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REACH Authorisation for DEHP in Medical Devices

Factsheet

September 2020

I. OVERVIEW & BACKGROUND

This factsheet addresses two consecutive but distinct processes within the Authorisation pillar of the REACH Regulation relevant for DEHP in medical devices:

1. **First, there is the process to amend the DEHP entry in Annex XIV (the "Authorisation List") of REACH.**

   Since February 2011, DEHP has been listed in Annex XIV of REACH but only in respect of its hazards for human health. As a result, the use of DEHP in medical devices is currently exempt from the REACH Authorisation requirement as per Articles 60(2) and 62(6) of the REACH Regulation.

   This situation is set to change by virtue of the July 2019 recommendation of the European Chemicals Agency which proposes modifying Annex XIV of REACH in order to recognise also the environmental hazards posed by DEHP. As a result of this proposed change, the "human health exemption" for DEHP in medical devices would no longer apply.

   However, in order to give these changes legal effect, the adoption of a final decision by the European Commission is required.

   On **page 4** of this factsheet we provide a provisional timeline for the final adoption of that amendment to DEHP's entry in Annex XIV.

2. **Secondly, there is the process whereby economic operators may apply to the European Chemicals Agency to obtain a REACH Authorisation for the use or placing on the market within the EU/EEA of DEHP in medical devices and in vitro diagnostics.**

   Such applications will become possible once the process in Step 1 (described above) is complete.

   The majority of this factsheet is devoted to the process of applying for a REACH Authorisation.

- On **pages 5-6** we address important issues around the scope of REACH Authorisations.

- On **page 7** we provide a general timeline for the REACH Authorisation process.

- On **pages 8-10** we provide detailed information on the key stages of that process, an overview of the most relevant rules and guidance, and a "reality check" based on EPPA's experience with this process.

Key abbreviations and acronyms used in this factsheet

EU/EEA: European Union / European Economic Area

ECHA: European Chemicals Agency

BIU: Broad Information on Use

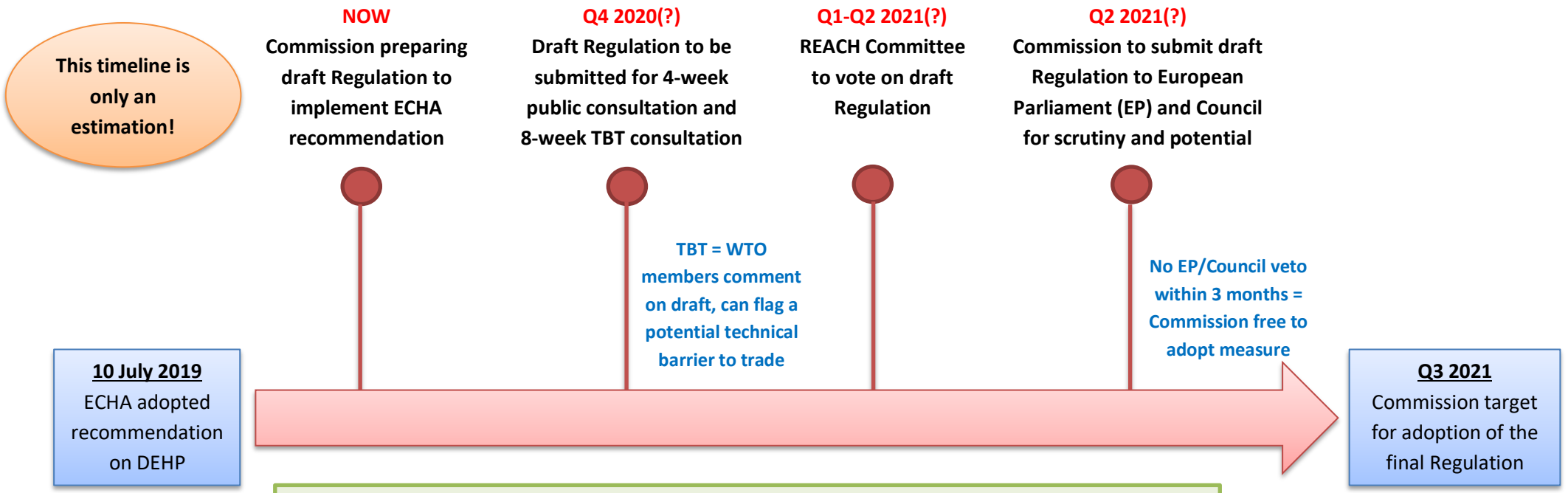
RAC: Risk Assessment Committee

SEAC: Socio-economic Analysis Committee

TBT: Technical Barrier to Trade

SEA: Socio-economic Analysis

REMINDER: The 10 July 2019 recommendation of ECHA concerning the endocrine-disrupting properties of DEHP (for the purposes of its REACH Annex XIV listing) and consequent removal of the Authorisation exemption for medical devices is **not automatic**. In order to take legal effect, it requires a formal decision of the European Commission, which has not yet been adopted. A timeline for the adoption of this Commission decision is provided below.



The final Regulation will set down:

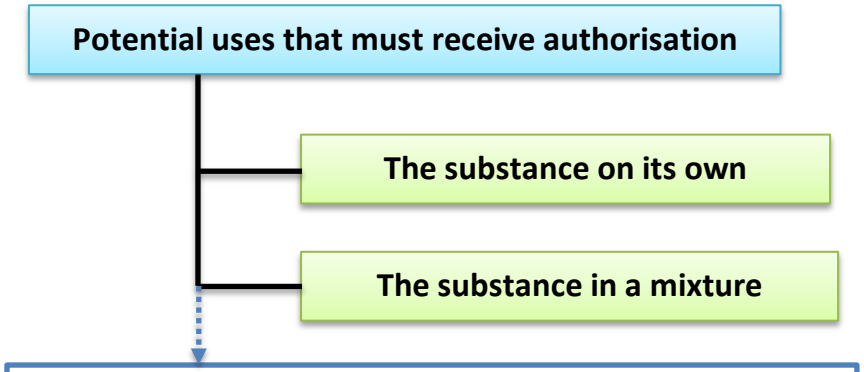
(1) The **latest date by which an operator may submit an application** for Authorisation to continue using or placing DEHP on the market in the EU/EEA → **ECHA recommends 18 months from entry into force of the final Regulation (guesstimate: Q1 2023)**

(2) The **"sunset date"** after which the use or placing on the market of DEHP in the EU/EEA will be prohibited unless an Authorisation is granted under REACH, or unless an application for Authorisation was submitted before the deadline set in point (1) above → **ECHA recommends 36 months from entry into force of the final Regulation (guesstimate: Q3 2024)**

II. SCOPE OF AUTHORISATIONS UNDER REACH

- Once the July 2019 recommendation of the European Chemicals Agency is formalised in a decision of the European Commission (see page 4), the use or placing on the market[1] within the EU/EEA of DEHP in medical devices and in vitro diagnostics **will no longer be covered by the "human health exemption"** to Authorisations under REACH, i.e. **Article 60(2) & 62(6)** of Regulation 1907/2006.

- Remember that REACH Authorisations are **use-specific**:
  each specific use within the EU/EEA of a substance must be authorised.



By contrast, the use or placing on the market within the EU/EEA of an **article containing DEHP** would **not** be subject to the REACH Authorisation requirement.

However, note that the **incorporation** of the substance into an article is a use which would be subject to the Authorisation requirement, unless specifically exempted.

- Take note that an Authorisation granted under REACH **would relate only to the use and/or placing on the market (including import)** of DEHP within the EU/EEA. **It would not relate to the manufacture** of that substance.

There are two ways to obtain a REACH Authorisation: either demonstrate that the substance's risks are adequately controlled and below the threshold level **(provided that a threshold and dose-response relationship is derived for DEHP as an environmental endocrine disruptor),** or show that its socio-economic benefits outweigh the risks.

Given that, under the current understanding, there are significant uncertainties surrounding the appropriate derivation of thresholds and dose-response relationships for endocrine disrupting substances, **the DEHP application should rather focus on the second option**, i.e. demonstrating that the socio-economic benefits of DEHP outweigh the risks arising from the MD/IVD uses of DEHP and showing that there are no suitable alternatives.

[1] Under REACH, "placing on the market" includes **supplying or making available to a third party** within the EU/EEA (whether in return for payment or free of charge) as well as **importing** into the EU/EEA.

Examples of DEHP uses in medical devices

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

For years, DEHP has been one of the most commonly used plasticisers in medical devices.

On the topic of REACH Authorisation exemptions, MedTech Europe has prepared its own Q&A for members' use.

You can access it here.

- **The following uses of DEHP within the EU/EEA would be eligible for exemption[2] from Authorisation under REACH**:

Scientific research and development (SR&D)

"any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year." (REACH Regulation, Article 3(23) & 56(3))

In practice this includes cases where the substance is used, on its own or in a mixture:

- In **analytical activities using (IVD) medical devices at a laboratory scale**, e.g. in a reagent, calibrator, control kit. IVDs for veterinary and animal health purposes are also covered. (Q&A 1442)
- In **analytical activities such as monitoring and quality control**, including for measuring another substance or property, e.g. when used as an extraction solvent or reagent, or to validate the technical specification or performance of a product. (Q&A 585)

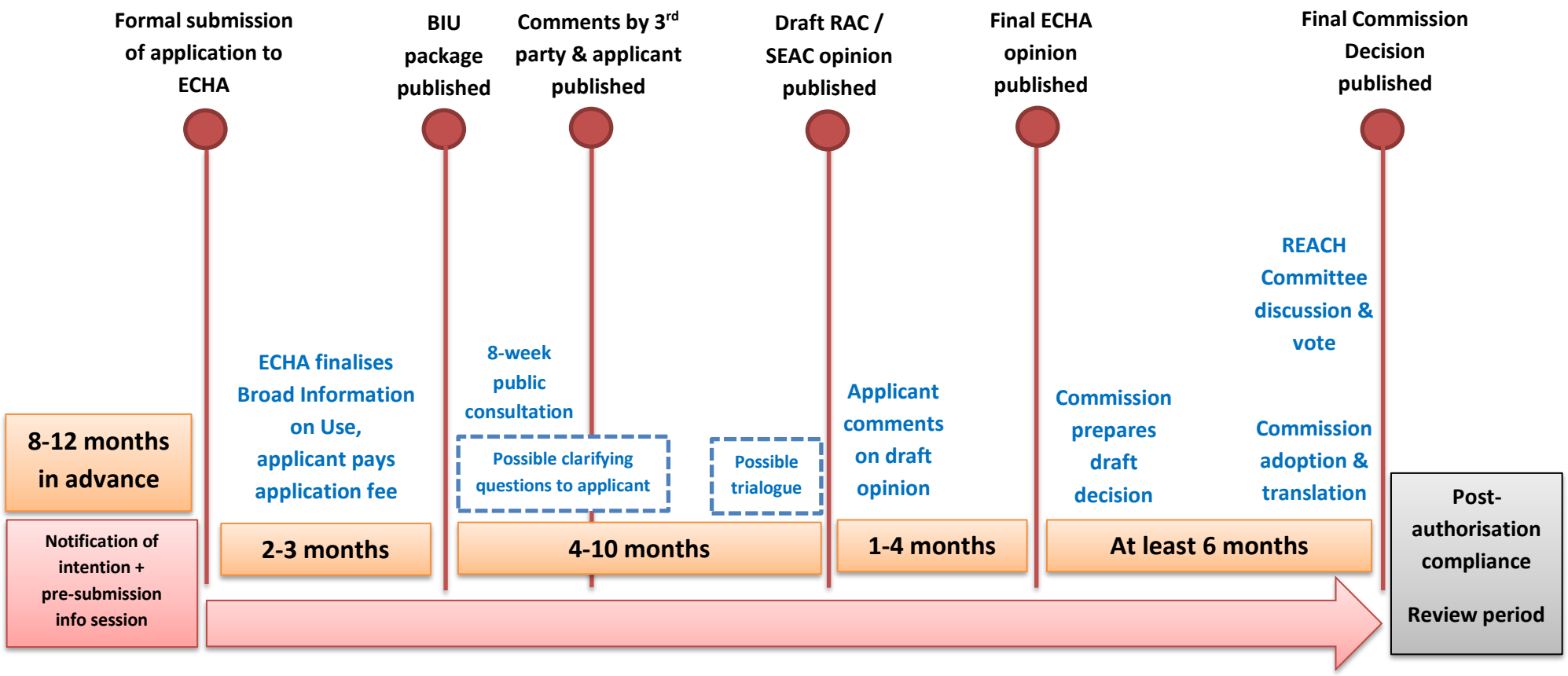
The SR&D exemption does **NOT** apply to **sampling activities**. (Q&A 1153) It is also not relevant for the use of a substance in articles (**see page 5**).

The exemption **MAY** apply to **use of the substance in upstream life-cycle stages to produce (IVD) medical devices**, e.g. a reagent used together with an analytical apparatus is exempted, but mercury in thermometers is not (Q&A 1443, see also 1030, 1442 and 1498).

More useful information on the scope of REACH authorisations is provided at ECHA's Q&A Support page.

[2] REACH currently foresees an exemption for medical devices regulated by the three Medical Device Directives (MDDs) where the substance in question has been identified in Annex XIV for human health concerns only. However, this exemption will no longer apply for DEHP in medical devices once the ECHA recommendation is formalised. Also note the gradual phasing out of the three MDDs as Regulations 2017/745 and 2017/746 enter into application in the coming years.

III. PROCESS FOR OBTAINING AUTHORISATION UNDER REACH: GENERAL TIMELINE & KEY MILESTONES



Remember that this timeline is <u>purely indicative</u>. In practice, deviations can occur depending on the file.

On the following pages, we discuss these real-life considerations in more detail and provide useful advice.

IV. PROCESS FOR OBTAINING AUTHORISATION UNDER REACH: KEY STEPS, RULES AND ADVICE

NOTE: Each individual application for authorisation is subject to the three-stage process described below.

1. Pre-ECHA stage

Notification of intention

Information session

Preparing your application

Submitting your application

RELEVANT RULES & OFFICIAL GUIDANCE

You must first **notify ECHA (preferably 8 months in advance)** of your intention to submit an application. You may also request a **teleconference information session with ECHA** to clarify substantive or procedural issues.

Guidance on how to notify & on information sessions
Submission windows in 2020-23

It is vital to ensure that your application is well-prepared and includes all the required information:

- **Description of use(s)**
  How to develop a use description
- **Chemical Safety Report**
  Preparing a chemical safety assessment & Format
  Preparing a downstream user chemical safety report
  Format for succinct summary of operational conditions and risk management measures
- **Analysis of Alternatives**
  How to prepare an AoA (pp. 40-93) & Format
- **Socio-economic Analysis**
  Preparing a socio-economic analysis & Format
- **Substitution Plan**
  Preparing a Substitution Plan (pp. 94-102) & Format

ECHA has also published a checklist for an authorisation application.

EPPA REALITY CHECK

From the outset it is important to consider business strategy and the best way to apply. In particular**, is it better for the application be submitted by upstream suppliers or downstream users?** What are the complications of going against suppliers? You should **develop an "application strategy"** with particular focus on: the timeline and cost of gathering and analysing the necessary data (especially on workplace exposure and potential alternatives) and the complexity of the supply chain.

Define precisely the use(s) of DEHP you are seeking. Failure to do so may adversely affect factors like the conditions of authorisation or the length of the review period.

In our experience, the **SEA** poses less difficulties for downstream users (since the supplier must provide the data). Note that in the initial feed application for DEHP, multiple actors across the supply chain collaborated but it took two years and much work to compile the required data.

Regarding Substitution Plans, we advise you to note the significance of the 2019 EU General Court ruling in terms of "**suitable alternatives available in general.**"

Prior to submitting your application, we strongly recommend that you have a meeting (TIS) with ECHA to get useful feedback on your dossier.

2. ECHA Stage

ECHA receives application

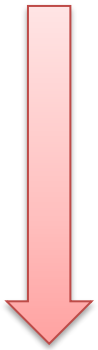
Public consultation on possible alternatives

Round of questions from RAC and SEAC rapporteurs

Potential trialogue

RAC/SEAC draft opinion

RAC/SEAC final opinion



RELEVANT RULES & OFFICIAL GUIDANCE

ECHA will check the application, in particular that the **Broad Information on Uses (BIU)** is sufficient for the public consultation. When the invoice is paid, ECHA considers the application received.

The **8-week public consultation**, which begins upon publication of the BIU, aims to gather information on possible alternative substances or technologies for the uses you have applied for. **Interested parties** (e.g. alternative providers, citizens, NGOs, authorities) are invited to comment. The applicant may be asked to provide additional information. Public versions of the comments, including any responses by the applicant, will be published on the ECHA website.

Guidance on publicising application information

The draft opinion on the application is prepared by two bodies: the Risk Assessment Committee (RAC) and the Socio-economic Analysis Committee (SEAC), each appointing a rapporteur for the application. As an applicant you should expect **3-6 rounds of questions from the rapporteurs, plus a 10-day turnaround for providing the response**.

RAC/SEAC common approach , working procedure and format for drafting opinions

If questions remain, the rapporteurs may suggest a trialogue, which is an opportunity to discuss any technical and scientific aspects of the application. Third parties who have submitted information to the consultation may be invited to participate.

Guidance on trialogues and third party participation

The applicant has 2 months to comment on the **draft RAC/SEAC opinion**. Generally, within 4 months, the RAC and SEAC will adopt their **final opinion** taking into account the applicant's comments.

ECHA sends the opinion to the Commission, Member States and the applicant. Non-confidential versions are published on ECHA's website.

EPPA REALITY CHECK

Note that the consultation is an opportunity potentially for NGOs to voice opposition against a particular substance. It is therefore important for the applicant to remain vigilant about comments coming from interested parties.

DEHP has a high political profile, so input from NGOs can be expected to trigger questions, especially with regard to the alternatives. EPPA can provide advice on how to deal with these various aspects, including requests for additional information.

The trialogues offer a **very valuable opportunity to present your case and answer complex technical questions**. Questions on alternatives and risk management measures can be particularly challenging and require good preparation from the applicant.

The applicant will be given the opportunity to review the RAC/SEAC opinion and indicate the presence of confidential business information before its publication. Remember that politically sensitive files may attract comments from NGOs, which are typically rather general.

3. Post-ECHA stage

Commission prepares draft decision on authorisation

Commission submits draft to REACH Committee

REACH Committee votes on draft

Commission adopts decision

Publication of decision in Official Journal

RELEVANT RULES & OFFICIAL GUIDANCE

The final ECHA opinion is received by the European Commission, specifically the **Directorate-General for Industry, Internal Market, Entrepreneurship and SMEs (DG GROW)**.

Within 3 months of receiving the final opinion, the relevant unit of DG GROW (Unit D.1 "REACH") will prepare a draft implementing act either granting or refusing authorisation in line with ECHA's conclusions.

The Commission submits the draft to the competent comitology committee for authorisations, known as the **REACH Committee**. Chaired jointly by DG GROW and the Directorate-General for Environment (DG ENV), this 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).

For REACH authorisations the examination procedure applies, which means the vote on the draft 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.

Once the REACH Committee gives its approval, the Commission will **adopt** the implementing act via its own internal procedure, also preparing the necessary **translations** of the act into all official EU languages. Finally, a **summary of the decision** will be published in the **EU Official Journal** indicating that it will take legal effect.

List of authorisation decisions adopted by the European Commission

Overall, the process from the Commission sending the draft decision to the REACH Committee to final adoption and publication of the decision generally takes a minimum of 3 months.

EPPA REALITY CHECK

In our experience, the Commission can be a black box at this stage of the process, with many elements not visible to the applicant. It is particularly important to be active here because when the Commission is preparing the draft decision, crucial elements such as the review period, conditions of use and suitability of alternatives are clarified. Action taken at this stage is primarily up to the individual applicants, focused on their specific use cases.

Member States can also be a source of challenges. Although in most cases they do not contest the ECHA conclusion, it has happened that certain Member States use the opportunity of the REACH Committee to present objections or arguments not raised during the ECHA stage. In some cases, the review periods recommended by ECHA were questioned and shortened. This can create uncertainty and a lack of transparency for the applicant.

In addition, **the authorisation decision can be challenged before EU courts**. For example, after an appeal introduced by Sweden, the Court of Justice annulled the authorisation decision of 7/3/2019 for PY.34 & PY. 104.

The authorisation procedure is rigid and not typically adapted to business reality. New authorisation applications should be submitted in case of: name change after authorisation already granted; increase in sales volume; move production to another Member State; change in production methods; unexpected installation halt; authorisation holder no longer in supply chain; complex merger, etc.