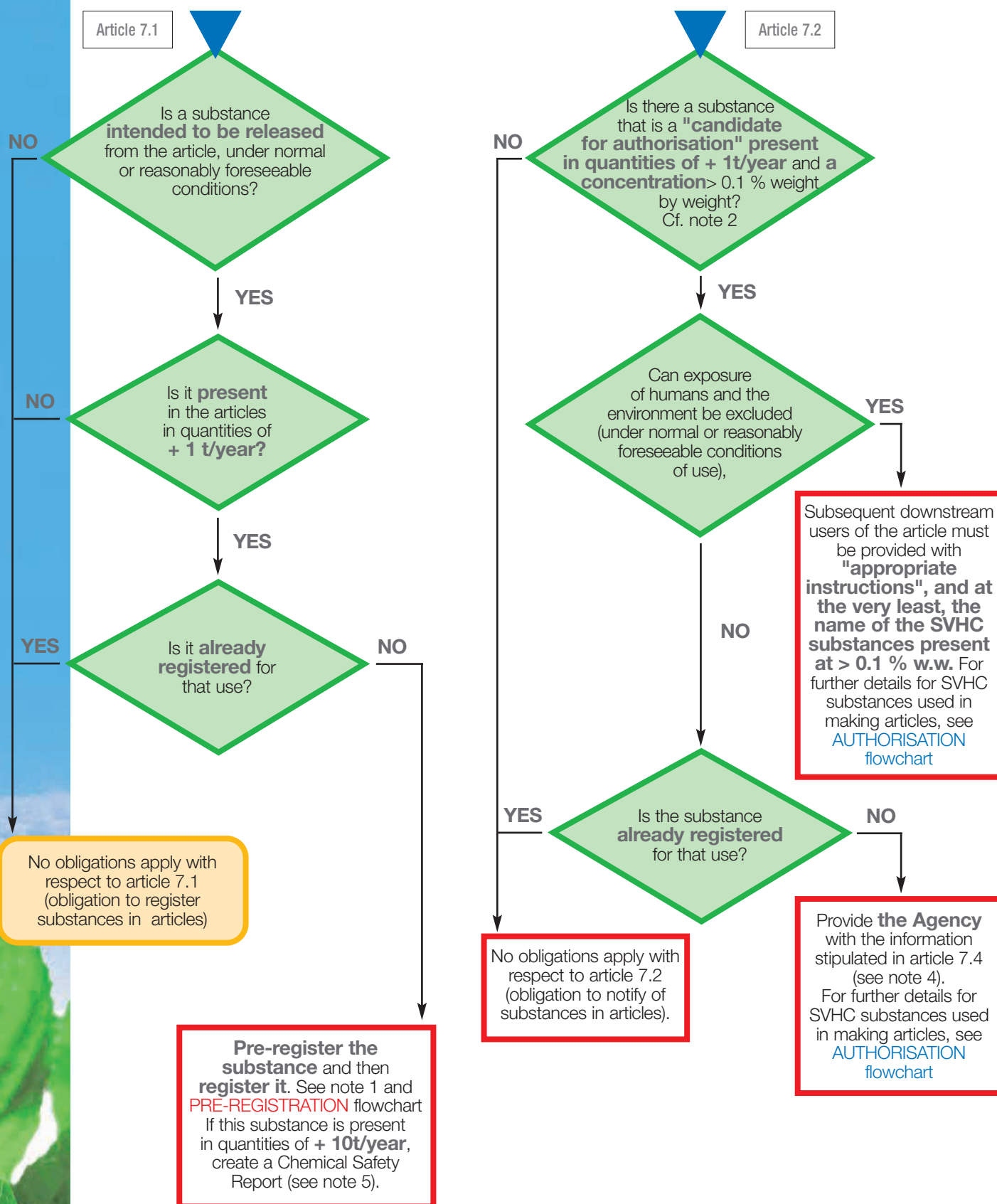


ARTICLES flowchart 1

My company produces or imports articles

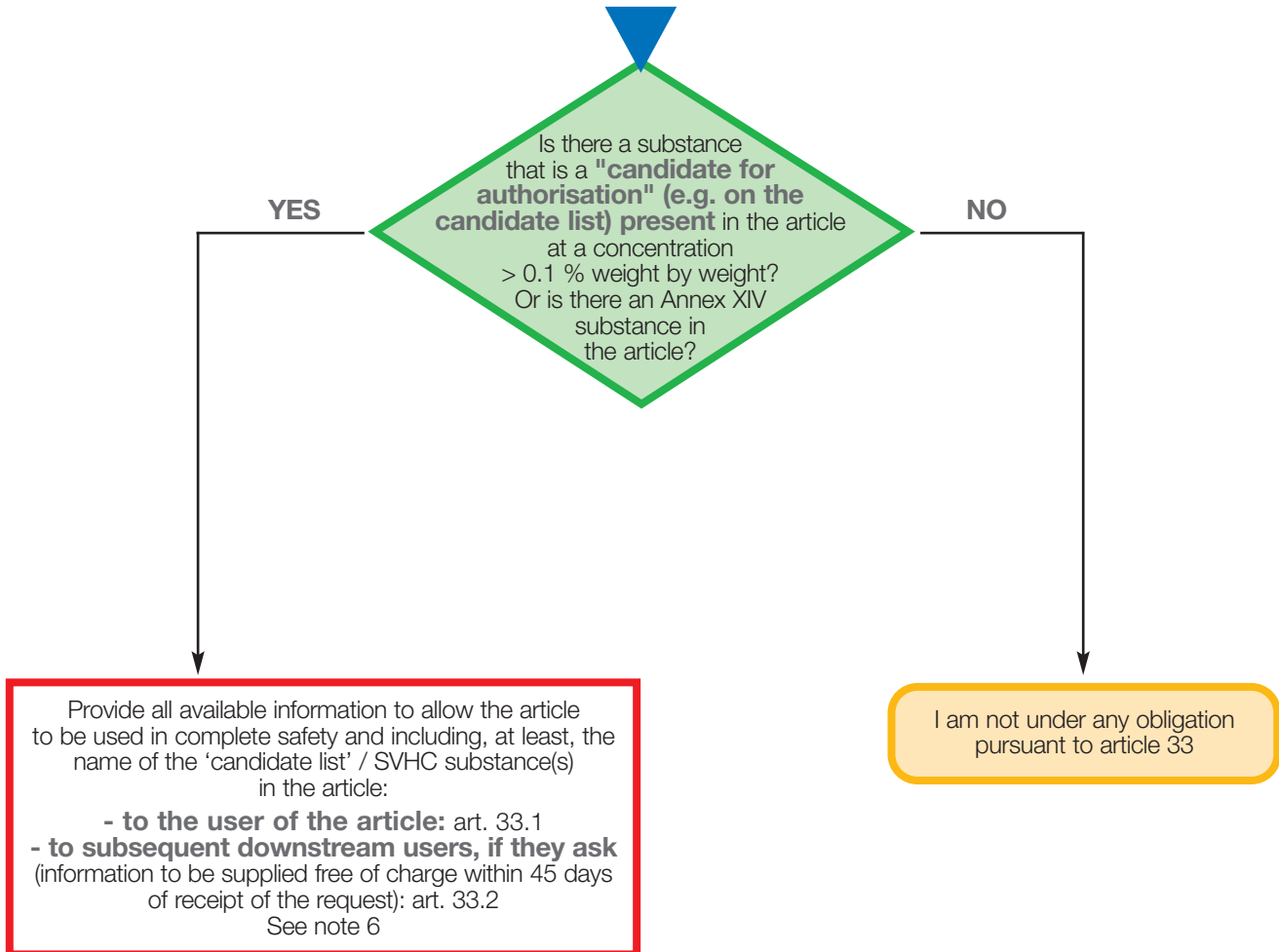
Two series of questions must be asked in succession



ARTICLES Flowchart 2

Downstream communication as a "supplier of articles"

(producer, importer, entity placing on the market)



Notes for the ARTICLES Flowcharts

Remark: in the flowcharts "I" corresponds to a legal entity: a company with three subsidiaries represents 4 distinct legal entities.

PREAMBLE

• Lack of clarity on obligations relating to substances in articles.

An article, in the REACH sense, is 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". Parts and components are therefore articles.

There are only two provisions (art. 7 and art. 33) in the Regulation that cover the obligations regarding the substances in articles. **There are still a large number of issues that need to be resolved:**

- on the basic definition of an article (is steel strip a solid preparation or an article? The European Commission has not yet reached its decision),
- on the calculation of the tonnage or concentration thresholds (should we consider the article as a whole, or each material? Do different part numbers represent different articles?),
- on the notion of "substance intended to be released under normal or reasonably foreseeable conditions of use".

Answers are expected in application guidelines written by the Commission and representatives of industry, RIP 3.8 (RIP for Reach Implementation Project).

• Optimistic presumption...

REACH presumes that all producers know all of the substances in all of the articles they produce or import. Some preparations used to manufacture articles or other preparations, can have variable constituents even if they conform to a specification. Therefore even two batches of the same standard material could lead to different obligations within REACH.

Note 1. Possibility of an obligation to register for a substance "intended to be released" by the article.

Article 7.1 of the Regulation states that any producer or importer of articles must register a substance present in these articles if all the following conditions are met:

- a) The substance is present in these articles in quantities greater than or equal to a total of **1 t/year** per producer or importer;
- b) The substance is intended to be **released** under normal or reasonably foreseeable conditions of use;
- c) The substance has not already been registered for that use.

Note 2. Presence of a substance that is a "candidate for authorisation" in an article, above certain concentration and tonnage thresholds (art. 7.2).

Amongst the substances said to be of "very high concern", the Agency will identify certain substances on a "candidate list for authorisation".

These candidate substances will then be included, or not, in annex XIV "Authorisation" (*this means: prohibited unless authorised*). An initial list will be drawn up by the Agency in 2008 or, at the latest, by 1 June 2009. Other recommendations will be added to this list every two years.

Note 3. Can exposure of humans and the environment be excluded (under normal or reasonably foreseeable conditions of use), including disposal?

If exposure can be proven to be prevented, then Article 7.3 states that the producer/importer does not have to provide the information to the Agency. The producer/importer still must provide "appropriate instructions" to the user of the article.

At present, no explanation is available defining exposure of human beings and of the environment, including disposal.

Note 4. Information to be provided to the Agency relative to article 7.2

This information must be provided:

- if a substance of very high concern is present in the articles in quantities above the stipulated thresholds,
- **and** if that substance has not been registered
- **or** if the producer/importer cannot exclude exposure to that substance (see note 3)

Article 7.4 gives the list of information to be provided: identity of the producer, identity of the substance, its classification, a brief description of the use(s) made of the substance(s) contained in the article.

Entry into force of the obligation to notify: from 1 June 2011, then six months after a substance has been included on the above-mentioned list.

Note 5. Chemical Safety Report

For a substance "intended to be released" present in quantities of > 10t/year, the producer or importer of articles must create the Chemical Safety Report (CSR) provided for in article 14 and described in annex I. The production of this report is expected to be time consuming and expensive.

The CSR includes a chemical safety evaluation (identifying the health hazards, physicochemical hazards, environmental hazards, persistent and bioaccumulative nature).

Note 6. Communication of information to the user of the article and the end consumer if he asks for it

This communication of information is provided for in article 33. It applies once the 0.1 % concentration threshold is passed (the tonnage used/imported/manufactured is irrelevant). It applies to all "suppliers of articles", which includes the producer, importer, distributor or any other actor in the supply chain who places an article on the market.

It is required for any substance identified by the Agency as being a "candidate for authorisation" (see note 2). The obligation will come into force as soon as the list identifying this type of substance is issued by the Agency (2008 or, at the latest in June 2009).