

# European Photo and Imaging Association<sup>1</sup>

## EPIA REACH<sup>2</sup> Guidance Document IV Substances in Articles of the Imaging Industry Equipment - Practical implementation

With this Guidance Document IV, EPIA wants to extend the guidance about Substances in Articles in the Imaging Industry as given in the previous Guidance Document III.

In this add-on EPIA presents its views on possible practical implementation steps (= how) to achieve compliance with the REACH requirements for articles (= what) for the different types of articles typically manufactured or imported by the photographic industry.

Typical Articles within the Imaging Industry include two categories:

- ⇒ Articles manufactured starting from the chemical building blocks (e.g. photographic film, paper, plates, screens)
- ⇒ Articles manufactured in an assembly process of other articles (e.g. photographic equipment)

### I. Summary of previous EPIA Guidance regarding Substances in Articles

EPIA Guidance Document III on “Substances in Articles of the Imaging Industry” includes

- a. an overview of REACH obligations for Manufacturers/Importers of Articles
- b. a recommendation to establish an adequate Inventory List, also for substances in Articles
- c. flow charts to establish possible requirements under REACH for substances in Articles

In this way Guidance Document III gives tailor made guidance for articles in the photographic industry presenting detailed information on what possibly needs to be done to achieve compliance with REACH. It also recommends to establish an inventory list – including substances incorporated in articles – to allow verification at any point in time regarding possible requirements under REACH for substances in those articles.

For the above items a. and b. a summary is taken from this Guidance Document III:

<sup>1</sup> EPIA represents photo imaging companies and European national associations of photo imaging companies. The membership includes manufacturers of photographic products and the national associations CIPHO (Chemieverband Imaging und Photo e.V.), PIC (Photo Imaging Council) and Federchimica.

<sup>2</sup> REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

- **Obligations under REACH for Manufacturers/Importers of Articles**

The Manufacturer/Importer of articles may have the obligation to

- ⇒ **Register** certain substances intended to be released from articles (**article 7.1**)
- ⇒ **Notify** certain substances of very high concern (SVHC)<sup>3</sup> in articles (**article 7.2 and 7.3**)
- ⇒ **Notify** Classification and Labelling (C&L) of intentionally released substances meeting the criteria of DIR 67/548/EC (**article 112 and 113**) (>> *will proceed to GHS<sup>4</sup> Legislation*)
- ⇒ **Inform** the supply chain about certain SVHC substances in articles (**article 33**)

depending on the *amount* and the *type* of substance *released from* or *present in* the articles.

- **Establishing an adequate Inventory List for substances in Articles**

Based upon the REACH requirements laid down in Article 7.1 (registration), 7.2 and 7.3 (notification), Article 33 (communication down the supply chain) and Article 112/113 (notification of the C&L of intentionally released hazardous substances), EPIA recommends considering all imported or manufactured articles for inclusion in the Inventory List. A breakdown should be made, to *all* substances intended to be released from the articles and to *all* SVHC appearing on the so-called candidate list (Article 59) and present in concentrations >0.1 % (w/w).

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<sup>3</sup> SVHC = Substances of Very High Concern; substances included in the candidate list (Article 59)

<sup>4</sup> GHS = Globally Harmonised System of Classification and Labelling of Chemicals

## II. Practical implementation

In this section EPIA presents its views on possible practical implementation steps (= how) to achieve compliance with the REACH requirements for articles (= what) for the different types of articles typically manufactured or imported by the photographic industry.

Typical Articles within the Imaging Industry include two categories:

- ⇒ Articles manufactured starting from the chemical building blocks (e.g. photographic film, paper, plates, screens)
- ⇒ Articles manufactured in an assembly process of other articles (e.g. photographic equipment)

### a. Articles manufactured starting from the chemical building blocks

For those articles in the imaging industry that are manufactured starting from the “chemical building blocks” (substances and preparations) – such as photographic film and paper, printing plates, phosphor screens a.o. – the manufacturer generally will have the possibility to **build a complete inventory** (such as described in EPIA Guideline I and Guideline III), **including a breakdown** of the article **to the substance level**.

In such cases EPIA is recommending to build such an inventory list because it will allow verification regarding possible requirements under REACH for substances in those articles at any point in time.

### b. Articles manufactured in an assembly process of other articles

In the imaging industry we have however a second category of articles – e.g. equipment – where the manufacturing is in fact an assembly process, building the final piece of equipment from parts and subparts.

A schematic presentation of such a process is given in annex 1.

The EPIA REACH WG is of the opinion that for this type of articles an approach of trying to build a full inventory of substances – i.e. compiling a database with the complete part-lists of all components and subcomponents and make a break-down for each of them to the chemical substance level (including information on weight fraction in the final equipment etc) - would not result in a workable approach to fulfill possible REACH requirements.

Therefore – **for equipment** – the REACH WG proposes a “**process approach**” as a pragmatic and workable approach to ensure legal compliance. This process could involve several elements including some or all of the following:

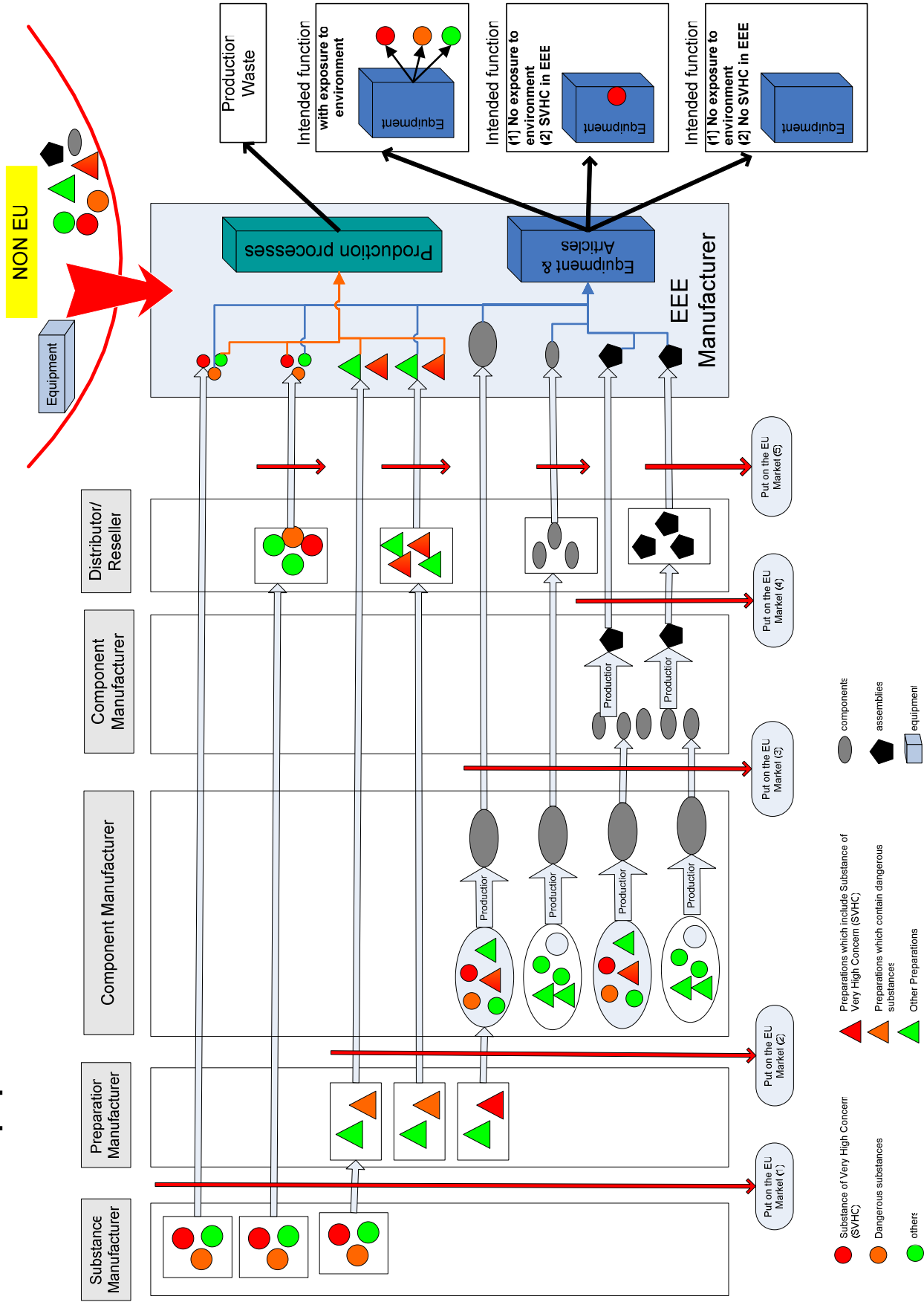
- (a) issue a list of substances subject to REACH obligations when present in articles (equipment) under certain conditions
- (b) request self declaration by suppliers of components regarding this list, indicating either adherence to the list or providing adequate information in case of non-adherence
- (c) incorporate such a requirement in the technical specifications of all components purchased
- (d) incorporate such a requirement in the terms of conditions for all components purchased
- (e) perform a risk assessment regarding potential REACH obligations for equipment produced or imported, based upon expert judgment
- (f) for equipment possibly subject to REACH obligations, take further action such as additional information gathering and/or audit of suppliers

As a reference – and in some way as a simplified precedent – “Table 2: Typical Compliance Documentation List”, taken from the RoHS Enforcement Guidance Document issued by UK Authorities in May 2006, is given in annex 2.

### **Disclaimer**

The present document was developed by experts from the photochemical industry to their best knowledge and judgement, but no liability whatsoever is accepted in respect of this document. The text of the REACH Regulation is decisive in all cases.

# Annex 1: Equipment Production Process



## **Annex 2: RoHS Enforcement Guidance Document**

Version 1 – issued May 2006

### **Table 2 - Typical Compliance Documentation List**

#### **Route A**

##### **Process-based Technical Documentation**

*(Typical information relating to the producer's internal system to ensure RoHS compliance)*

##### **Compliance Assurance System (CAS)**

- 1) A definition of the purpose of the system, its essential requirements and specification. This specification should cover compliance both within the company and within the supply chain
- 2) A formally defined process which implements the requirements of the system and is integrated within the organisation's quality and management systems
- 3) A technical documentation system (paper and/or electronic) to support the process and measures to assure conformity with the requirements of the system together with necessary training, tools and infrastructure.

##### **Evidence of Active Control of the CAS**

- 4) Results of internal and supplier audits to validate Compliance Assurance System and/or processes. i.e. the supplier's ability to assure compliance.
- 5) Evidence that the system is being followed including results of product specific conformance assessments comprising items such as product assessments (including justification of RoHS categorisation and use of exemptions), materials declarations, procurement, inventory and production controls and substance analysis where appropriate
- 6) Overview of any internal data system used for the management of RoHS compliance data

#### **Route B**

##### **Product/Part-based Technical Documentation**

*(Typical information relating to a product's/part's physical attributes that ensures RoHS compliance of a specific product)*

- 7) Producers' or suppliers' warranties /certificates declaring that the use of the restricted substances is within the permitted levels
- 8) Producers' or suppliers' completed materials declaration for each part (including revision for revised parts) and justification of RoHS categorisation and use of exemptions. These declarations would be limited to the list of RoHS substances, not full materials declarations
- 9) Analysis report for homogeneous materials\* in parts/components, (which could be the producers or suppliers own internal or external test results). The test results should refer to homogeneous materials\* in parts/components.
- 10) Those who use approach B only (SMEs) must also provide evidence that procedures are being followed to show that materials declarations have been assessed to determine if they can be trusted. Enforcement authorities will also need to see documented compliance procedures

<p>* the term "homogeneous materials" is used in the RoHS Directive, but is <u>not</u> used or mentioned in the REACH legal text</p>
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