



Nuremberg, August 2023

## Classification of products for manual writing, drawing and painting as "article"

## **Position Paper of**



**European Writing Instrument Manufacturer's Association (EWIMA)** 

Industrieverband Schreiben, Zeichnen, Kreatives Gestalten e.V. (ISZ)

and members

#### **Summary**

According to applicable regulations (REACH (EC) No.1907/2006) writing instruments must be considered as articles (see chapter 1 for definitions). The general definitions in the legal text give room for controversial interpretations. Supporting guidance documents are itself not consistent with a clear opinion on considering writing instruments as articles or mixtures (chapter 3). This can lead to requirements by customers or national authorities to handle writing instruments like chemicals. Implications like hazard labelling of writing instruments containing minor amount of classified chemicals which is disproportionate in comparison to the absence of a known or potential risk (see chapter 4 for the perspective of the end-consumer and chapter 5 for potential implications for considering writing instruments as mixtures). Additionally, it leads to more volume of packaging, which is contrary to the EU objective to protect the environment with less packaging waste.

Contrary opinions on legal requirements and different interpretations demand the need for clarification outlined in this position paper of the industry.

Technical arguments in chapter 2 as well as the use of ECHA's decision tree for a clear distinction between articles and mixtures in chapter 3 support the EWIMA position and also the overall acceptance of the position paper by customers. At present industry is neither faced with legal enforcement by national authorities nor national jurisdiction or a clarifying decision by the EU Court of Justice has been published.





## **Table of contents:**

1	Def	initions	3		
2	Arg	uments	4		
	2.1	Writing instruments are objects	4		
	2.2	Shape, surface and design are essential	4		
	2.3	Writing instruments are complex objects with high functionality	5		
	2.4	Chemical composition is important but secondary	5		
	2.5	Writing instruments are articles with intended release of a substance	5		
	2.6	Writing instruments are no chemical storage container	6		
	2.7	The size of the writing media container is not arbitrarily scalable	6		
	2.8	No free chemical is present	6		
3	ECH	IA perspective	6		
4	Che	hemical exposure, risk and consumer protection9			
5	Labelling				
6	Ref	erences	10		
Α	ppendi	x A: Technical information of writing instruments	11		
Α	ppendi	x B: ECHA's Decision Tree	13		
		x C: Classification of products for manual writing, drawing and painting as "article" or	19		
Α	ppendi	x D: Membership lists	20		





#### 1 Definitions

No legal text defines or classifies writing, painting or drawing instruments (in the following text the general term "writing instruments" is used). However, the products are affected by the European Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (in the following named as REACH regulation). For the purpose of the regulation, definitions are given to differentiate between substances, mixtures, articles, polymers and monomers (compare Art. 3 (1-6)). A proper assignment in one of the categories is necessary in order to apply the correct legal requirements.

Article 3 of the REACH regulation defines:

an **article** as "an **object** which **during production is given a special shape, surface or design** which determines its function **to a greater degree than** does its chemical composition" (Art.3 (3))

a substance as "a chemical element and its compounds in the natural state [...]" (Art. 3 (1))

and a **mixture** as "a mixture or solution composed of two or more substances" (Art. 3 (2)).

Writing instruments do not match the definition neither of a substance nor of a mixture. In the understanding of the regulation writing instruments meet the criteria of being articles. This position paper manifests this classification and the corresponding arguments and technical information are given in chapter 2. In chapter 3 specific product examples are listed and the differentiation to products which are classified as mixtures to the understanding of our association and their members. In Appendix C a non-exhaustive list of stationery products and their classification as article or mixture is shown.

Manufacturers of the European Union operate globally. In other countries "articles" are defined in the respective dangerous chemicals law. For years, writing instruments have been in general considered as articles. This has never been disputed.

Additionally, articles are consequently in the scope of the general consumer product safety. Manufacturers are obliged to carry out risk assessments dedicated to their products. The EU Commission published a Regulation on General Product Safety (EU) 2023/988 repealing the General Product Safety Directive 2001/95/EC. According to the Regulation on General Product Safety a "**product** means any item, [...] which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers [...]".<sup>1</sup>

Furthermore a "'safe product' means any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers;"

In some languages even the corresponding noun in both regulations is the same. REACH defines articles as objects, in German language "**Gegenstand**" and the Regulation on General Product Safety uses also the German word "**Gegenstand**" for defining a "product".

\_

<sup>&</sup>lt;sup>1</sup> Full text: 'product' means any item, whether or not it is interconnected to other items, supplied or made available, whether for consideration or not, including in the context of providing a service, which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;





According to Art. 7 1(b) of the REACH regulation, articles can contain a substance, which "is intended to be released under normal or reasonably foreseeable conditions of use". The word "release" is not defined within the regulation. The process of writing can be considered as such an intended release of a substance from an article. A writing instrument containing a liquid writing medium will, upon writing, release the solvents contained in the "ink", but only via the matrix on which is written on. In this sense, there is a release of substances upon use, but not a release of ink. However, in our understanding "release" means, that a substance has left a containment and there is no further control by the user under the conditiones of the current use. Because of that, our position is that there is a "transfer" of the writing media to a surface rather than a "release".

Writing instruments are consumer products and meet the definitions for products, objects and articles. These definitions are still valid despite the presence of a mixture within the writing instrument.

## 2 Arguments

Writing instruments are articles or objects which during production are given a special shape, surface or design which determines its function to a greater degree than does its chemical composition:

#### 2.1 Writing instruments are objects

They are typically produced in a multi-step process out of multiple single parts. During the production the shape, surface and design of the final instrument is given step by step. The writing medium is thereby an integral part of the writing instrument. At the end, the whole object is one unity and functions only when every single part function and fit together. Shape, surface, design and the chemical composition of every part is important to guarantee the technical functionality and therefore the intended use. The writing medium, in general, is a liquid or solid mixture of substances and is incorporated in writing instruments as one of these necessary parts. In order to use a writing instrument as a tool for writing, the writing medium has to be present, has to have the right chemical composition and the tool has still to be in the right shape to enable the intended use. The writing instrument can be used as stand-alone article without any additional auxiliaries needed. During writing the medium is consumed, while transferring to a substrate. When the writing medium is completely consumed, the writing instrument loses its function and as a result becomes useless.

## 2.2 Shape, surface and design are essential

Writing instruments are specifically designed and intended for hand-operated (manual) precise writing or colouring. Due to ergonomic human requirements, e.g. optimal fitting to the hand and fingers, the special shape promotes ergonomic writing. This **specific shape** of pens has been developed in the course of time and improved permanently. The special surface is characterized by optical and haptic properties. While making the pen looking attractive, the surface supports firm grip as well as a pleasant feeling while writing. The special design is intended to direct the consumer's attention to the pen. It gives the writing instrument an individual appearance and with that it has a strong influence on the consumer's purchasing decision. Special shape, surface and design have been given **during production**. Therefore, the intention of the size, shape and design is to perform a good





writing experience and not to store a mixture. These are the preconditions for the outer parts and optical appearance which have to be fulfilled in order to enable a writing instrument to perform its intended function which is writing. The existence of the appropriate writing medium is of course still necessary.

#### 2.3 Writing instruments are complex objects with high functionality

The functionality of the use of writing instruments is determined primarily by the technical and physical properties of the single parts. Parts of a writing instrument are specifically designed to achieve a precisely defined and constant transfer of the writing media (e.g. ink) at a miniscule rate that essentially dries instantly. Every single part of a writing instrument (e.g. writing media, capillary reservoir/ink feeder, tip) has to fit in with others in a technical manner that assures the performance. Examples of the complex functionality is given in Appendix A. The properties, are again achieved **during the production process** of the writing instruments.

## 2.4 Chemical composition is important but secondary

The chemical composition is divers and is not limited to ink/paste. A writing instrument is constituted of different materials like metal, alloys, coatings, plastics, wood, wood composites, minerals, etc. In this context it is clear, that writing instruments and writing media can contain chemicals which are subject to the REACH regulation. The ink's composition is specific for the intended application of the writing instrument and contains different solvents, colouring agents and additives. The composition is also specific for the type of writing instrument. However, an exchange of ink or a simple change of the composition is possible to a certain degree and in certain cases (while further ensuring the writing function) but not arbitrarily random. Certain variations of the chemical composition can be realized without a significant effect on the basic writing, painting or drawing function. According to REACH Article 7 (b) an article can also be able to release a substance under conditions of intended use (see next argument).

Nonetheless, the shape is still crucial in order to manufacture an object out of these materials, that is able to write. A change in shape or design of the parts can lead to either loss of function or loss of ergonomics. Even refills have to have the exact size and shape to function as such. Therefore, one can conclude, that **shape**, **surface and design** determine the function of writing instruments and refills **to a greater degree than** its chemical composition.

## 2.5 Writing instruments are articles with intended release of a substance

The article 7 (b) of the REACH regulation extends the definition of an "article" according to article 3 with a specific function of an "article" related to its chemical content, without losing the classification as being an "article". Therein considered are articles that contain substances which are "intended to be released under normal or reasonably foreseeable conditions of use". This term can be applied to writing instruments with the concretisation, that writing instruments do not release a substance but transfer ink which is a combination of more than one substance. Thereby some contained substances like solvents can be released during writing. Furthermore, a writing instrument rather transfers a substance to a surface, where it is fixed permanently, than releasing the substance in terms of freeing the chemical. With the consequence of either a loss of control over the substance or making it available for a further process step or use. This legal definition extension of an "article" suggests very clearly that writing instruments have to be considered as "articles".





#### 2.6 Writing instruments are no chemical storage container

The function of writing instruments is writing and drawing, it is considered as a tool for writing and there is no specific functionality of an intended chemical storage. The ink or paint contained in writing instruments serve to perform the intended use of writing instruments and are not the main purpose of the writing instrument. Thereby the ink is meant to be used only together with a writing instrument and vice versa. This is in contrast to the function of a chemical storage, where the content of a container is used separately from the container.

## 2.7 The size of the writing media container is not arbitrarily scalable

It would be mistakenly inadequate with respect to the complex function of all parts involved to consider writing instruments simply as "containers" for the writing media. It is possible to enlarge the size of a container without losing its function to contain, store or transport the ink. But the parts of a writing instrument as well as the ink volume cannot be enlarged over a certain limit. The functionality, mainly parameters like appropriate ink laydown and security against leakage is not given anymore when increasing the ink volume and therefore changing the pressure circumstances in writing instruments. Moreover, a writing instrument will not function anymore for manual writing when the user cannot hold the writing instrument with all its technically necessary parts in his hand.

## 2.8 No free chemical is present

The substances / ink contained in a pen is not meant to be handeled outside the pen or independent of the pen. The technology foresees a very distinct transfer of ink in order to achieve a good writing result. This transfer is only possible during writing (intended use). The ink can be incorporated in a filter, an adsorb or a reservoir. When using writing instruments with capillary reservoirs no free chemical is present. The ink laydown is measured between 0,1 and 2,5 mg/m during writing. For marker and highlighter, the ink laydown is between 5 and 18 mg/m. Furthermore, when ink is transferred, it is immediately absorbed by the substrate (e.g. paper) or dries instantly (permanent/white board marker).

It can be summarized that writing instruments are articles in terms of the REACH regulation because the functional interaction of shape, surface, design, functionality and chemical composition is crucial for its function as writing tool and the performance of its intended use.

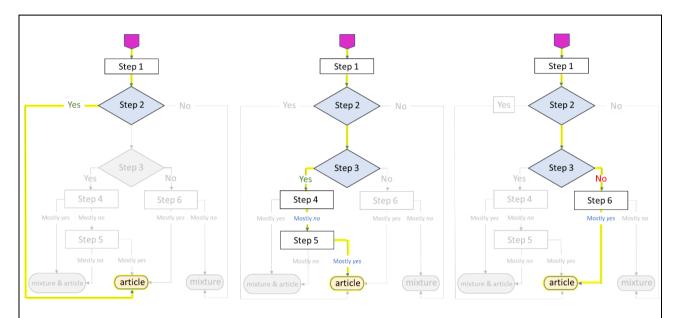
#### 3 ECHA perspective

The European Chemicals Agency (ECHA) published several guidance documents in order to give advice to the parties concerned to fulfil the REACH obligations. These have been revised and updated in the past years. It is clearly stated in the guidance documents that the text of the REACH regulation is the only authentic legal reference and that the information in the guidance documents does not constitute legal advice. The ECHA does not accept any liability with regard to the contents of the guidance documents.



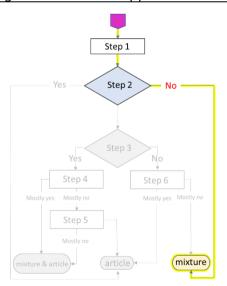


The *Guidance on requirements for substances in articles* <sup>2</sup> gives assistance on the differentiation between article and substance/mixture using a decision tree, which is shown in Appendix B. In our understanding and interpretation using the decision tree leads to the answer, that writing instruments are articles. See figure below. A full and detailed answer to all questions is given in Appendix B. Please find also enclosed the table Classification of products for writing, drawing and painting as "article" or "mixture" in Appendix C with the result of using the decision tree for the whole product range.



Decision-making paths for the following product categories: Writing instruments in general, like fiber-tip pens, ball point pens, fountain pens, pencils, and also accessories like sharpener, eraser, ruler, correction tape.

See Appendix B for the whole argumentation and Appendix C for the whole product range.



Decision-making paths for the following product categories: Ink cartridges, paint in bottles, correction fluid.

See Appendix B for the whole argumentation and Appendix C for the whole product range.

\_

<sup>&</sup>lt;sup>2</sup> https://echa.europa.eu/quidance-documents/quidance-on-reach (version 4.0, June 2017, p 18)





In the *Guidance on information requirements and chemical safety assessment* <sup>3</sup> a chapter has been published on "Consumer Exposure Assessment". Consumer exposure estimation must be assessed considering inhalation, dermal and oral intake. Pens are mentioned in this chapter as example for articles where a migrating substance might be intaken by e.g. children. In the same chapter ball pens are mentioned as an example for an article subcategory in the article category AC13 plastic articles. In another chapter about "Environmental Exposure Assessment" <sup>4</sup> the release rates of substances from articles are described. The "release of ink from a pen" might be considered as such.

The European Chemical Agency has also published guidance documents with contrary statements. E.g. in the *Guidance on requirements for substances in articles* <sup>5</sup> writing materials are put on the same level as printer cartridges. Giving different functions (writing vs storing) and a different judgement of the importance of shape, surface, design and chemical composition we see a clear differentiation between a writing instrument and a printer cartridge. Moreover, a writing instrument is used "stand alone", whereas a printer cartridge is meant to be used with a printer (a separate device is necessary). See also our product differentiation and our interpretation of the decision tree questions.

Another tool of the European Chemical Agency (ECHA) to give guidance is a database with questions and answers about their processes and regulations. In 2020 the question "Do writing instruments (pens, markers, etc.) require labelling in accordance with CLP?" was answered with "yes". In comparison to other opinions by ECHA in this answer the ink is defined as mixture which needs to be labelled according to the CLP regulation, regardless of the context of the incorporation in a writing instrument.

the replaceable ink cartridge or refill, which need to fulfil the labelling requirements of CLP."

The examples should be applied to guide decisions on similar borderline cases, e.g. writing materials would (in analogy with the printer cartridge) be considered as combinations of an article (functioning as a container) and a substance/mixture.

6 https://echa.europa.eu/de/support/qas ID 1724 full answer: "Yes, they do. All substances and mixtures that fulfil the criteria for classification as hazardous in accordance with the CLP Regulation are subject to the labelling requirements of CLP. For example, where the ink used in a pen is classified as hazardous, that will lead to labelling obligations. Where the ink reservoir is a fixed component of the pen or marker as it is placed on the market, the pen/marker needs to carry the appropriate labelling. If full labelling is not possible, then the exemptions set out in Article 29 and points 1.5.1 and 1.5.2 of Annex I to CLP can be used. In the case of empty (blank) pens and re-fillable pens, the pen body does not need to be

labelled, as the body of the pen is an article which is not the container of the ink. The hazards depend on the ink used in

<sup>&</sup>lt;sup>3</sup> https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment; (Chapter R.15 version 3.0 June 2016, p 27, 56) "The substance is contained in an article and migrates to the surface. Licking and sucking (e.g. by children) may promote leaching of the substance from the article matrix. This option [...] is applicable for example when a substance migrates from a pen, cutlery or textiles." (p 27) Table R.15-8 AC13: Plastic articles, Article Subcategory: Plastic, small articles (ball pen, mobile phone) (p 56)

<sup>&</sup>lt;sup>4</sup> <a href="https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment">https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment</a>; (Chapter R.16: version 3.0 February 2016) The release is controlled by the user of the article (e.g. release of ink from a pen) and therefore dependent on use frequency and use time per event. The release is constant over the time of use to ensure its function. (p 167)

<sup>&</sup>lt;sup>5</sup> https://echa.europa.eu/guidance-documents/guidance-on-reach; (version 4.0 June 2017, p70):





## 4 Chemical exposure, risk and consumer protection

The main intention of using a writing instrument is to ensure the intended writing result. The process of writing is complex and therefore the transfer of the writing medium is designed to be precisely adequate. Very small quantities are sufficient for a satisfying service life of a writing instrument. The necessary volume is between 0,1 ml and 10ml. Ball point pens range between 0,25 and 1,2 ml, fine liner and rollerball pens range between 1 and 3 ml, highlighter and marker between 5 and 10 ml with few exceptions to 20 ml. The volume of the writing media is determined by the intended writing duration and limited by physical and functional requirements.

The writing media are divers in condition (solid, liquid, gel-like, substrate-binded, etc.) and composition (aqueous or solvent based, small quantity additives like pigments, dyes or preserving agents). The hazard classification of one chemical within the system cannot be equalised or even compared to the "risk of using a writing instrument" with a small quantity and minimal exposure. The use of certain harmful chemicals is also limited or even restricted by regulations like the toy safety directive 2009/48/EG (soon to be a regulation) or Annex XIV and Annex XVII of the REACH regulation. In addition, manufacturers are obliged to maintain the so called SCIP database with articles containing substances of very high concern (SVHCs) at a concentration above 0,1 % weight by weight (w/w) to inform consumer transparently.

Using a writing instrument under the intended use, there is no relevant exposure to the writing medium at all, even if the writing instrument is not a closed system and ink is transferred by the pen, it becomes immediately incorporated with the substrate (e.g. paper, board). There is never a time when the ink is accessible or a free chemical.

Using a writing instrument under foreseeable conditions, it might happen to draw intentionally as well as unintentionally on the skin of fingers or hands. Considering a miniscule transfer rate of 0,1 to 18 mg/m, the fact that ink is never composed of 100% harmful chemicals and the natural barrier of the skin, the knowledge, risk and the probability of a harm is not given.

Destruction of writing instruments is neither intended nor foreseeable use. Even unintended misuse provides no harmful exposition and therefore no realistic risk. In none of intended or foreseeable uses the exposure to chemicals are significant or harmful.

According to chapter 1 manufacturers have to perform risk analysis to ensure safe products. There are no cases known with an injury or intoxication caused by chemicals in writing instruments.

The average consumer is no chemist and therefore is not trained to read chemical labelling. Interested consumer may want to know the chemical composition or rather the avoidance of certain chemicals with bad reputation. They have the option of reaching out to the customer service departments of the manufacturer at any time in order to get a technical competent but understandable answer specific to their question.





## 5 Labelling

If you hypothetically consider writing instruments as mixtures, then they have to be treated like chemicals. The following implications are conceivable:

- 5.1 Labelling a single pen is highly unpractical. The EU Commission itself confirms in a supporting explanatory memorandum<sup>7</sup> that "adhering to the standard labelling rules is sometimes **disproportionately expensive or even impossible in practice**" in the context of writing instruments. As a result, writing instruments need to be sold exclusively in blister packages, no single item sell is possible. An immense invest is necessary to add additional packaging lines and to develop and design packaging. Consequently, writing instruments become more expensive.
- 5.2 More packaging mean more packaging waste. There are many initiatives, even regulations, with the exact opposite intention. Producing additional avoidable packaging waste is fully contradictory against the global trend of sustainability. From the responses of the Member States to the Commission in a survey, the impression is that additional packaging waste through necessary labelling is to be avoided from the point of view of the Member States.
- 5.3 End consumer are misled, because for a layman the chemical labelling implies a potential risk. A "commonly educated and informed consumer", who can anticipate "foreseeable use" need a realistic risk assessment. This is done by the manufacturer and is not achieved by the CLP labelling. The EU Commission confirms here also that "there is a limited risk of exposure".

#### 6 References

This position paper was created by a joint working group of the "European Writing Instrument Manufacturer's Association" (EWIMA) and the German Association "Industrieverband Schreiben, Zeichnen, Kreatives Gestalten e.V." (ISZ). See Appendix D for the complete association membership lists.

<sup>&</sup>lt;sup>7</sup> https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12975-Revision-of-EU-legislation-on-hazard-classification-labelling-and-packaging-of-chemicals\_en (page 11)

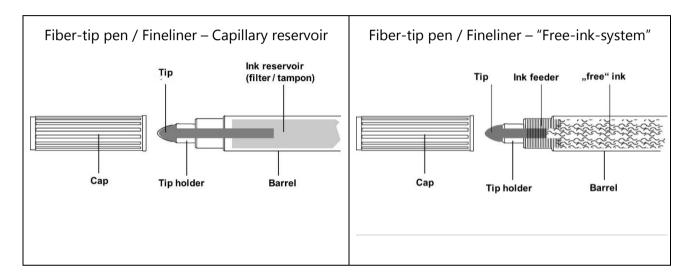




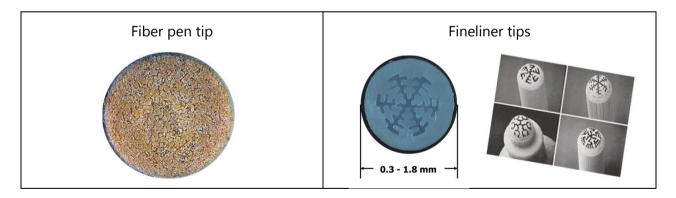
## **Appendix A: Technical information of writing instruments**

## Fiber-tip pens / fineliner and marking pens

The transfer of ink from a fiber-tip pen for instance is closely related to capillary forces, increasing in a cascade from the capillary reservoir/ink reservoir to the tip and finally to paper or other suitable writing or painting carriers. Especially due to capillary forces, physically controlling the ink reservoir (filter/tampon), there is no release of ink if a pen is left cap-less in a horizontal or vertical position with the tip downwards.



Writing instruments/marker pens designed without an ink reservoir use a complex ink feeder system combined with a tip to transfer a defined amount of ink on paper. A release of ink, e.g. by dropping or squirting or emitting to the environment does not take place.



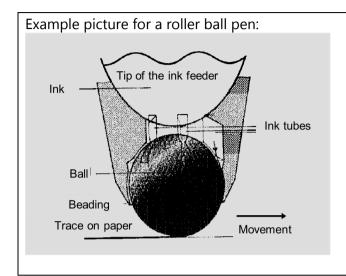
Fiber-tip pens typically contain 1 to 3 ml ink ( $\sim$  20% of pen weight). This correlates with a writing length of about 500 m (trace on paper) and thus would lead to an **application of 2-6 \mul per meter**. Marking pens typically contain 5 ml ink ( $\sim$  20% of pen weight). This correlates with a writing length of about 500 m (trace on paper) and thus would result in an **application of 10 \mul per meter**.





#### Ball point pens, roller ball pens, gel ink ball pens

A small movable ball at the tip of the refill provides the transfer of ink from a ball point pen. Due to the movement of the ball on the writing surface, ink is transferred to the paper.



To ensure the ink transfer by capillary forces whilst writing, the suitable distance between ink feeder and ball is about 0,02 to 0,05 mm. The technical properties of the ball to allow its easy movement in the ball socket are responsible for writing quality and comfort in use.

There is no release of ink, if a pen is left in a horizontal or vertical position with the tip downwards. A release of ink, e.g. by dropping or squirting or emitting to the environment is not possible. Refills typically contain 250-1200 mg ink. This correlates with a writing length from 2000 m - 10 000 m and thus would lead to an application of 0,1 to 0,12 mg/m.

The amount of ink transferred whilst writing manually in a correct manner on paper is not comparable with the amount of ink/paint applicated with a brush from a bottle or a container. The release of ink from a writing instrument to a significant extent is only likely with massive destructive force, which eliminates the function of a product.

#### Solid materials intended to leave a precise trace

Solid materials intended to leave a trace (e.g. pencils) need to have a specific shape and design to be hand-held for correct function and to be point source for precise drawing. Therefore, solid materials as such, e.g. in form of chunks, granules, flakes or powder would not allow correct writing, painting or sketching. The shape of the solid material influences the function of these writing instruments to a greater degree than the chemical composition.





# **Appendix B: ECHA's Decision Tree**

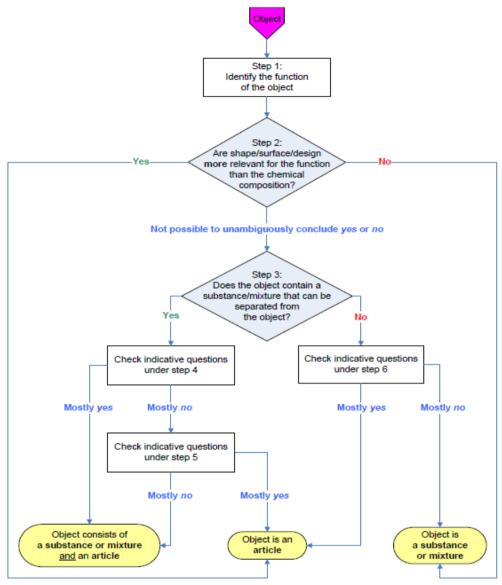
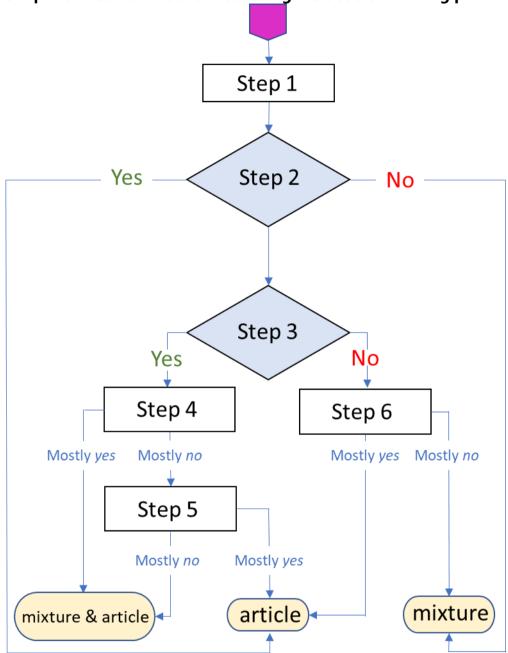


Figure 2: Decision-making on whether an object is an article or not





# Simplified decision tree for describing the decision-making path:

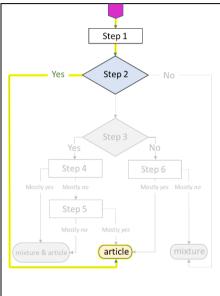






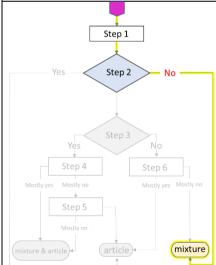
## Decision-making paths for writing instruments and other relevant products:

The first question at Step 1 "Identify the function of the object" is important for later decisions. The function of writing instruments is simply writing or drawing, a refill is able to write (e.g. in case of a ball-point pen refill) and an ink cartridge, is not able to write and its function is rather the storage of the writing media. Refills like a ball-point pen refill, with an incorporated writing technology have also the function of writing at a later point.



Step 2: "Are shape/surface/design more relevant for the function than the chemical composition?" With respect to chapter 2 (especially arguments 1-3, in addition with the very important technology of the single parts enabling a writing instrument to write, this question can be certainly answered with "yes", which leads to the immediate result, that writing instruments are considered as articles.

Product
categories:
Writing
instruments
in general,
see below for
further
distinctions;
Also,
accessories
like
sharpener,
eraser, ruler,
correction
tape

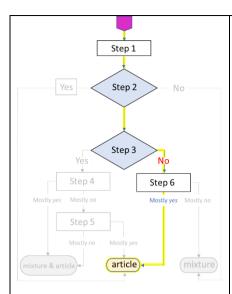


Step 2: "Are shape/surface/design more relevant for the function than the chemical composition?" For products with no function of writing this question can be answered with "no". For the function of storing writing media, shape, surface and design of the bottle, tube or container are not the critical characteristics for the products.

Product
categories:
Ink
Cartridges,
paint in
bottles,
correction
fluid







Even in specific cases, where the chemical composition is the result of a targeted recipe development and can be considered as relevant, shape, surface and design of the functional parts are still essential for the proper usability and function of the writing instrument. Therefore, if it is not possible to unambiguously conclude yes or no to the question of step 2, the decision tree leads to the following question of Step 3: "Does the object contain a substance/mixture that can be separated from the object?" If the gradually ink transfer is understood as separation see next block for further answers. Since Art. 7 of the REACH regulation allows for articles to have an intended release of substances under normal or reasonably foreseeable conditions of use, we tend to answer this question with no. A separation of the object and the complete amount of ink at once under intended or foreseeable conditions is not possible. Due to manufacturing processes the writing media as substance or mixture, is strongly incorporated in the pen body to fulfil its technological requirements to transfer the right amount of writing media to the writing substrate (see details under chapter 2 and Appendix A). For writing instruments like marker, fiber-tip pens, roller-ball pens, etc. the answer to question 3 is no. Therefore, answering the question with "no" leads to indicative questions 6a-d:

Question 6a: "Does the object have a function other than being further processed?" Yes, writing instruments are ready to use articles for so called end-use function. No further processing is necessary or practised. Question 6b: "Does the seller place the object on the market and/or is the customer mainly interested in acquiring it because of its shape/surface/design (and less because of its chemical composition)?"Yes, the main intention of a consumer is to have a proper writing instrument. Even when the consumer has specific conditions on the chemical ingredients, shape, surface and design are still dominant, because they buy a function and not a mixture.

Specific product categories: Fiber-tip pens, ball point pens, fountain pens, pencils, see Appendix C for further products

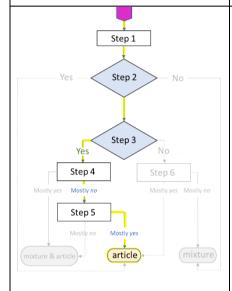




Question 6c: "When further processed, does the object undergo only "light processing", i.e. no gross changes in shape?" Not applicable because no further processing.

Question 6d: "When further processed, does the chemical composition of the object remain the same?" Not applicable because no further processing.

Answering the indicative questions with *mainly yes* leads to the result, that writing instruments are articles.



Even in specific cases, where the chemical composition is the result of a targeted recipe development and can be considered as relevant, shape, surface and design of the functional parts are still essential for the proper usability and function of the writing instrument. Therefore, if it is not possible to unambiguously conclude yes or no to the question of step 2, the decision tree leads to the following question of Step 3.

When the separation of mixture and article is understood as the writing process, the question of Step 3: "Does the object contain a substance/mixture that can be separated from the object?" has to be answered with "yes". This leads to indicative questions 4a-c.

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? No, the writing media itself is not capable of writing.

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? No, a writing instrument is not a dosing pump. Writing as a result of the substance transfer to a surface like paper is the main function, not the discharge itself.

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

Product
categories:
Fiber-tip
pens, ball
point pens,
fountain
pens, pencils,
see Appendix
C for further
products





useless and leading to the end of its service life? Yes, e.g. for single use pens and pencils, but no for refillable writing instruments like fountain or roller-ball pens.

Independent of the last question the predominate answer is still "no" and leads to indicative questions of Step 5:

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? Yes, writing instruments without writing media cannot write. Ink is an integral part of the writing instrument (like the fluid in a thermometer).

Question 5b: *Is the main purpose of the object other than to deliver the substance/mixture or its reaction products?* Yes, in analogy to the answer of question 4b.

Question 5c: Is the object normally discarded with the substance/mixture at the end of its service life, i.e. at disposal? No, writing instruments normally are discarded when the cartridge is empty and the ink is completely consumed. If the cartridge is not yet empty, the writing instrument can be discarded without a needed disassembly. The indicative questions of Step 5 can be mostly answered with yes, therefore also this decision tree path leads to the result that writing instruments are articles.





# Appendix C: Classification of products for manual writing, drawing and painting as "article" or "mixture"

(as defined according to Art. 3 (European Regulation (EC) 1907/2006 - REACH)

- → "article" means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
- → "mixture" means a mixture or solution composed of two or more substances;

	Definitely considered as "Article"		Definitely considered as "Mixture"
	Fiber-tip pens and fiber-tip refills (e.g. fineliner, marker, fiber-tip pens)		Ink cartridges, ink in containers: Fountain pen ink cartridges, fountain pen ink in bottles Indian ink / China ink
ıstruments	Ball point pens and ball point pen refills (e.g. ball point pens, gel pens, roller ball pens)	Inks, paints	Paint in bottles, containers, tubes, tins or tablets (e.g. finger paint, water colour, paint for use in play / didactical / creative / artistic use)
Writing and drawing instruments	Fountain pens		Modelling clay, modelling material, casting material for use in play / didactical / creative / artistic use
Writing ar	Wood / Plastic cased pencils (e.g. black lead pencils, coloured pencils for use in play/ didactical / creative / artistic use), mechanical pencils and leads		
	Technical drawing instruments (e.g. technical pen)		
	Valve markers		
	Sharpener		
S	Eraser	Accessories	
Accessories	Ruler, stencil		
cces	Compass		
d	Correction tape	<b>d</b>	Correction fluid
	Glue tape		

This list does not claim to be exhaustive.





# **Appendix D: Membership lists**

# Membership list of the "European Writing Instrument Manufacturer's Association" (EWIMA):

ADEL	aurora trading	BALLOGRAF®  60 YEARS OF SWEDISH WRITING QUALITY
BiC®	CARAN P'ACHE Genève	CARIOCA
(C) centropen®	colart	DERWENT
du de martini	DOBELL 🛆	<b>Jokumental</b> power your pen
edding®	<b>\$</b> FIL <b>a</b>	PLASTICS ENGINEERED BY  GEHR  ®
HUTT®	OOAI	JOWO BERLINER SCHREIBFEDER GMBH
ROEL NOOR ROEL NOOR	<b>Kores</b> ®	KOTOBUKI
KREUL seit 1838	STEFAN WUPIETZ KG	LA-CO Markal
LAVY	Schroben - Kenstrichnen	A Luxut











Membership list of the "Industrieverband Schreiben, Zeichnen, Kreatives Gestalten e.V." (ISZ):

aloh	FABER-CASTELL A K A D F M I E	<b>Okumental</b> power your pen
edding®	FABER-CASTELL	GEHR
HUTT®	JOWO BERLINER SCHREIBFEDER GMBH	KREUL
STEFAN EUPIETZ KG	KOTOBUKI	Design. Made in Germany.
E LINZ schröter - kenunichnen	A Luxut	<b>LYRA</b> Germany
NORIS®	<b>Pelikan &amp;</b> Group	Pentel.
POREX Filtration Group*	Robert E. Huber	SCHMIDT® Technology
Schneider \\\	<b>⊘</b> STABILO°	STAEDTLER
Star Minen	STOCKMAR	** Tombow