Workshop for

MedTech Europe
from diagnosis to cure

on

REACH Authorisation for DEHP in Medical Devices

21 September 2020

Objectives of this workshop

- Explain the upcoming regulatory changes at EU level concerning the use of DEHP in medical devices and IVDs, and associated timelines
- Take you through the EU-level process that will soon apply for obtaining an authorisation to use DEHP in MDs/IVDs within the EU/EEA
- Give you concrete advice on how to navigate this authorisation procedure successfully, relying on EPPA's experience with the process
- Provide an interactive setting where you can seek clarifications about the topic and raise any other important questions

DEHP: one of the most commonly used plasticisers in medical devices

- **Blood bags & Intravenous bags**
- **Nutrition pockets**
- **Tubing**
- **Catheters**
- **Respiratory masks**
- **Disposable gloves**

Under the EU's REACH framework for chemicals, DEHP currently benefits from an **exemption** which means its use in such MDs/IVDs within the EU/EEA market **does not require a specific Authorisation under REACH**

But this is about to change…

Imminent changes to DEHP's status at EU level

- **In July 2019, the European Chemicals Agency (ECHA) recommended that the endocrine-disrupting properties of DEHP for human health and the environment be recognised under the EU's REACH Regulation**
    - Consequently, the use of DEHP in MD/IVD within the EU/EEA **will no longer benefit from the "human health exemption"** currently applying under REACH

- **This ECHA opinion is expected to take legal effect within the next 12 months**

- **Once the extension of Annex XIV on ED properties of DEHP is adopted, you will have to apply for an Authorisation under REACH in order to continue using DEHP in MD/IVD (or placing it on the market) within the EU/EEA**

REACH ANNEX XIV AMENDMENT FOR DEHP RELEVANT FOR MD/IVD:

A PENDING PROCESS

“Expiry” of the human health exemption for DEHP in MD/IVD:

Timeline of the process at EU level

When the ECHA recommendation is formalised (circa Q3 2021) the final Commission decision will set down:

1) The "latest application date"

- The latest date by which you will be able to submit an Authorisation application under REACH to continue using or placing DEHP on the EU/EEA market for MD/IVD (**estimate: Q1 2023**)

2) The "sunset date"

- After this date the use of placing on market of DEHP in MD/IVD will be banned **unless** you have obtained a REACH Authorisation or have submitted a REACH Authorisation application before the "latest application date" (**estimate: Q3 2024**)

REACH AUTHORISATIONS:

SCOPE AND APPLICATION PROCESS

Scope of REACH Authorisations: key facts

- **They are "use-specific": each envisaged use of DEHP must be explicitly authorised**
    - This includes using the substance on its own, or in a mixture
    - The use or placing on market of an **article** containing DEHP would not require REACH Authorisation (although the incorporation of DEHP into an article would be covered)
- **The REACH Authorisation would relate only to the use and/or placing on the EU/EEA market, including import, of DEHP** (i.e. **not** the manufacture)

Scope of REACH Authorisations: key facts (II)

- **Certain uses of DEHP for scientific research and development would be exempt from the REACH Authorisation requirement, e.g.**
  - Analytical activities using MD/IVD at a laboratory scale (reagent, calibrator)
  - Monitoring and quality control
  - Certain upstream life cycle stages to produce MDs/IVDs

Must be carried out under controlled conditions in a volume less than one tonne per year

Applying for an Authorisation under REACH:

The basics

- You must submit an **application for Authorisation to the European Chemicals Agency (ECHA)**, an independent EU agency composed of scientific experts

- **ECHA evaluates** your application, carries out a public consultation and issues a scientific **opinion on whether or not Authorisation under REACH may be granted**

- The ECHA opinion is **formalised in a decision adopted by the European Commission** (after consultation with Member State officials), then takes effect following its publication

Applying for an Authorisation under REACH:

Two possible approaches

ROUTE 1:

Show that the risks of DEHP are adequately controlled and below the threshold level

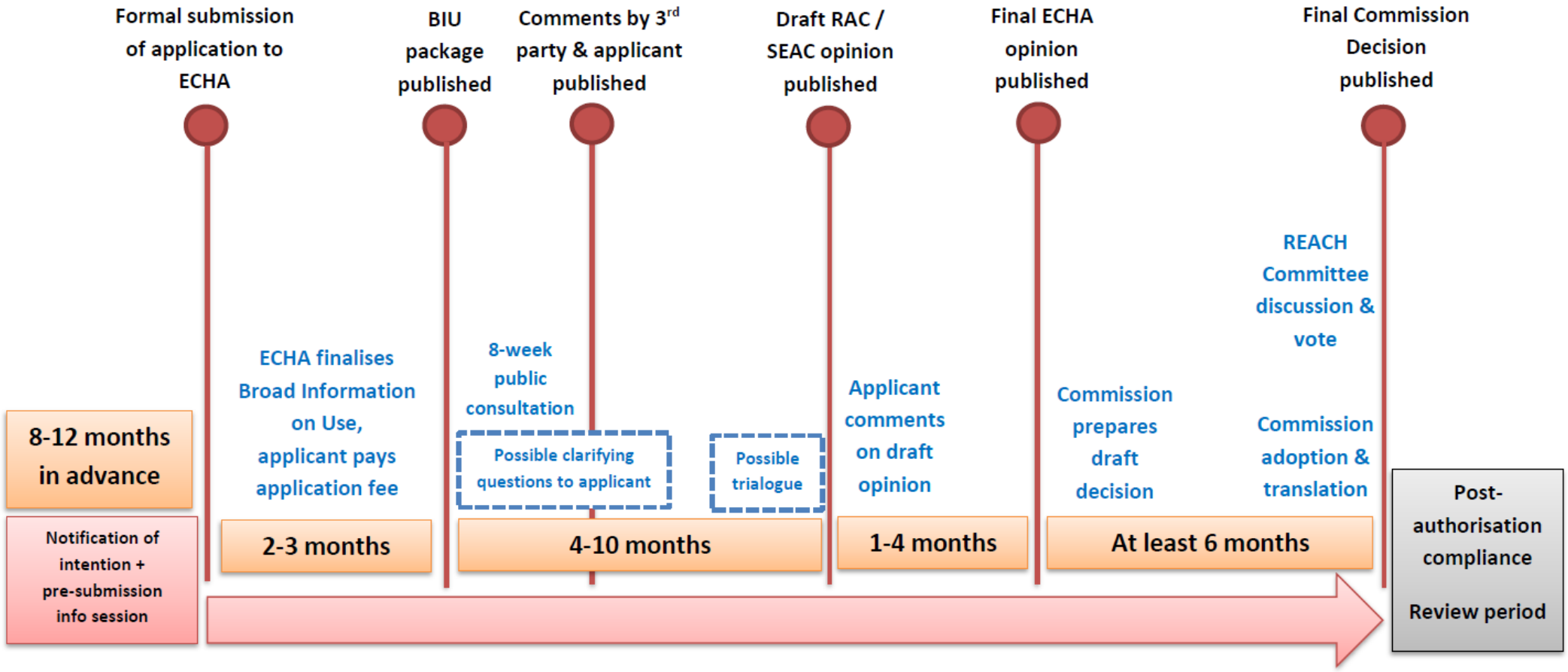
ROUTE 2:

Show that the socio-economic benefits of DEHP outweigh the risks arising from MD/IVD uses, and that there are no suitable alternatives

ROUTE 2 may be the best option, given current uncertainties around the appropriate derivation of thresholds and dose-response relationships for endocrine disrupting substances

Applying for an Authorisation under REACH:

Timeline of the process at EU level



The Authorisation process in depth

1. Pre-ECHA stage

Notify ECHA in advance of your intention to submit an application

Organise a teleconference information session with ECHA to clarify any substantive or procedural issues

Prepare your application

Submit your application to ECHA

It is vital to make sure your application contains all the required information:

- **Description of use(s)**
- **Chemical Safety Report**
- **Analysis of Alternatives**
- **Socio-economic Analysis**
- **Substitution Plan (if nec)**

The Authorisation process in depth

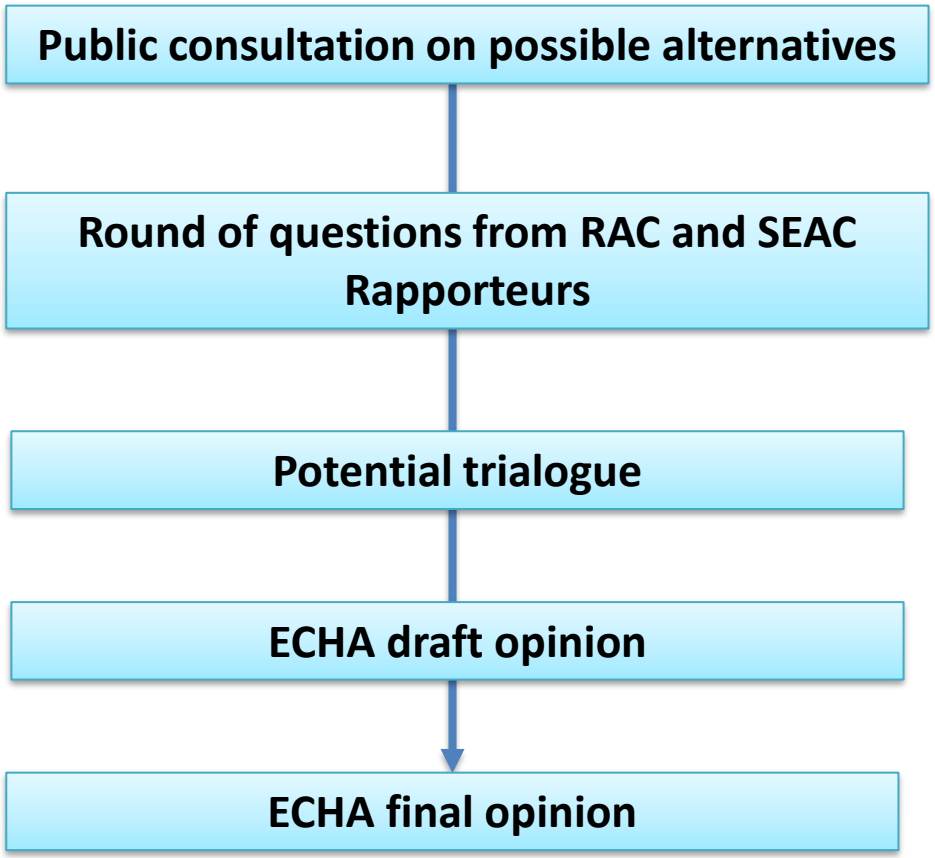
1. Pre-ECHA stage

EPPA REALITY CHECK

- Develop an **application strategy** early on: decide who should submit (suppliers or downstream users?), assess cost of gathering and analysing the data, and conducting the Socio-Economic Analysis
- Define precisely the use(s) of DEHP you are seeking!
- A pre-submission meeting with ECHA is strongly recommended

The Authorisation process in depth

2. ECHA stage



EPPA REALITY CHECK

- Public consultation is an opportunity for NGOs to advocate against a substance: DEHP has a high public profile!
- Trialogues can be a valuable opportunity to address complex technical questions
- Remember to indicate any confidential business information before publication

The Authorisation process in depth

3. Post-ECHA stage

Commission prepares draft decision on (non-)authorisation

Commission consults REACH Committee on draft decision

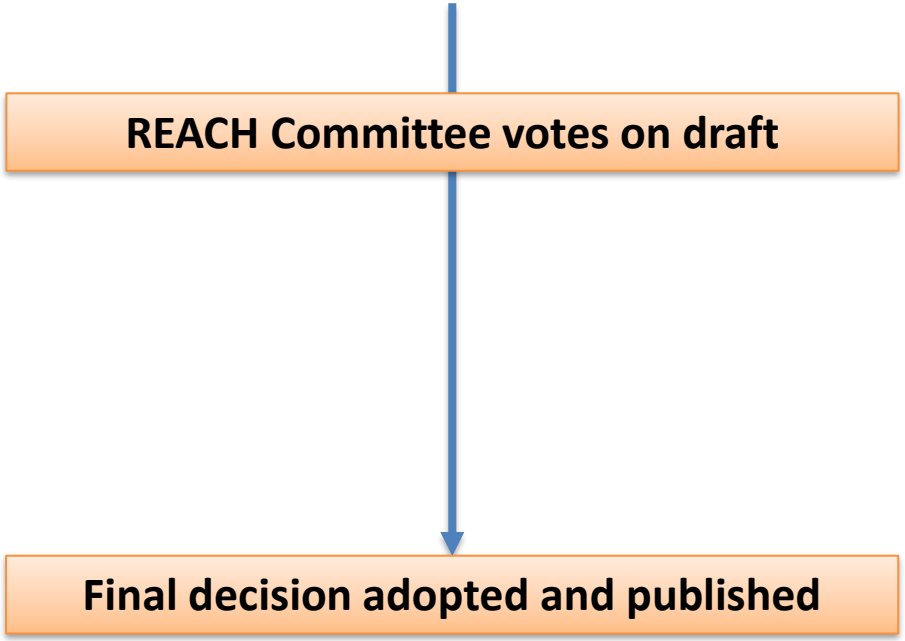
Draft is prepared by the REACH unit of DG GROW within 3 months of receiving the ECHA opinion

The REACH committee is composed of representatives of Member State authorities responsible for chemicals.

The REACH Committee will, if necessary, have a discussion on the draft and then move to a vote (unless there are fundamental disagreements that require further ECHA analysis).

The Authorisation process in depth

3. Post-ECHA stage



For REACH authorisations the examination procedure applies, which means the vote is by qualified majority:

- 55% of Member States (i.e. 15 out of 27),
- Representing at least 65% of EU population.

If a qualified majority is not reached, the Commission can either re-draft or submit the same draft to the Appeal Committee for an additional vote.

The Authorisation process in depth

3. Post-ECHA stage

EPPA REALITY CHECK

- The Commission can be a black box when drafting the final decision
- Risk of Member States raising new issues in the REACH Committee that might delay the authorisation process
- Authorisation procedure is rigid and not typically adapted to business realities

ANY QUESTIONS?