Brussels, 30 November 2015

# EDA/TASK FORCE QUESTIONS TO ECHA and RELATED ECHA ASWERS/CLARIFICATIONS

# on CLASSIFICATION OF ARTICLES UNDER REACH

## BACKGROUND/RATIONALE

The EDA is working towards developing a potential Member States common position on Ammunition Classification under REACH, supported at the technical level by the EDA REACH Task Force comprised of Member States REACH experts.

During the initial stages of this work, it was decided by the EDA and Task Force to base the ammunition classification work on the related ECHA guidance documents for "Requirements for Substances in Articles" ([1] and [2]). More specifically, the ECHA flowchart in Figure 2 (page 7) of April 2011 guidance (also Figure 1 (page 9) of June 2011 guidance) and related questions of par. 2.4 of April 2011 guidance) describe the step-by-step process followed, reflected currently in Annex 1.

When classifying the different types of ammunition, the questions/steps mentioned in the ECHA guidance are considered very important, and therefore, their exact scope needed to be very clear. Following review of the questions and bearing in mind the need to apply these to classify the specific type of material (ammunition) several clarification questions came up by the EDA/Task Force. These questions were forwarded by EDA to ECHA. ECHA reviewed the questions and provided responses.

The current document summarises such questions posed and answers received. The development of this document was deemed necessary for transparency purposes and to provide to all stakeholders (including industry) a common picture of the detailed basis that was taken into account by the Task Force when conducting work on ammunition classification.

## QUESTIONS POSED BY EDA/TASK FORCE

Following detailed review, the following clarification questions on the ECHA guidance steps/questions, were raised by EDA to ECHA for further clarification on 31 March 2015 :

- **Step 4, Question 4b**
    - The question states "Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?".

[1] ECHA Guidance on Requirements for Substances in Articles - Version 2 - April 2011
[2] ECHA Guidance on Requirements for Substances in Articles - in a Nutshell - June 2011


European Defence Agency | Rue des Drapiers 17-23 B-1050 Brussels | www.eda.europa.eu

- This is a question of great significance which sometimes, based on answering “Yes” or “No”, determines if the ammunition will be considered as “combination of an article and a substance/mixture” (if the answer is Yes”) or if step 5 will be followed – potentially leading to an “Article” (if answer is “No”) (Note : Question 4a is predominantly “No” and answer to question 4c is predominantly “Yes”). Most specifically the detailed review of many ammunition types revealed that their classification is very dependent on if “reaction products” are considered when answering the question, or not.

- It is noted that the REACH regulation does not regulate “reaction products” which are considered out of scope (exempt).

- In addition, in accordance with Article 7.1 of the REACH regulation, in order a producer or importer of articles to register to to ECHA, any substance contained in an article, it is necessary (Article 7.1(b)) that “the substance is intended to be released under normal or reasonably foreseeable condition of use”.

- Therefore, clarifications are required on the rationale for including the “reaction products” element, as part of the overall considerations, when answering Question 4b.

- Step 5, Question 5c

  - The question states “Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal?”.

  - Does the term “end of service life” refer to time that ammunition are actually used/expended, or to the time until which ammunition that are kept in storage, can be safely used (i.e. if this point in time passes and ammunition is not used in the field, they would need to be discarded due to not being considered safe to use anymore)?

  - Therefore, clarifications are required on what the term “end of service life” actually means.

- Step 4, Question 4c

  - The question states “Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?”.

  - The sentence “thereby rendering the object useless and leading to the end of its service life?” might be suitable when referring to “objects” which are not ammunition (e.g. a printer toner cartridge). However, when applied to certain types of ammunition after their use, the sentence does not make real sense. For example, if the object is a bomb or mine, it is not considered that after exploding the bomb is rendered “useless”, nor does the explosion is considered that it leads to the “end of service

life" (especially on the meaning of the term "service life" refer also to related clarification under Question 5c above).

- Therefore, clarifications are required on the following : when classifying ammunition, would it be acceptable to apply Question 4c as "Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object?", i.e. without considering the sentence "thereby rendering the object useless and leading to the end of its service life?".

ECHA ANSWERS TO QUESTIONS POSED

On 2 June 2015, ECHA provided the following responses to the questions posed :

- The workflow included in section 2.4 of the Guidance contains the relevant steps to follow when deciding whether an object is an article or not under REACH Regulation. In step 1, it is required to identify the function of the object, defined as the "basic principle determining the use of the object", according to section 2.1. The function of the object is a key guiding element in the next workflow steps, in particular when answering the indicative questions included in those steps. In more difficult cases, the indicative questions included in steps 4 to 6 should be used to support the evaluation in a holistic approach in line with the main purpose of each of those steps for reaching the final decision.

- **Response to Question 1: "Step 4, Question 4b"**

The term "reaction products" in the Question 4b is used to cover the release or controlled delivery from the object of substances which result or could result from a chemical reaction that takes place, for example,

- upon the end use of the object;
- when there is an incidental exposure to another substance or environmental factors such as air, moisture, microbial organisms or sunlight;
- from the inherent decomposition of substances (incidental) in the article during e.g. storage or transport;
- during the possible action of a substance in or on the article to perform a specific function (e.g. prevent an unwanted reaction such as oxidation or corrosion.

In the specific case of ammunitions, based on the information provided by EDA, it appears to us that the term "reaction products" could be used to cover the substances which are generated during the end use of the ammunition (object), i.e., the products resulting from the reactions that take place during its end use. However, the term "reaction products" needs to be interpreted in the scope of each specific case. It is up to the assessor to answer to the indicative Question 4b based on the understanding and available information on the specific case.

Concerning the third and fourth bullet point of the question, ECHA would like to clarify the following:

- The "reaction products", as defined above, are exempted from the registration obligation according to Annex Vof REACH, which does not mean that they are exempted from all REACH provisions;

- Under Art. 7(1), regarding the registration obligation, the requirement for a *substance intended to be released from an article* is only fulfilled if there is a deliberately planned release within an accessory function (to be differentiated from the main function) of the article. This accessory function of the article would not be achieved if the substance was not released. The release of a substance from an object that fulfils the main function of the object is not regarded as "intended release" for the purpose of REACH. In this case the object usually would be considered as a combination of an article (functioning as a container or a carrier material) and a substance/mixture, and not as an article with intended release of a substance/mixture.

- **Response to Question 2: "Step 5, Question 5c"**

The term "*end of service life*" in Question 5c of step 5 (and also in Question 4c of step 4) in the workflow means the end of the period of time that an object is (expected) to be used for the purpose for which it was produced/manufactured. In other words, the point in time when after the use of the object, it can no longer perform its main function. At the "*end of service life*", in principle, the object is useless, being therefore disposed and entering in its waste stage.

Based on the information provided by EDA, if the ammunitions are kept in storage and the period of time that allows their safe use in the field expires, then they need to be discarded. In such cases, although they were not used to perform their function, the ammunitions have reached their "end of service life". It should be noted, that based on their identified function, this seems to be an exception due to safety reasons. In these exceptional cases, the objects are discarded with the substance/mixture at the end of its service life, but ***normally***, this is not the case. Thus, most likely, in the case of ammunitions, the answer to Question 5c is "No".

- **Response to Question 3: "Step 4, Question 4c"**

The object is rendered useless if it is not able of performing its main function as defined in step 1 of the workflow. By eliminating the part of the question "thereby rendering the object useless and leading to the end of its service life?", this question may not allow sufficient differentiation from Question 4b, in order to identify certain objects for which one can get further insight that the chemical content of the object is an integral part thereof. The Question 4c as it is written also contributes to assess if the substance/mixture is disposed together or separately from the other parts of the object.

For these reasons, it does not seem appropriate, nor necessary in the particular case of ammunitions, to disregard the excerpt "thereby rendering the object useless and leading to the end of its service life" as part of the Question 4c.

For the particular case of ammunitions such as bomb and mine, the Question 4c as it is written is applicable as ECHA explains below.

Even if the service life of the object is very short or coincides with the use phase as it appears to be the case of ammunitions such as bomb and mine, the last part of the Question 4c still seems applicable to such objects. After exploding (consumption of the explosive substance/mixture and release of reaction products), is the object (bomb or mine) still able to perform its main function? Is the remaining part(s) of the object (bomb or mine) still useful or able to perform the object's main function? It seems that the answers to these questions are negative. It appears that after the use phase of the ammunition (e.g. bomb or mine), the remaining parts of the ammunition are not able of performing the function of the object as a whole, and thus rendering the object useless and leading to the end of its service life. Furthermore, the remaining parts of the ammunition are, in principle, disposed separately.

## FURTHER QUESTIONS POSED BY EDA/TASK FORCE

Taking into account ECHA answers provided, and based on further work conducted by the Task Force, further questions were raised by EDA/Task Force which were posed to ECHA on 4 September 2015 (in **bold**). Related answers were received by ECHA on 16 September 2016

The questions and answers are as follows :

- General questions:

**Differences of interpretation around question 4b:**

- **MAINLY (according to the function defined under step 1) = ?, why no reference to step 2?**
- **Ammunition as a (strict?) container ( which delivers substance or reaction products) = ?**
- **Substances and reaction products: What is the scope: chemicals, physical phenomena (light, energy…)?**
- **Reaction products: why taken into account since they are not for REACH processes (registration, authorisation…)?**

- Specific questions:

MAIN FUNCTION, SHAPE, SURFACE, DESIGN

**Why are the step 1 and step 2 questions not developed / raised again in step 4 in order to deal with the previous ambiguity? What is the link of 4a, 4b and 4c with these first 2 steps?**

ECHA's answer :

Regarding step 1, as already mentioned in ECHA's previous answer, the function of the object (as defined in this step) is a key guiding element in the next workflow steps (section 2.4 of the

Guidance), in particular when answering the indicative questions included in those steps. One should always answer the indicative questions (e.g. questions 4a to 4c) and draw the relevant conclusions keeping always in mind that function. This explains the link between step 1 and step 4.

There is no direct link between step 2 and step 4. The step 2 works as a kind of shortcut step for straightforward cases. It is used to save time during the assessment. When one can unambiguously conclude that the shape, surface or design of the object (physical appearance) is more relevant for the function (defined under step 1) than its chemical composition, then one can conclude at this stage that the object is an article, without needing to proceed to the next steps in the workflow. Step 3 and the following steps are used to access more difficult cases.

- **Question 1: main function: basic principle determining the use of the object**

ECHA's answer :

The "basic principle determining the use of the object" is related with use of the object and the result of using an object and less related to the quality of the result. The function of the object can be roughly determined by analysing what its producer/supplier wants it to be used for and what the end user acquiring it expects it to do. Several examples are provided in the Guidance.

- **Question 2: shape, surface, or design more relevant than chemical composition of the object?**

ECHA's answer :

The question ""shape, surface, or design more relevant than chemical composition of the object" for the function of the object?" should be answered during the assessment to decide whether an object is an article or not, on a case by case basis, using the guidelines provided in section 2.4 of the Guidance. If the case is straightforward, one can immediately answer to the question under step 2, for example a wax crayon is to be regarded as a mixture, because its function is to bring pigment to paper and the chemical composition is more relevant for this function than the shape/surface/design of the wax crayon. However, in a more complex case, as for example a pen which function is to bring ink to paper, it is difficult to answer unambiguously to the question under step 2. Therefore, it is recommended to proceed to step 3 and following steps accordingly to the workflow.

**In ammunition:**

- **Main function is to get the effect (e.g. smoke screen) or release the inside or reaction products (e.g. smoke screen) ?**

ECHA's answer :

Based on the reasoning given above, the function of a smoke screen seems indeed to be making an effect or creating a smoke flow. During the making of the effect or creating a smoke flow, the smoke screen releases or delivers in a controlled way the substance/mixture contained in it or its reaction products.

- influence of its shape and design to obtain a velocity, duration … could be important, even if it is a container
    - E.g. smoke screen for military operation (triggered in a particular place, for a specific duration…) which is different from smoke screen for a show (no specific constraints) => can the effect, the function be considered different?

ECHA's answer :

A higher degree of technical sophistication of the object "smoke screen" may improve the functioning and the quality of the result (velocity control, duration, etc.), but it does not seem to change its function as such. Thus, the factors mentioned do not seem relevant to determine the function of the smoke screen device.

CONTAINERS

Container:

- Does a smoke screen acts mainly as a container for the release or delivery of substances or reaction products?

    - Do the many components inside the ammunition which make the ammunition effect successful (reaches a specific location, works for a given duration or has a given impact) change its status from a container to a more complex object?
        - The example about printer cartridges in the ECHA guide doesn't really help because it is not a complex object: most militar ammunition is more similar to a full printer from which the cartridge or the ink (in those cases when the ammunition content is not an article itself) could be but shouldn't be removed except for end of life since it wouldn't be operational anymore if removed. And during operational use of some ammunition such as smoke screen , the substance or the reaction products are released through a complex reaction monitored by a number of components in order to achieve a given duration, intensity, at a specific location etc.

ECHA's answer :

It is difficult to answer this question without a full description of the smoke screen device and how it works to perform its function. If the main function of the object is closely related with the substance/mixture contained in the object and with its (controlled) release or delivery, it is usually a strong indication that the object acts mainly as a container. As mentioned before, one should assess if the degree of technical sophistication of the object changes its function. One should also check if the smoke screen device can be considered a set of objects as explained in section 2.2 of the Guidance. Finally, in order to assess whether the smoke screen device is an article or not under REACH, it is recommended to follow the decision-making workflow and making the assessment using a holistic approach, taking into account the identified function of the object.

SUBSTANCES AND REACTION PRODUCTS

**Nature of released substances and reaction products:**

- **What is the scope: chemicals (which ones?), physical phenomena (light, energy…)?**
    - **Only chemical substances or mixtures? => physical phenomena out of scope: ammunition emitting light would be out of the scope since the reaction occurs inside the container and there is only release of photons (at least in relation with main function)**
    - **Released substances which are inert would also be out of scope?: metals (chaff: pure metals or alloys?, alloys out of scope?), talc, plaster…**

ECHA's answer :

Accordingly to Article 1 of REACH, the Regulation applies to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles and to the placing on the market of mixtures. Therefore, its scope covers all substances and mixtures fulfilling the definition of Articles 3(1) and 3(2) and not exempted in Article 2 or other provisions in specific titles of REACH. The scope of REACH includes inert substances, talc, plaster metals and alloys (e.g. Recital 31 of REACH). The REACH regulation aims to ensure a high level of protection of human health and the environment from the risks that can be caused by certain substances/mixtures during exposure to those substances/mixtures. The scope of the REACH covers hazards posed by substances or mixtures that result from a specific classification according to the CLP Regulation, e.g. in physical hazard classes, which may involve certain physical phenomena (cf. "Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.7a: Endpoint specific guidance" available at http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

**Reaction products**

- **Why taken into account? : Are the reaction products in the scope of REACH one way or another? (are not in REACH processes)**
    - **Registration asks for studies showing risks are managed for the substance uses, why reaction products only in guide on articles?**
- **Reaction products could influence the main function if inside or outside ammunition**
    - **E.g.: gas generators: reaction products = gas, airbags: no reaction products outside envelope so no release but is there a release once normal use is over ? (recovery/removal of bag before installing a new one is no more part of use but there may still be exposure)**

ECHA's answer :

The term "reaction products" is mentioned in other REACH guidance documents, e.g. "Guidance for Annex V", "Guidance for identification and naming of substances under REACH and CLP",

"Guidance for monomers and polymers". As mentioned above, the scope of REACH Regulation includes, in broad terms, all substances, including "reaction products" released or delivered during the use of articles. These "reactions products" released during the use of an article are, in principle, exempted from the registration obligation, as mentioned in our previous answer. However, it does not necessary means that they are not within the scope of REACH. In order to achieve the goals of REACH, information need to be generated by industry in order to ensure the safe use of chemicals (cf. Article 1(3)), this means that they have to assess the risks posed by substances during the exposure to those substances. The definition of use under Article 3(24) is very broad. In addition, according to Annex I of REACH, the assessment of the risks arising from each identified use of a substance should consider all life-cycle stages, including where relevant the service-life of articles and the waste stage. The exposure estimation under the risk assessment, accordingly to the same Annex, entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels. In conclusion "reaction products" are not only relevant in the Guidance on requirements for substances in articles, but in general, they are relevant for the risk assessment of a substance in any identified use. For example, ECHA recommends the applicants for authorisation to include in their dossiers an assessment of the original substance and take into account in that assessment, where relevant, its reaction products, as well as degradation products, to the extend they can.

Regarding the last point, the function of an object is determined under step 1 of the workflow for the object as whole and not for parts of the object (including a substance/mixture contained in the object). Then, during the decision-making on whether an object is an article or not under REACH, one than needs to assess closely the "role" of the substance/mixture for the function of the object. This is made by following the different steps of the workflow. It needs to be assessed on a case by case basis, if the "reaction products" are released or not (cf. the detector tube example in the Tables 4 and 5 of Appendix 1 to the Guidance) from the object during use or at the waste stage (or both) and take that assessment into account when applying the workflow.

Annex 1

## ECHA FLOWCHART AND RELATED QUESTIONS

## on ARTICLES CLASSIFICATION

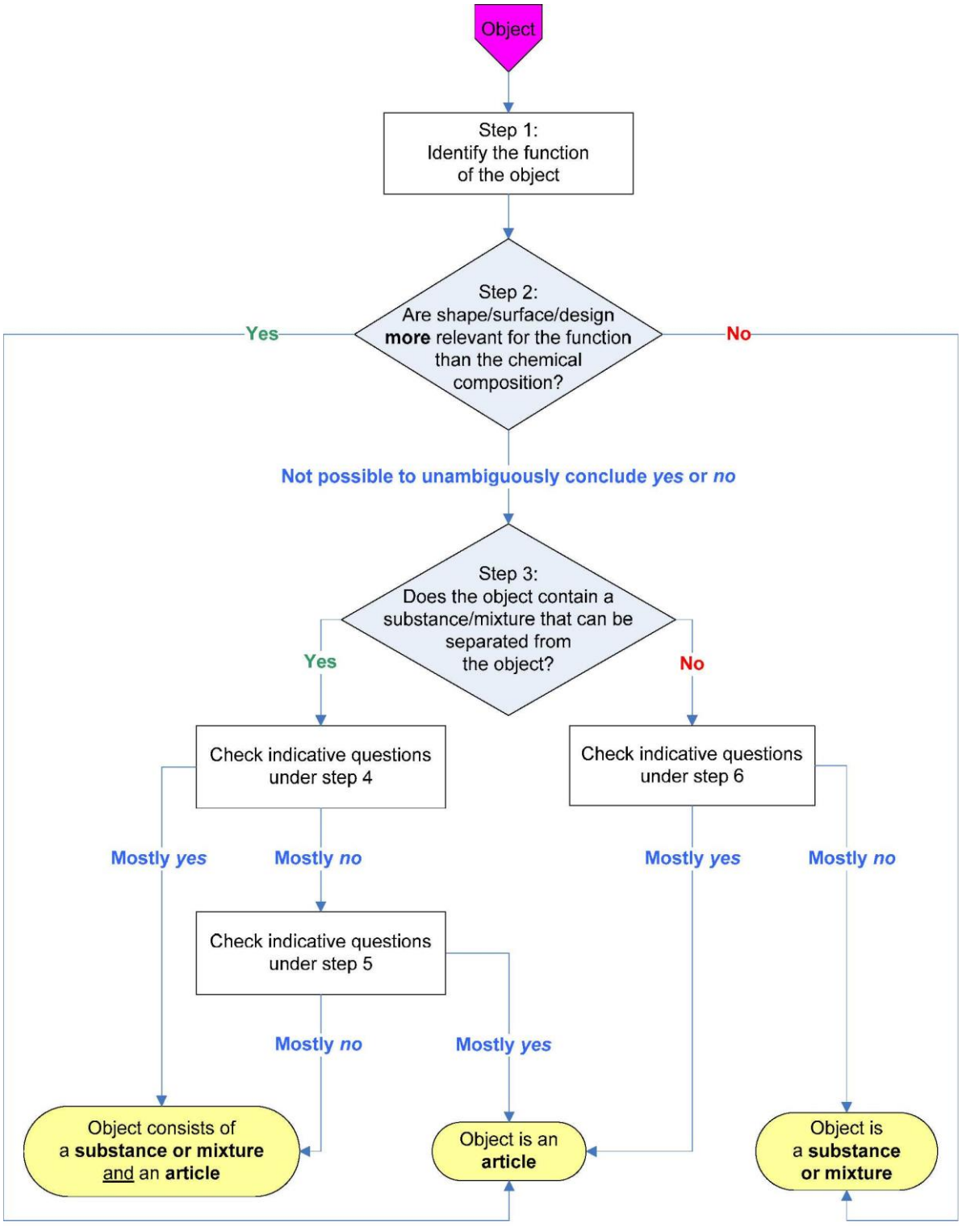


**Figure:** Flowchart illustrating decision-making on whether an object is an article or not

Step 1: Define the function of the object in line with section 2.1.

Step 2: In many cases applying the REACH definition of an article is straightforward. The decision on whether an object is an article or not can then directly be made by comparing the importance of physical and chemical characteristics for achieving the object's function.

**If you can unambiguously conclude that the shape, surface or design of the object is more relevant for the function than its chemical composition, the object is an article. If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture.**

**If it is not possible to unambiguously conclude whether the object fulfils the REACH definition of an article or not, a deeper assessment is needed; for this proceed with step 3.**

Step 3: Determine if the object, which may be constructed in a very simple or highly sophisticated manner, contains a substance or mixture that can be physically separated from the object (e.g. by pouring or wringing out). The substance or mixture in question, which can be solid, liquid or gaseous, can be enclosed in the object (like e.g. the liquid in a thermometer or the aerosol in a spray can), or the object can carry it on its surface (like e.g. a wet cleaning wipe).

**If this applies to the object, proceed with step 4, otherwise proceed with step 6.**

Step 4: For determining whether the chemical content of the object is an integral part thereof (and therefore the object as a whole is an article as defined under REACH) or if it is a substance/mixture for which the rest of the object functions as a container or carrier material, the following indicative questions should be answered:

*Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?*

*Question 4b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?*

*Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?*

**If you can answer these questions predominantly with *yes* (i.e. 2 of 3) rather than *no,* then the object should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture.**

It is to be noted that an importer or supplier of such an object is also considered to be an importer or supplier of a substance/mixture. As such he might also have obligations other than those of importers and suppliers of articles described in this guidance document. This means that

substances in a container or on a carrier material might e.g. have to be registered, or be supplied with a safety data sheet. **Importers and suppliers of a "combination of an article and a substance/mixture" therefore have to separately check if obligations for the article apply and if obligations for the substance/mixture apply.**

Step 5: If the answers to the indicative questions under step 4 are mostly no, you should use the following questions to cross-check whether the object as a whole should indeed be considered as an article and not as a combination of an article (functioning as a container or a carrier material) and a substance/mixture.

*Question 5a: If the substance/mixture were to be removed or separated from the object, would the object be unable to fulfil its intended purpose?*

*Question 5b: Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?*

*Question 5c: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal?*

**If you can answer these questions with *yes* rather than *no,* then the function of the object is likely to be determined rather by the physical properties shape, surface and design, than by the chemical composition. The object is then regarded as an article with an integral substance/mixture (i.e. the substance/mixture forms an integral part of the article). The substances (as such or in a mixture) that form an integral part of the article have only to be registered under the conditions described in section 3.2.**

Step 6: **According to the assessment made under step 3, the object does not contain a substance or mixture that can be physically separated. Deciding whether the object fulfils the REACH definition of an article or not may however still be difficult in certain cases. Common examples are raw materials and semi-finished products that are further processed to final articles, but other cases might exist. In these cases, where making a decision is difficult, you may use the following indicative questions in order to better determine whether or not the object is an article. These questions can only be used to support the evaluation of the importance of the chemical composition versus the shape/surface/design in relation to the function and thus facilitate the application of the article definition.**

*Question 6a: Does the object have a function other than being further processed?*

*If the object predominantly has other functions (i.e. end-use functions), then this may be an indication that it is an article according to the definition of REACH.*

*Question 6b: Does the seller place the object on the market and/or is the customer mainly interested in acquiring the object because of its shape/surface/design (and less because of its chemical composition)?*

*If the object is mainly put on the market or acquired because of its shape/surface/design, this is an indication that the object is an article.*


European Defence Agency | Rue des Drapiers 17-23 B-1050 Brussels | www.eda.europa.eu

*Question 6c: When further processed, does the object undergo only "light processing", i.e. no gross changes in shape?*

*"Light processing", such as drilling, surface grinding or coating, may improve or modify an object's shape, surface or design for carrying out a function and is thus frequently applied to objects which are already articles. Thus, if only "light processing" is applied, this is an indication that the object is an article.*

*Processes leading to gross changes in shape, meaning changes of depth, width and height of an object, are not regarded as "light processing". These can for example be primary shaping processes (such as casting or sintering) or forming processes (such as extrusion, forging or rolling). If the object preserves at least one of its characteristic dimensions (depth, width and/or height) when further processed, the process can be regarded as "light processing".*

*Question 6d: When further processed, does the chemical composition of the object remain the same?*

*A change of the chemical composition in the next processing steps may indicate the object being a mixture. However, some treatments of an object which is an article may result in a change in its overall chemical composition, but not in the status of the object being an article. Examples are printing onto the surface, painting, applying coatings, dyeing etc.*

Not all questions may apply to all objects and the weight of evidence of the answers to the questions may vary from case to case. However, in concluding whether the object is an article or not, the answer to various of the relevant indicative questions should be considered and not only the answer to one of them. Predominantly answering with *yes* to the questions indicates that the object is an article. Predominantly answering *no* to the questions indicates that the object is a substance or mixture.