

**REACH**→**LAW**

COMPLIANCE. SUSTAINED.

# MOCA AfA Project Status Information Session

**January 2018**

[www.reachlaw.fi](http://www.reachlaw.fi)

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# Aim

To provide a brief overview of the status of the MOCA application for Authorisation

For access to the application documentation, the Final Opinion, and other relevant documents, please click on the following link:

<https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/15329/term>

## Use Definition

### Use Applied for:

*Industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production*

## Application Type:

### Upstream

Covers actors in the Suzhou supply chain

# MOCA

- Substance scope

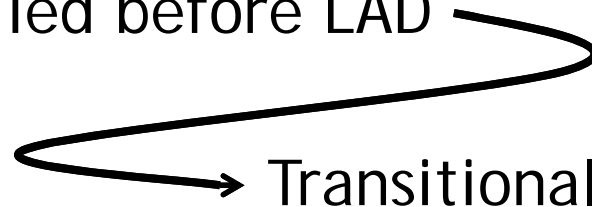
Substance name	Harmonized classification (CLP)
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	Acute Tox. 4 * <b>Carc. 1B</b> Aquatic Acute 1 Aquatic Chronic 1

- Dates

Latest application date (LAD):	Sunset date (SD): (LAD + 18 months)
22nd May 2016	22nd November 2017

# The Sunset date

- Suzhou applied before LAD

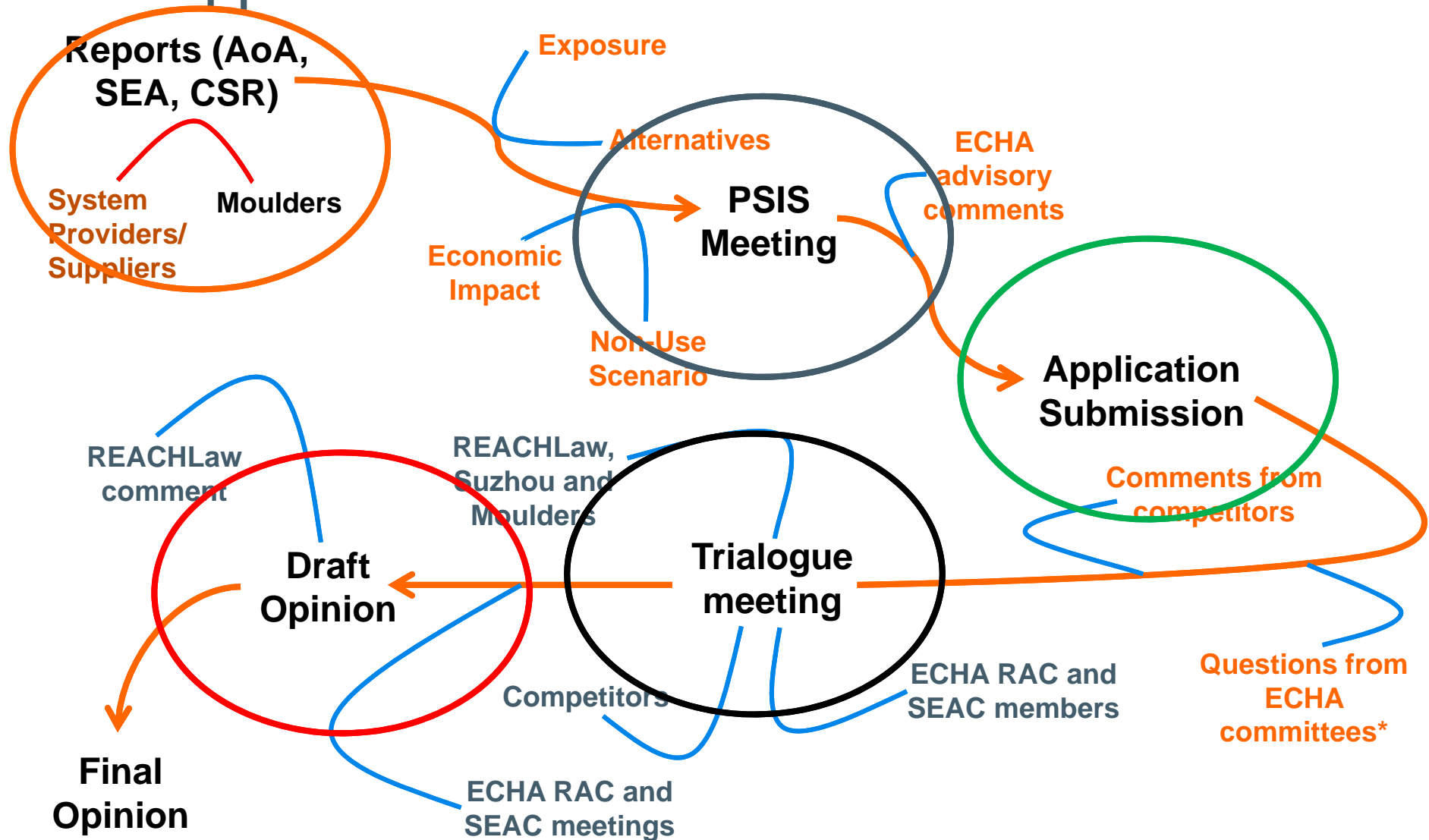


Transitional Arrangements  
(Article 58(1)(c)(ii) of the REACH  
Regulation)

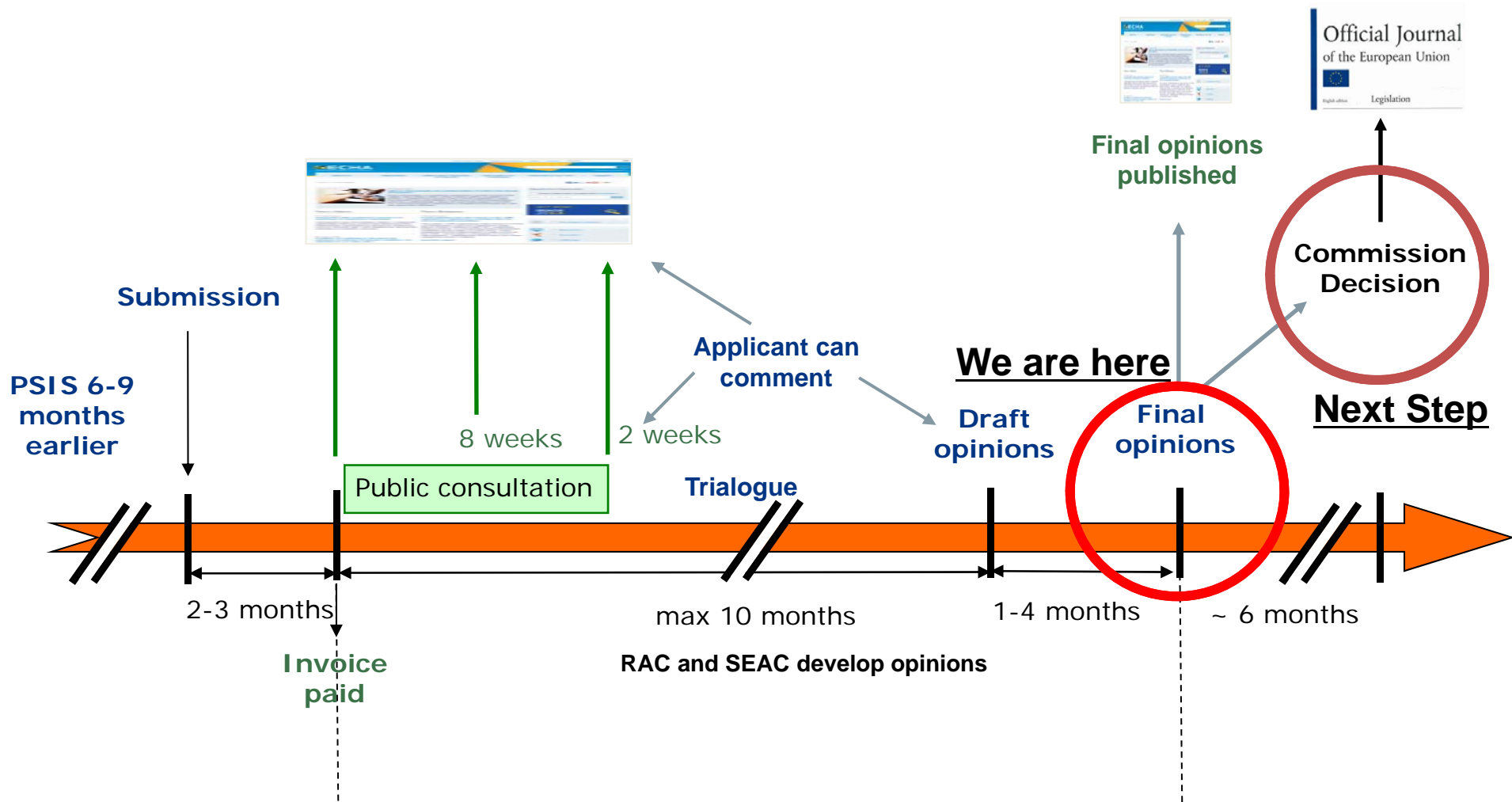
*“(c) transitional arrangements:*

*(ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;”*

# The Application Process



# Decision making: ECHA process



Source: ECHA (June 2015)

# ECHA Conclusions

- Benefits of continued use of MOCA outweighs the risks to human health
  - Overall net benefit from granting the authorisation is expected
- An overall feasible alternative to MOCA does not seem to exist
- Broad up-stream application covering many companies:
  - Uncertainty as regards the potential for some substitution in the supply chain
  - Granting long review period may delay substitution, where possible
  - Scope potentially covers products/product parts and industries, where substitution is feasible
  - Specific products/product types, technical specs and industries involved where substitution is infeasible needed to be highlighted
  - Third parties convinced that a solution for substitution can be found for all products/product parts



# REACHLaw Comment

- Limited scope within the supply chain to substitute
  - 4 years is not enough time
- Concerns about delayed substitution unwarranted
  - Movement away from MOCA pre-dates REACH
  - Moulders use the best solution depending on the product
    - Engineering solution
  - Current alternatives provide limited substitution scope
- Longer Review Period allows moulder to better prepare
  - Investment planning and customer expectation
  - More time for R&D, avoids regrettable substitution
  - Impacts minimised on SME enterprises
  - Economic impacts would trend to zero
  - 4 years is punitive; some aspects of non-use scenario potentially realised

# Outcome

- ECHA has recommended a 4 years Review Period
  - Can continue use of MOCA if in Suzhou supply chain until 11/2021
  - Opinion consistent with similar broad, upstream applications
- Final Opinion of ECHA sent to the EC
  - Final Decision 6 months - 1 year
- Conditions of Use elaborated
  - Next Slides

# Conditions of Use (1)

## What are Conditions of Use (CoU)?

- EC wants to minimise the potential for exposure to hazardous chemicals of:
  - Workers
  - Environment
- Users of MOCA must comply with Conditions of Use
  - Will be formally communicated *via* update to MOCA e-SDS AFTER EC Decision
  - Must be able to show compliance to national inspector, if inspected
- Normal part of the Authorisation process
- CoU outlined in ECHA Opinion
- Can be modified by EC

# Conditions of Use (2)

## Automatic Moulding Process

- Automation and containment of the moulding process, including glove box for the loading of MOCA, automatic transfer of MOCA to the reactor and enclosed system for melting and mixing phase can be considered to represent the good practice and shall be adopted.
- Exposure control/containment measures shall be fitted with extraction ventilation (LEV), unless it can be shown (by measurements) that emissions to the air are negligible.
- LEVs shall be used in loading, sampling as well as dispensing and moulding phases. Casting ovens shall be equipped with extraction.
- Regular maintenance program of the extraction ventilation system shall be implemented.
- Regular cleaning and maintenance program of the glove box, including the structural integrity of the gloves, shall be implemented.
- Appropriate working clothing (with long sleeves) and chemical resistant gloves shall be used in all tasks involving the use of MOCA.

## Conditions of Use (3)

### Manual Moulding Process

- LEV shall be applied when MOCA pellets are loaded from the drums to the melter.
- Melting shall be done in an enclosed system with extraction.
- Mixing step shall include LEV, and it shall be done using automatic stirrer to prevent close contact and exposure of worker due to splashes.
- Regular maintenance program of the extraction ventilation system shall be implemented, including testing of its effectiveness.
- The dispensing and moulding phases and curing ovens shall be equipped with local extraction.
- Appropriate working clothing (with long sleeves) and chemical resistant gloves shall be used in all tasks involving the use of MOCA.
- When MOCA is moved from one place to another (moving melted MOCA to mixing area) closed containers shall be always used.

## Conditions of Use (4)

### Training and general housekeeping practices (Both)

- Workers shall be regularly (at least yearly) trained in the proper use of PPE, and proper storage of gloves and RPE.
- RPE shall be used as described in WCSs. Supervision shall be provided to ensure availability, correct use and maintenance of all PPE.
- Procedures that would address the housekeeping shall be implemented by all users of MOCA.
- Any spillages of MOCA or PU mixture shall be cleaned immediately by using appropriate cleaning methods.
- Following each batch, cleaning of work surfaces, which may contain traces of MOCA, shall be performed to prevent build-up of MOCA to work surfaces.
- Access of non-authorized persons to the areas in which MOCA is used will be prevented.
- Any containers of MOCA shall be stored closed.

# Conditions of Use (5)

## Monitoring activities (Both)

- Exposure of all workers working within the premises in which MOCA is used shall be followed by regular, twice per year biomonitoring campaigns. If urinary levels are repeatedly low, frequency of monitoring may be reduced.
- Measurement of surface contamination shall be conducted.
- The information gathered in the monitoring campaigns shall be used to review and improve the risk management measures (RMMs) and operational conditions (OCs).
- The outcomes and conclusions of any review must be documented.
- The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities.
- Wipe and powdering tests of a representative sample of end-products shall be performed to ensure that the levels of MOCA in the final product are below classification concentration cut-off limit 0.1% w/w.

## Conditions of Use (6)

### Prevention of environmental emissions (Both)

- LEV filters/scrubbers shall be used to minimize air emissions.
- In order to prevent any waste water releases washing of empty containers shall be prohibited



## So What's Next?

- EC will make its Decision
  - To date they have not disagreed with ECHA
- In the meantime moulders should:
  - Investigate the importance of MOCA and if it can be replaced in some of your products
  - Begin substitution, where possible
  - Begin planning for implementation of "Conditions of Use", where applicable
- Once Decision is made:
  - e-SDS will be updated
  - All Downstream Users (Moulders etc.) must notify ECHA of use
- Own application?

## Contact details

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