business practice to periodically deploy an external auditor.

Reporting procedures prescribe the steps (e.g. notification procedure) to be taken internally and externally in case of a suspected or known incident of non-compliance.

Finally, corrective actions are the set of remedial actions to guarantee that a non-compliance will not take place again.

What are the steps involved?

Provide for control mechanisms as part of the regular operations to monitor the workflow within the organisation to ensure that any wrong doings are detected in an early stage. For example, one approach is to use the four eyes principle for a technical classification or export screening result. Consider the roles of both administrative staff and researchers in the process of monitoring.

Develop and perform audits to check the design, adequacy and efficiency of the ICP.

Make sure to include all elements of the ICP into the audit.

Ensure that all staff, including students, feel confident and reassured when they raise questions or report concerns about compliance in good faith.

Establish whistleblowing and escalation procedures to govern the actions of staff when a suspected or known incident of non-compliance has occurred.

Document any suspected breaches of national and EU dual-use export control legislation and the associated corrective measures in writing.

Take corrective actions to adapt the export control operations or the ICP according to the findings of the performance review, the ICP system audit or the reporting. It is recommended to share these findings, including the revision to procedures and corrective actions with all staff concerned and the top-management. Once the corrective actions have been implemented, it is recommended to adapt the policies and procedures of the ICP as necessary and communicate the changes within the organisation.

A dialogue with your competent authority can contribute to damage control and possible ways to strengthen the research organisation's export control system.

3.2.6 Recordkeeping and documentation

Proportionate, accurate and traceable recordkeeping of dual-use export control related activities is essential for a research organisation's compliance efforts. A comprehensive recordkeeping system will help a research organisation to comply with the EU and national documentation retention requirements³⁶, review and improve its compliance measures and, it will facilitate cooperation with competent authorities in case of a dual-use export control enquiry or a verified non-compliance.

What is expected from research organisations?

A research organisation's document retention policy has to comply with relevant obligations set in the national law or practice (e.g. obligation to keep and track documents relating to an export authorisation for at least a certain amount of time) and it could provide for additional requirements when conducting research featuring controlled items, technologies and software. Decisions made and steps taken during the various export screening procedures (e.g. an internal document describing the technical decision to classify an item or a collaborative project) may be in the organisation's best interest to maintain. For example, if all required records are captured and correctly filed, this will allow for an efficient search retrieval during risk assessment procedures for future projects but also during periodic audits. Quite importantly, effective

³⁶ Please see general obligations stipulated in Articles 20 and 22.8 of the EU dual-use Regulation and consult, where appropriate, your national authority for the specifics of recordkeeping obligations.

recordkeeping and documentation will demonstrate the course of actions followed when a suspicion or case of non-compliance arises.

Research activities are most of the time a joint enterprise and therefore, maintaining appropriate records of all sensitive activities can be a genuinely collective effort. In the case where a research organisation undertakes or could undertake controlled research in collaboration with other organisations, special clauses could be inserted in the formal agreements specifying the obligations of all involved parties to abide by the applicable export control law. Such clauses could clarify whose responsibility is to apply for a license and comply with the ensuing recordkeeping requirements. It is necessary that all involved parties take the required steps to observe recordkeeping requirements and ensure that their actions do not run against the laws of the EU Member State where they are based³⁷.

What are the steps involved?

Verify the legal requirements for recordkeeping (period of safekeeping, scope of documents, etc.) in the national legislation of the EU Member State where the organisation is established.

In order to make sure that all relevant documentation is at hand, consider determining the record retention requirements in the contracts with collaborators.

Create an adequate filing and retrieval system for the dual-use export control. Electronic systems with performant indexing and search functionalities are essential.

Ensure that export control related documents are maintained in a consistent manner and can be made available promptly to your government or other external parties for inspections or audits.

It is recommended to keep a record of past contacts with the competent authority, also in relation with end-use(r) controls for non-listed dual-use items and in case of technical classification advices.

3.2.7 Physical and information security

Physical and information security refer to the set of internal procedures that are designed to ensure the prevention of unauthorised removal of or access to dual-use items by the organisation's staff, contractors, collaborators and visitors. They are designed to function in synergy with other internal security procedures implemented by a research organisation and they are particularly useful for monitoring and tracking the intangible transfers of technology.

³⁷ Depending on the Members State's licensing procedures, it is possible for the consortium's coordinator –when based in the EU- to apply for a license on behalf of its partner organisations. For more information, please contact your national authority.

While physical and information security standards are not foreseen by the EU dual-use regulation, monitoring and safeguarding access to controlled items can ensure that no unauthorised export will take place either wilfully or by negligence.

What is expected from research organisations?

Security risks emanate from both external and internal threats to an organisation. Moreover, when designing internal procedures, it is often more efficient and effective to take into account the whole spectrum of threats and develop mechanisms which address both external and internal risks.

Having appropriate security measures preventing the unauthorised access or removal of controlled dual-use items can be used for achieving different objectives. For instance, a system monitoring who has access to what premises/laboratories can help an organisation to comply with both security protocols required for certain types of research and export control and sanctions obligations setting restrictions in the access and use of dual-use equipment by third country nationals. In a similar way, access to controlled dual-use technology via the internal servers of the research organisation should be restricted on a need-to-know basis as much as possible and sensitive electronic transfers should be monitored accordingly.

In order to safeguard sensitive projects involving dual-use or other security relevant items, a research organisation can implement a so-called Technology Control Plan (TCPs). TCPs represent a set of internal measures for identifying and mitigating risks in an integrated manner thereby addressing both physical and information security and export control aspects.

What are the steps involved?

Physical security

Ensure, according to the research organisation's risk assessment, that controlled dual-use items are secured against unauthorised removal, access or use by all staff including students, visiting scientific staff and external collaborators. Measures to be considered include, for example, physically safeguarding the items, the establishment of restricted access areas and personnel access or exit controls.

Information security

Establish internal policies and procedures for secured storage of and access to controlled dualuse software or technology in electronic form, including antivirus checks, file encryption, audit trails and logs, user access control and firewall.

In the case of handling export controlled information in the context of an international collaboration make sure that the necessary precautions are applied also by the organisation's

partners. Such a requirement could be specifically included in the agreement/contract setting up the collaboration.

Consider using classification schemes (e.g. markings) when transmitting software and technology containing sensitive or export controlled information.

If applicable to your organisation, consider protective measures such as end to end encryption for uploading software or technology to the 'cloud', storing it in the 'cloud' or transmitting it via the 'cloud'³⁸.

Section 4 - Regulatory framework

This section describes the basics of the EU dual-use export control regime under Regulation (EC) No 428/2009³⁹. In case of questions or doubts, please contact your competent authority⁴⁰.

This section in particular should not be interpreted as legal advice.

4.1. EU list of dual-use items

Annex I to Regulation (EC) No 428/2009 contains the list on dual-use items. This list is divided into 10 categories:

- Category 0 Nuclear materials, facilities and equipment
- Category 1 Special materials and related equipment
- Category 2 Materials processing
- Category 3 Electronics
- Category 4 Computers
- Category 5 Telecommunications and Information security
- Category 6 Sensors and Lasers
- Category 7 Navigation and Avionics
- Category 8 Maritime
- Category 9 Aerospace and Propulsion

These categories are a consolidation of the control lists by four export control regimes (Nuclear Suppliers Group, Missile Technology Control Regime, Australia Group and Wassenaar

³⁸ In connection to clarifications you may need in connection to recommended IT security standards, please address your queries to the competent national authority of the Member State where your organisation is established.

³⁹ COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items - (Recast) - (OJ L 134 29.5.2009, p. 1) - http://data.europa.eu/eli/reg/2009/428/oj

⁴⁰ A list of national competent authorities is available on DG TRADE website (https://trade.ec.europa.eu/doclib/html/158374.htm)

Arrangement) and by the Chemical Weapons Convention. Each category is further divided into subcategories and into dedicated control entries.

The subcategories are the following:

- A = Systems, equipment and parts
- B = Test, inspection and production equipment
- C = Materials
- D = Software
- E = Technology

In general, items listed in subcategories B, C, D and E relate to listed items under subcategory A. In a few cases there are dedicated stand-alone controls under these subcategories. The ten categories and five subcategories are a first breakdown of the list and may facilitate browsing through the relevant control entries.

From all the subcategories, only the terms "software" (subcategory D) and "technology" (subcategory E) are defined in the EU dual-use control list.

- Software means a collection of one or more "programs" or 'microprograms' fixed in any tangible medium of expression.
- "Technology" means specific information necessary for the "development", "production" or "use" of goods. This information takes the form of 'technical data' or 'technical assistance'.

Furthermore it is important to consider the determination of controlled dual-use software or technology in conjunction with

- the Nuclear Technology Note and the Nuclear Software Note for dual-use items listed in Category 0.
- the General Technology Note and the General Software Note for dual-use items listed in Categories 1 to 9.

This means that in order to be classified as listed dual-use technology, the technical data or technical assistance must contain specific information for the development, production or use of the goods specified in categories 0 through 9.

For category 0 (nuclear items), listed dual-use technology is the specific information that is 'directly associated with any goods controlled in Category 0'. This is a broad description; hence the range of controlled nuclear technology is bigger than compared to the controlled technology in category 1 to 9.

For category 1 to 9, only that part of "technology" that is "required" for the "development", "production" or "use" of goods controlled in Categories 1 to 9, is controlled according to the

provisions of Categories 1 to 9. "Required" is defined as that part of the information which is peculiarly responsible for achieving or extending the controlled performance levels, characteristics or functions from the dual-use control list. These controlled performance levels, characteristics or functions are generally very specific and high, hereby thus limiting the technology that meets the "required" threshold.

Hence, for category 1 to 9, only this specific information is to be considered listed dual-use technology. The aim of definition of "required" is to focus the technology controls on the specific technology that makes an item subject to license. Importantly, listed dual-use technology remains under control even when applicable to any uncontrolled item.

4.2. De-control notes for "software" and "technology"

The below de-control notes for "software" or "technology" are inserted in the Nuclear Technology Note (NTN), the Nuclear Software Note (NSN), the General Technology Note (GTN), and the General Software Note (GSN) in Annex I to the EU dual-use Regulation.⁴¹ These de-control notes only apply to listed software and technology, not to listed goods such as equipment, materials, samples and components.

- For listed dual-use software, except for category 0, there are two main de-controls possible: software that is "generally available to the public" and software that is already "in the public domain".
- For listed dual-use technology there are three de-controls possible: "technology" that is
 the result from "basic scientific research", "technology" that is already "in the public
 domain" and the minimum necessary information for patent applications. The latter does
 not apply to category 0 technology.

Only listed dual-use "software" or "technology" can benefit from the decontrols mentioned in the Software and Technology Notes. It is thus paramount to determine whether or not the research output, and if so what part(s), meets the technology control entry in subcategory E and thus also the definition of technology ("technology").

As indicated above, technology means *specific information necessary for* the "development", "production" or "use" of goods. What is covered by *specific information necessary for* is not defined. Generally, the following information is not considered to be specific enough to be falling under the technology definition:

 Safety data sheet (SDS), material safety data sheet (MSDS), or product safety data sheet (PSDS);

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⁴¹ Please check the Nuclear Technology Note, the Nuclear Software Note, the General Technology Note, and the General Software Note in Annex I to the dual-use Regulation for possible additional exemptions on minimum necessary object code and minimum necessary technology.

- Sales brochures, catalogues and excerpts thereof, which, in their respective form, are intended or may be intended for an indefinite number of interested parties and which are made available to them without individual changes to the contents;
- Schematic diagrams, block diagrams, process diagrams (without detailed data);
- Technical performance data, key performance indicators;
- Electrical and mechanical connection and consumption data;
- Labelling characters;
- Parts lists if no reference can be made to drawings;
- Norms and standards that are generally available and not specific to a company product;
- Articles from trade journals and comparable publications;
- General process and procedure descriptions (in the case of production plants);
- Delivery specifications (e.g. for chemicals and other auxiliary materials);
- Photos (without detailed information on geometric sizes, materials used and electrical/electronic components);
- Exploded drawings/elevations without detailed dimensions;
- Sectional views (schematic and without material and detailed data);
- External dimensions.

4.2.1 In the public domain

The EU dual-use regulation defines "in the public domain" as follows: "technology" or "software" which has been made available without restrictions upon its further dissemination (copyright restrictions do not remove "technology" or "software" from being "in the public domain").

This EU guidance emphasises that controlled dual-use technology that is not yet in the public domain cannot be de-controlled under the "in the public domain" de-control note. Only technology that is already in the public domain can benefit from the de-control "in the public domain". That means that a to-be research output (publication, conference material, …) can only benefit from this de-control if the listed dual-use technology that it contains is already in the public domain.

If a researcher refers to or integrates proliferation sensitive information from other sources that is already in the public domain, then it does not make the research output automatically controlled dual-use technology. The fact that such listed dual-use technology became available in

the public domain without a licence, is a violation of export control regulations, but this cannot be attributed to this researcher.

4.2.2 Basic scientific research

The EU dual-use regulation defines "basic scientific research" as 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.

While not stated explicitly, it refers to fundamental research, hereby excluding from de-control non-fundamental research or applied research. This definition poses implementation challenges as it remained unchanged for many years, and due to the changed nature of the research ecosystem.

This guidance provides two criteria to assist in determining whether the de-control note "basic scientific research" is relevant: the Technology Readiness Level and the prevalence of industry funding.

Both criteria do not determine whether the de-control note should apply. This has to be decided on a case-by-case basis via the internal export screening procedures and, where appropriate, in consultation with the competent authority.

- Technology Readiness Level (TRL) is a scale (1 to 9) originally developed by the United States National Aeronautics and Space Administration (NASA) and later taken over by the European Space Agency (and others) to assess the status of development of space technologies. TRL is a tool commonly used by the research community, as well as research funding bodies, including the European Research Agency, to assess the market readiness of new and emerging technologies. For export control purposes, research output stemming from TRL 1 and 2 research are generally considered basic scientific research⁴². The eligibility of research output stemming from TRL 3 and 4 are to be assessed on a case-by-case basis. Research output stemming from research above TRL 4 is not considered as basic scientific research. See Appendix 8 for a description of the different Technology Readiness Levels.
- Industry funding (sponsor) involved: Research that is externally funded by an industry partner is likely to result in a commercial development, regardless of whether the project is initiated by industry itself or a public body. Furthermore, in many cases (via contractual arrangements) the industry funder (or sponsor) could be given the opportunity to review and comment on publications (or presentations) prior to their release and to request the (temporary) exclusive use of research results. These types of collaboration can be

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⁴² In case your research with TRL 1 to 3 is being funded by a military end-user or you suspect military end-use, please consult your export control contact point in your research organisation or your competent export control authority.

indicative that the resulting research output will not be basic scientific research. In some cases, industry indeed funds fundamental research with no strings attached concerning publications or other research output. In such cases, the basic scientific research decontrol could be considered if it involves listed dual-use technology and the TRL level is low enough.

4.2.3 Minimum necessary information for patent applications

The General Technology Note contains an exemption for the minimum necessary information for patent applications. This minimum information needed to submit a patent application is thus exempt from export controls. This de-control makes no distinction between national, EU or international patent applications. Once the patent information is published in the public domain, it is no longer subject to export controls.

4.3 Controlled activities

There are four different types of activities that require an authorisation, two of which are constant (export and transfer) and two which occur on a case-by-case basis (transit and brokering).

- An authorisation is always required for the export of dual-use items listed in Annex I to Regulation (EC) No 428/2009 from the customs territory of the European Union.
- In some cases, authorisations are required for the export of dual-use items not listed in Annex I. See sub section 4.4. for such controls on export for non-listed dual-use items (catch-all controls).
- The transfer within the EU of some items requires an authorisation. This applies to items listed in Annex IV to Regulation (EC) No 428/2009.
- The transit or brokering of 'listed dual-use items' may be prohibited or may require an authorisation, respectively, if the item is or may be intended, in its entirety or in part, for uses referred to in Article 4(1) of Regulation (EC) No 428/2009. It is the competent authority that decides whether an authorisation is required or a transit is prohibited. Some EU Member States have adopted national measures concerning the transit or brokering controls for non-listed dual-use items. A list of National Measures adopted by Member States in accordance with Regulation (EC) No 428/2009 is published and regularly updated by the European Commission⁴³.

Page **45** of **64**

⁴³ Information Notice on measures adopted by Member States in conformity with Articles 4, 5, 6, 8, 9, 10, 17 and 22 of the EU dual-use Regulation. This is available on the DG TRADE dual-use webpage.

4.4 Controls on export for non-listed dual-use items (catch-all controls)

Some items do not meet the technical specifications of Annex I, but are nonetheless proliferationsensitive due to their technical possibilities or suspected end-use of concern.

Under article 4 of the dual-use Regulation national authorities can impose an authorisation requirement for dual-use items not listed in Annex I if there is a (suspected) connection with use in a WMD program, (suspected) military end-use in a country subject to an arms embargo⁴⁴ or (suspected) use of the item as a component in military equipment that has been exported without or in violation of an authorisation. This provision is known as the "catch-all control", and in such a case, where you have a suspected potential use of your items in one of the mentioned above cases, it is recommended that you contact your national authority for further information.

An EU Member State may also prohibit or impose an authorisation requirement on the export of dual-use items not listed in Annex I for reasons of public security or human rights considerations. A list of such national measures is compiled by the European Commission and published in the Official Journal. It is also available on the website of the European Commission.⁴⁵

Appendix 7 summarizes the licence requirements for exports and intra-EU transfers of dual-use items.

4.5 Types of authorisations

The EU dual-use Regulation foresees the following types of authorisations:

- Individual export authorisations: one or more dual-use items listed in Annex I from one exporter to one consignee (and one end-user, where applicable). The dual-use item(s) may be shipped in different parts and shipments.
- Global export authorisations: one or more dual-use items listed in Annex I from one exporter to one or more consignees (and one or more end-users, where applicable), in one or more countries.
- Union General Export Authorisations (EUGEAs) serve the aim to simplify the export of specific dual-use items to certain countries of destination available to all EU-based exporters who respect its conditions and requirements for use as listed in Annexes IIa to IIf. Annex IIa to IIf correspond to the 6 available EUGEAs (EUGEA 001 to EUGEA 006).
- National General Export Authorisations (NGEAs) are additional simplified authorisations for specific dual-use items to certain countries of destination as defined by national

⁴⁴ Currently, arms embargoes within the meaning of Art.4(2) of the EU dual-use Regulation apply to the following countries: See https://www.sanctionsmap.eu

⁴⁵ https://ec.europa.eu/trade/import-and-export-rules/export-from-eu/dual-use-controls/

legislation. These authorisations only apply to exporters based in the respective EU Member State⁴⁶.

- Authorisation for brokering services for a set quantity of specific dual-use items moving between two or more third countries.
- Transit authorisation for non-Union dual-use items that only transit the EU.
- Intra-EU transfer authorisation for Annex IV dual-use items from one EU Member State to another EU Member State

EU Member States may complement these authorisation requirements with national licence requirements or prohibitions.

Examples:

<u>Publication</u>

Researcher A would like to publish an article in an American journal. The article contains technology covered by Annex I to the EU Dual-Use Regulation (more specifically 3E001 in relation to the development of 3A002.c signal analysers) and will also be available outside the United States of America after its publication.

3E001 in relation to 3A002.c is covered by the items listed in EUGEA 001. The USA is one of the countries of destination authorised in the EUGEA 001. Researcher A however cannot use the EUGEA 001 to send the article to the American publisher as the exporter knows that the item will not remain in the EU001 country to which it is exported. This is the case here. The article will be available worldwide, as A is aware.

Export of second-hand dimensional inspection equipment

Research department B wants to sell a second-hand X-ray tomography system for three dimensional defect inspection to a university in Brazil. The equipment is listed under 1B001.f.1.

1B001.f.1. items are not included into EUGEAs (export after repair/replacement (EUGEA003) and temporary export for exhibition or fair (EUGEA 004)) covering Brazil as destination. This requires Research department B to apply for an individual licence as this involves one transaction to one end-user.

Important remarks

An approved authorisation (granted licence) is valid in all 27 EU Member States and can be used to export the items from anywhere in the Customs Union Territory.

⁴⁶ A list of valid NGEAs is available at https://trade.ec.europa.eu/doclib/html/158576.htm

The validity of licences is nationally determined.

4.6 Export controls and restrictive measures (sanctions)

Export controls and sanctions are both trade control measures that impose prohibitions or restrictions. While export controls are focussed on (non-) listed items and case-by-case export screening, sanctions are primarily focussed on restricting items and services to entities in specific countries (or in some cases all entities in entire countries).

See the EU sanctions map for an overview of all applicable sanctions at the moment: https://www.sanctionsmap.eu/.

4.7 Dual-use items versus military items

Dual-use items are generally distinct from military items. Military items are commodities (such as systems, equipment, components, materials, software or technology) that are in most parts specially designed or modified for military use, whereas dual-use items are controlled based on their technical specification. Military items are listed in the Common Military List of the European Union⁴⁷ or in national lists in EU Member States. 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 nerve agents, armoured or protective equipment, explosives and propellants.

Unlike the common EU dual-use export control system, the control system for military items is governed by each EU Member State.

The (stated) military end-use of research output or activity, does not automatically render this item specially designed or modified for military use. However, it may be an indicator, and obviously is useful information in the classification of military items and licence application assessment.

4.8 Control of technical assistance

There are two types of controls of technical assistance, one which is regulated in the dual-use Regulation and one which is regulated according to national law in the EU Member States.

Technology, according to the EU dual-use Regulation, may take the form of technical assistance. Technical assistance can be in the form of verbal instruction, training, passing-on of technical knowledge and skills or advisory services, including, by telephone or electronic means. Hence, the instruction of a colleague at a research institute can constitute technical assistance. The technical

Page **48** of **64**

⁴⁷ The latest version of the Common Military List of the European Union (equipment covered by Council Common Position 2008/944/CFSP defining common rules governing the control of exports of military technology and equipment) can be consulted via https://eur-lex.europa.eu/.

assistance must be specific enough to meet the technology thresholds in Annex I to the dual-use Regulation.

EU Member States may impose licence requirements or prohibition for other activities, such as the provision of technical assistance. This national control framework is not rooted in the EU dualuse Regulation but in Council Joint Action of 22 June 2000 concerning the control of technical assistance related to certain military end-uses (2000/0401/CFSP). Other than dual-use listed technology in the form of technical assistance listed in Annex I of the Dual-use regulation, it covers all other technical support related to the repair, development, manufacture, assembly, testing, maintenance or any other technical service intended for use in connection with the development, production, handling, operation, maintenance, storage, detection, identification or dissemination of chemical, biological or nuclear weapons or other nuclear explosive devices, or the development, production, maintenance or storage of missiles capable of delivering such weapons or related to military end-uses in destinations subject to an arms embargo.

Appendices

Appendix 1 - Research areas that are more likely to be impacted by dual-use export controls.

The following research areas are more likely to be impacted by dual-use export controls than other research disciplines. Please note the following: the list is non-exhaustive and may serve as (non-binding) tool to more easily identify relevant research. In this Appendix, the dual-use descriptors (right column) are rather general in nature. Specific export controls comprising sharp technical parameters are summarized in the Annex I to the EU dual-use Regulation, which should be consulted primarily.

Research areas	Dual-use descriptors
Biology and	Human, plant and animal pathogens
(nano)biotechnology	Toxins
	Biological protection, containment and handling equipment
Chemistry	Chemicals, polymers, lubricants and fuel additives
Advanced material science	Chemical manufacturing facilities, equipment and components such as pumps, heat exchangers, valves and distillation columns
	Chemical protection, containment and handling equipment
Nuclear physics and engineering	Nuclear reactors and specially designed or prepared equipment and components
	Nuclear material

Energy and	Optical and acoustic sensors	
environmental technology	Cameras	
Computer science	Source code	
and engineering	Computers	
Information and communications technology	Intrusion software related items	
	Telecommunications systems, equipment, components and accessories (including interception and jamming)	
	Information security hardware, software and technology (including encryption and cryptanalysis)	
Avionics and	Accelerometers	
aerospace engineering and	Gyroscopes	
design	Navigation (receiving) systems	
	Drones	
	Launch platforms	
	Satellites	
Electrical	Semiconductor	
engineering		
Optical engineering	Lasers	
	Optical sensors	
	Cameras	
Robotics and	Machine tools	
process automation	Robots, end-effectors and remotely controlled articulated manipulators	
Additive	Feedstock materials	
manufacturing (3D printing)	Manufacturing equipment	
Quantum technologies	Quantum cryptography	
Artificial intelligence and machine learning	Neural network integrated circuits	
	Neural computers	
	Electronic components	
Naval technologies	Surface vessels	

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Underwater vessels
Underwater vision systems
Power transmission and generation systems

Appendix 2 – Research scenarios of where export controls may come into place

The following are scenarios where dual-use export controls may come into place. The list is non-exhaustive.

Scenario	What does the EU dual-use Regulation say?	To be considered as well
Teaching, consulting, collaborating or working on research involving dual-use items inside EU territory with visiting third country researchers	The EU dual-use Regulation does not foresee controls for non-EU persons accessing dual-use items inside the EU Territory. Hence, no licence is needed as long as the controlled dual-use items remain inside the EU Territory. When the visiting third country researcher returns home with access to (or in possession of) the controlled dual-use item, then a licence is needed.	 In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. A licence may be required in case a sanctioned entity or a natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions.
Teaching, consulting, collaborating or working on research involving dual-use items outside EU territory	The EU dual-use regulation does not foresee controls for EU persons engaged outside the EU Territory in research involving dual-use items. Hence, no licence is needed in principle as long as there is no access to controlled dual-use items from within the EU Territory.	 In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. A licence may be required in case a sanctioned entity or natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions.
Organising inside EU territory a (virtual) conference/meeting/seminar/ or presenting at a (virtual) conference/meeting/seminar/ on research involving dual-use items	The EU dual-use Regulation does not foresee controls for non-EU persons accessing dual-use items inside the EU Territory. Hence, no licence is needed as long as the controlled dual-use items remain inside the EU Territory. When the visiting third country researcher returns home	 In some national cases, a technical assistance licence is required It is a good compliance practice to warn participants of licence requirements when exiting the EU Territory with the controlled item(s).

	•	with access to (or in possession of) the controlled dual-use item, then a licence is needed. If the conference/meeting/seminar is virtual and transmitted to a destination outside of the EU a license is needed.	•	A licence may be required in case a sanctioned entity or natural/legal person of a sanctioned destination seeks cooperation inside the EU Territory. In some cases such cooperation is prohibited according to EU sanctions.
Organising outside EU Territory a (virtual) conference/meeting/seminar/ or presenting at a (virtual) conference/meeting/seminar/ on research involving dual-use items	•	The EU dual-use regulation does not foresee controls for EU persons engaged outside the EU Territory in research involving dual-use items. Hence, no licence is needed in principle if orally presented, even when recorded on the spot, as long as there is no access to controlled dual-use items from within the EU Territory. if accompanied by presentation or other conference material where the information is not meeting the controlled technology threshold(s). The EU dual-use regulation requires a licence, if there is access to controlled dual-use items from within the EU Territory. if accompanied by presentation or other conference material (carried in paper, on laptop or other physical carrier such as USB stick) that	•	In some cases, based on national provisions, a technical assistance licence is required or the supply of technical assistance is prohibited. A licence may be required in case a sanctioned entity or a natural/legal person of a sanctioned country seeks cooperation inside the EU. In some cases such cooperation is prohibited according to EU sanctions
Publishing listed dual-use technology	•	Publications that include technology that meets the thresholds for dual-use control need an export authorisation. The intention to publish is		

	not enough to be considered to be in the public domain and is therefore not exempted from control. The export control authorities rely on the due diligence of universities to screen prepublications in sensitive research areas
	 In case a (draft) publication (or raw data) meets the thresholds for containing export controlled dual-use technology it is subject to export controls. This applies to both the pre-publication phase and to the actual publication phase. This applies as well to Master or PhD thesis that meet the controlled technology threshold(s).
Patented information and information for patent application	 No licence is needed in principle, as the export of patented information that is fully disclosed on the public record is considered to be "in the public domain" and hence exempted from export controls.
	 No licence is needed for the export of the minimum necessary information for patent applications.
Export of tangible dual-use items (goods)	 Research organisations may (re)sell, donate or lend dual-use items or temporarily export them for their own research projects. Regardless whether the items are new, a prototype or second-hand, they require a licence for export if listed in Annex I and for intra-EU transfers if listed in Annex IV of the EU dual-use Regulation.

Appendix 3 - List of red flags

Being vigilant for signs of suspicious enquiries is vital for countering the risks of the proliferation of Weapons of Mass Destruction, their means of delivery and the destabilising accumulation of conventional weapons. Sharing such information with your competent authority is highly recommended.

Your research

- your research involves innovative or alternative development, production or use processes for listed dual-use items;
- your partner requested unusual customisation of a standard product, or modification requests raise concerns about potential applications of the customized product;
- your research has known or suspected high or medium utility in dual-use, military, or sensitive applications.

End-use and end-user

- the partner/end-user is new to you (or your research organisation) and your knowledge about him/her is incomplete or inconsistent or it is difficult to find information about the partner in open sources;
- * the partner/end-user is tied to the military, the defence industry or a governmental research body in a country with an arms embargo and the stated end-use is civilian;
- * the partner/end-user does not seem to be familiar with the research and its performance characteristics (e.g. an obvious lack of technical knowledge);
- * the partner/end-user requests atypical development, production or use requirements that seems overly capable for the intended application;
- the contact information in enquiries (e.g. phone numbers, e-mail and addresses) is located in other countries than the stated affiliation of the partner, or changed to that over time;
- * the partner has an entity name in a language or with a reference that is unexpected for the country of establishment or residence;
- the mentioned website lacks content in comparison to what is normally found on a legitimate website;
- the partner/end-user is reluctant to offer information about the end-use of the items (e.g. via an end-use statement), to provide clear answers to commercial or technical questions which are routine in normal negotiations or to provide an end-use statement;
- an unconvincing explanation is given as to why the collaboration is required, given the partner's/end-user's normal business, or the technical sophistication of the items;

- unusual requirements for excessive confidentiality about customers, deliverables or specifications of research?
- unusual research project in any way, e.g. atypical research partners, performance thresholds, research steps and deliverables, without satisfactory explanation.

Shipment

for tangible items: unusual shipping, packaging or labelling arrangements are requested; usual incoterms for shipment, the sealing of containers/trucks and the confirmation of receipt by the consignee/end-user are refused; the partner/end-user asked that the goods be transferred to a forwarding address;

Funding, finance and contract conditions

- funding is offered by an entity atypical for your normal research partners;
- funder asks for non-publication of results or to withhold the dissemination of results for proprietary use, or with excessive Intellectual Property or confidentiality requirements;
- funder refuses to accept a clause that does not allow military end-use;
- unclear who the funder is (no website or any public information available);
- funder communicates only with email address that does not refer to a research organisation, public body or company;
- funder provides a unexplained or unusually generous large budget for a research agreement that does not contain concrete deliverables or milestones;
- funding from an overseas company that offers funding with no expectations or requirements beyond access to research findings;
- unusually favourable payment terms such as paying an unreasonable high price or full payment in advance;
- * the payment is made by other parties than the customer or stated intermediaries and follow another route than the products;
- routine installation, training or maintenance services are declined;
- the installation site is in an area under strict security control or is in an area to which access is severely restricted;
- unusual requirements for excessive confidentiality about final destinations, or customers, or specifications of items.

Appendix 4 - Helpful questions when setting up a research organisation's ICP

Research organisations may use the following non-exhaustive list of helpful questions when developing an ICP, or at a later stage to review an existing ICP. The answers to these questions should also not be understood as a reassurance of a proper ICP for dual-use export control.

1. Top-level management commitment to compliance

- Is a top-level management commitment clearly stating the research organisation's commitment to dual-use export controls available?
- Is the statement easily accessible for all employees?

2. Organisational structure, responsibilities and resources

- Did your research organisation nominate the person(s) in charge of answering employees' questions on the research organisation's compliance procedures, on a suspicious enquiry or on possible violations? Are the contact details of the responsible person(s) available to all staff?
- What are the parts or activities of your research organisation that are concerned by dualuse export control and compliance?
- In which part of your research organisation is the dual-use trade compliance personnel situated? Could there be a conflict of interests between compliance responsibilities and responsibilities concerning attracting research funding or securing research valorisation?
- In case your research organisation decides to outsource the dual-use trade compliance management, how is the interaction with your research organisation organised?
- How many people are either employed solely to deal with dual-use export control or have responsibility for it with other tasks? Are back-up persons available?
- How is the relationship between the export control staff and the top-level management organised, for example, concerning information exchange?
- Does your research organisation document and distribute the set of policies and procedures addressing dual-use export controls to all relevant personnel? In what format?
- Are there electronic tools available that assist your research organisation's compliance procedures?

3. Training and awareness raising

Does your research organisation provide for (tailored) compliance training or awareness raising activities?

- What compliance training or awareness raising formats does the research organisation offer? Examples are: external seminars, subscription to information sessions offered by competent authorities, in-house training events, etc.
- How is it ensured that dual-use export control staff are properly trained and well informed about all relevant laws and regulations

4. Export screening procedures

4.1. Item classification

- Are all export relevant products assessed against the EU and national dual-use control lists or restrictive measures, and who is responsible for this?
- Is your research organisation involved in the electronic transmission of dual-use software or technology? If so, how does the research organisation ensures compliance the controls on software or technology?
- Are there procedures in place for employees accessing controlled technology or software when visiting abroad?
- Is the classification of products received or manufactured by the research organisation recorded?
- Are changes in the national and EU dual-use control lists translated into the research organisation's classification procedures?
- When considering Article 22(10) of the Regulation (EC) No 428/2009, do the commercial documents relating to intra-EU-transfers of tangible dual-use items mention that those items are subject to controls if exported from the EU?

4.2. Risk assessment of the controlled activity

See Appendix 3 to this guidance for a non-exhaustive list of 'red flag' questions that can support your research organisation's export screening process to detect suspicious enquiries from customers.

- What are the procedures for dealing with positive and negative results from the risk assessment of the controlled activity?
- How are 'false positive' results (i.e. an unnecessary hit of concern) from the export screening assessment resolved?

Checks on embargoed, sanctioned or sensitive destinations and entities

During the risk assessment of the controlled activity, how does your research organisation take into account restrictive measures (including sanctions)?

Stated end-use and involved parties screening

- What are the internal procedures for the stated end-use and involved parties screening process?
- How are (new) involved parties screened? Do you periodically screen existing partners or funders again?

'Catch-all' controls for non-listed dual-use items

How is information of concern about the stated end-use (in the sense of the catch-all provisions⁴⁸) collected and put to use?

Diversion risk screening

Has your research organisation procedures in place for risk diversion screening?

4.3. License determination and application, including for controlled brokering, transfer and transit activities

- How is it ensured, that in each individual case the correct license type (individual, global or general licenses) is applied for/used?
- How is it ensured, that less obvious types of exports and other activities that are subject to restrictions are recognised as such and do not take place contrary to EU and Member State dual-use trade control laws?

4.4. Post-licencing, including shipment control and compliance with the conditions of the authorisation

- Does a final risk assessment of the controlled activity take place before the shipment or the transmission of dual-use items?
- How does your research organisation ensure that the terms and conditions (including reporting) of the licence(s) are being complied with?

5. Performance reviews, audits, internal reporting and corrective actions

- Are the daily relevant business operating procedures subject to a (random) dual-use trade control performance review?
- Does your research organisation have internal or external audit procedures in place?
- Does your research organisation have whistleblowing or escalation procedures in place?
- What corrective actions does your research organisation undertake in case of noncompliance?

⁴⁸ Article 4 of Council Regulation (EC) No 428/2009.

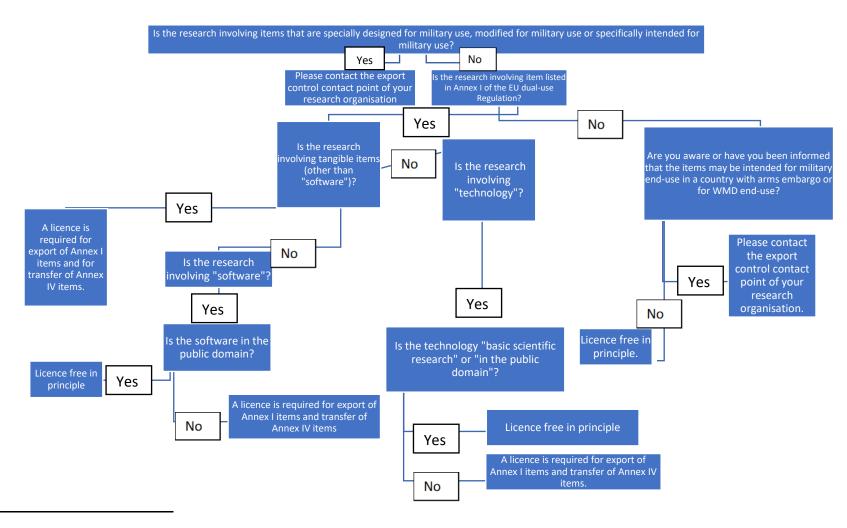
6. Recordkeeping and documentation

- What are the research organisation's procedures for filing and retrieving documents related to dual-use trade control? Did your research organisation consider including a record of past contacts with the competent authority?
- Are the legal requirements for recordkeeping known to the dual-use trade control staff and relevant commercial partners?
- Are records being inspected for completeness, accuracy and quality?

7. Physical and information security

- Does your research organisation implement cybersecurity measures to protect dual-use software and technology and ensure that they do not get lost, are easily stolen or exported without a valid license?
- Can your research organisation identify critical steps and related physical and information security vulnerabilities regarding dual-use items?

Appendix 5 - Flow chart of licence requirements for exports and intra-EU transfers of dual-use items⁴⁹



⁴⁹ This scheme does not include the licence requirements for items that are specially designed or modified for military use. Please consult the relevant information provided by your competent authority. Terminology in between quotes, (i.e. "software") refers to official definitions as provided by the EU-dual-use Regulation

Appendix 6 - Examples of possible compliance organisation structure in a research organisation

These examples were collected in the development of the drafting of the guidance and they have been anonymised.

Scientific staff

Vice-Chancellor Research

- provides academic leadership on export control (including management commitment to compliance)
- supports Heads of Department to raise awareness

Head of Department

- ensures appropriate levels of awareness among researchers of their responsibilities under the export control policy
- provides resources for training and implementation

Researchers

- ensures personal compliance with university export control policy
- identifies research involving dual-use items that may require export licences
- complies with licence conditions
- undertakes end-user due diligence

Administrative staff

Export Control Director

- has overall responsibility for development and implementation of the policy
- ensures that sufficient training is available for staff
- approves all licence applications
- seeks guidance from Legal Affairs Division regarding export control issues in contracts and research grants
- involves Technology Transfer Office and Research Funding Coordination Offices to integrate export controls in other university policies

Export Control Manager

- Supports researchers to
- assist researchers who seek advice on a case-by-case basis
- comply with the export control policy
- decides in whether a licence application is required
- prepare licence application
- understand licence conditions
- support end-user due diligence
- maintain appropriate records
- is contact point for competetent authority

Management

Executive Vice President

- provides compliance leadership (including management commitment to compliance)
- ensures sufficient resources for development and implementation of export control policy

Export Control Manager

- has overall responsibility for the development and implementation of export control policy
- monitors a long-term roadmap to maintain compliance
- ensures training and awareness
- •reviews licence reports
- •approves all licence applications
- is contact point with competent authority

Export Control Office

- •prepares licence applications
- •reviews legal documents
- •gathers and checks end-use certificate
- •performs end-user due diligence

Supporting divisions

Business development Division

- performs technical classification
- •performs end-user and end-use due diligence

Technical Division

performs technical classification

Purchase Division

- •supports gathering and checks of end-use certificate
- performs end-user due diligence

Information Security Division

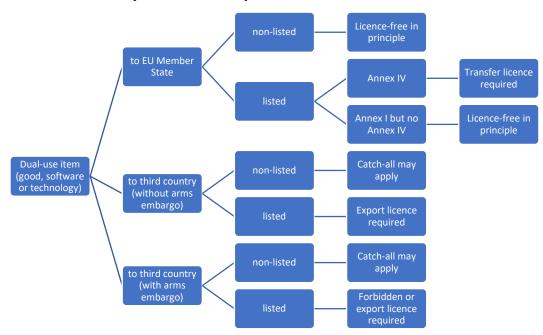
•develops and implements technology control plan

Logistics Division

- perform pre-shipment controls
- monitor shipments

Human Resources Division

 provides guidance on visiting thid country nationals



Appendix 7 - Summary of licence requirements for dual-use items⁵⁰

Appendix 8 - Technology Readiness Levels

TDI 4				
IRL 1 -	- basic	principl	es obs	served

TRL 2 – technology concept formulated

TRL 3 – experimental proof of concept

TRL 4 – technology validated in lab

TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)

TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)

TRL 7 – system prototype demonstration in operational environment

TRL 8 – system complete and qualified

TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

Appendix 9 - References and contacts

List of EU MS competent export control authorities: https://trade.ec.europa.eu/doclib/html/158374.htm

EU annual list of national measures: https://trade.ec.europa.eu/doclib/html/158576.htm

⁵⁰ Appendix 7 is a summary of licence requirements for dual-use items according to the EU dual-use Regulation. National regulations may impose additional licensing requirements. This Appendix does not include the licence requirements for items that are specially designed or modified for military use. Please consult the relevant information provided by your competent authority.