



# Biocidal Products Regulation (EU) No 528/2012

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Registration Requirements

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**REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 22 May 2012  
concerning the making available on the market and use of biocidal products**

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20240611>

<https://parlament.mt/media/135700/ln230-of-2025.pdf>

<https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>

- Definitions
- Main Requirements of the BPR
- Product types
- Overview of authorisation procedures
- Common issues
- Conclusions / Recommendations

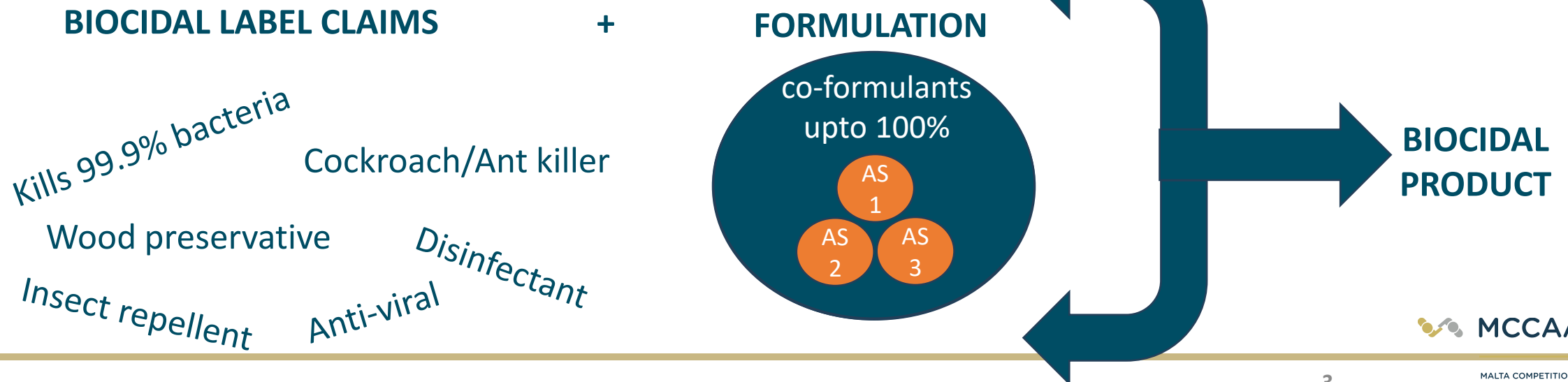
# REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012

## concerning the making available on the market and use of biocidal products

**Biocidal Products (BP)** are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the **active substances (AS)** contained in the biocidal product.

An active substance is a substance or a micro-organism that has an action on or against harmful organisms.

### What are the attributes of a biocidal product?



The basic principle in the Biocidal Products Regulation (EU) No 528/2012 is that a biocidal product must be authorised before it can be made available on the market or used in the European Economic Area (EEA) and Switzerland.

This takes place in two consecutive steps;

- First, the active substance is evaluated and, provided the criteria are fulfilled, is then approved in a specified product-type.
  - The approval of active substances takes place at Union level; once approved, an active substance may be incorporated into biocidal products formulations and used anywhere in the European Economic Area (EEA) and Switzerland.
  - This is an ongoing process. While evaluation has been finalised for some active substances, evaluation is still ongoing for many other active substances.
- The second step is the authorisation of each single biocidal product consisting of, containing or generating the approved active substance(s).
  - The approval of a biocidal product takes place at Member State level.
  - Biocidal Products must be registered with the MCCA, as the Competent Authority in Malta, prior to their importation/placing on the Maltese market.

A biocidal product cannot be made available on the EU market unless the active substance(s) contained in the product originate from approved suppliers that are included on the **Article 95 list** for the relevant product type(s).

<https://echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers>

<https://echa.europa.eu/information-on-chemicals/active-substance-suppliers>

Biocidal products are classified into 22 biocidal **product-types (PT)**, grouped in four main areas.

Main Group 1 – Disinfectants

PT1 – PT5

Main Group 2 – Preservatives

PT6 – PT13

Main Group 3 – Pest control

PT14 – PT20

Main Group 4 – Others (including antifoulings)

PT21 – PT22



PT1

PT3



Biocidal products are **everyday products** used by both the **general public** and **professional** users.



PT14



PT21



PT18

PT2



There is an ongoing evaluation process of all **active substances** at EU level . While evaluation has been finalised for some active substances, evaluation is still ongoing for many other active substances.

## APPROVED

## NOT APPROVED

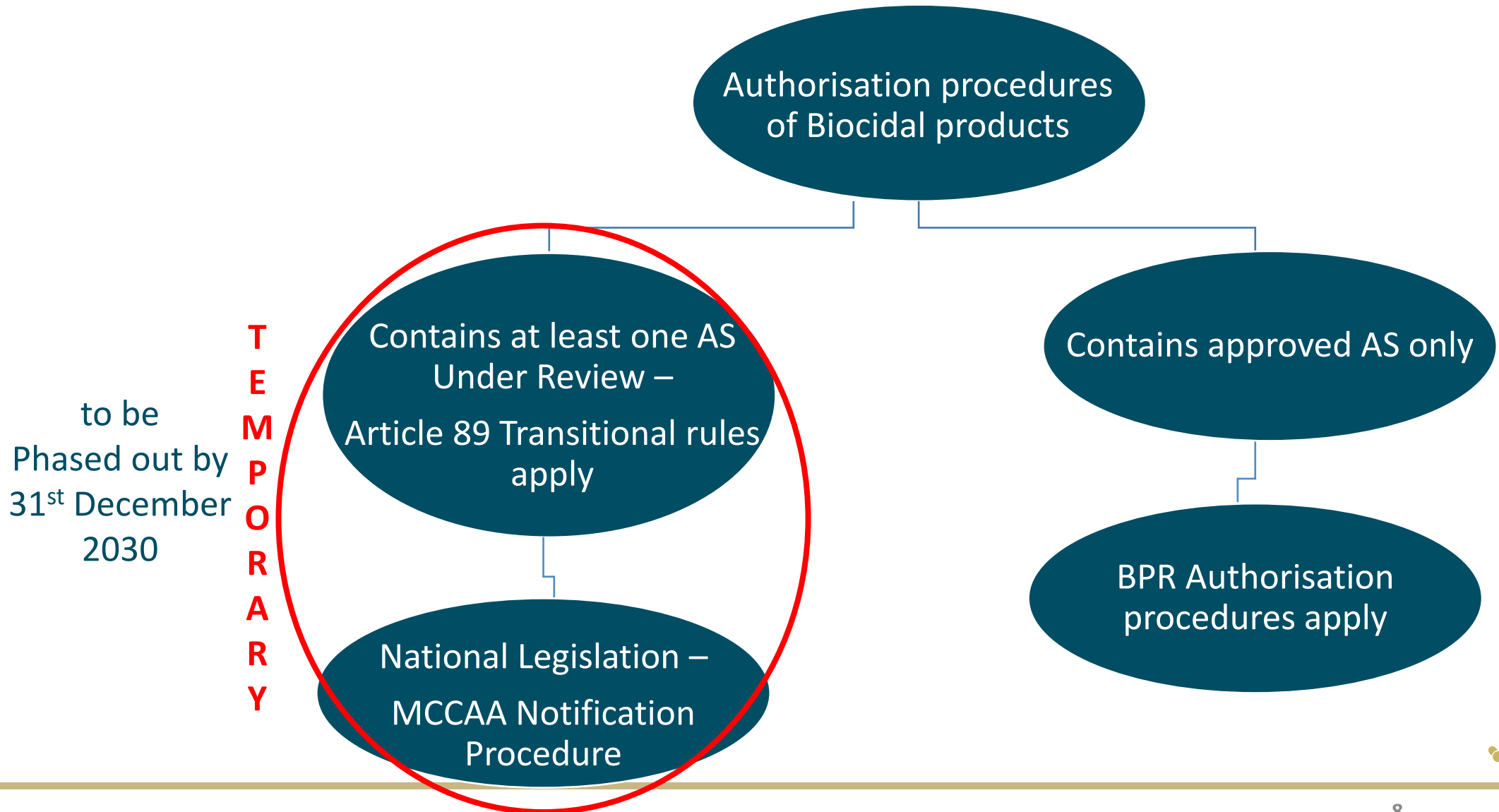
## UNDER REVIEW

The evaluation status of each active substance of interest may be viewed via the following **ECHA database** that is publicly available (always search by inputting the CAS number of the substance);

<https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status	Related authorised biocidal products
(RS)- $\alpha$ -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	257-842-9	52315-07-8	PT18	01/06/2020	31/05/2030	Belgium	Approved	156
<del>(RS)-3-Allyl-2-methyl-4-oxocyclopent-2-enyl (1R,2S)-2,2-dimethyl-3-(2-methylprop-1-enyl)-cyclopropanecarboxylate (mixture of 2 isomers 1R:trans: 1R/S only 1:3) (Esbiothrin)</del>	<del>807-421-6</del>	<del>260359-57-7</del>	<del>PT18</del>			Germany	Not approved	
Tetramethrin	231-711-6	7696-12-0	PT18	UNDER REVIEW		Germany	Initial application for approval in progress Competent authority evaluation	

Different registration procedures for biocidal products exist and must be followed depending on the identity of the **active substance/s** present in the formulation of the product.





## Authorisation procedures of Biocidal products

The purpose of the BPR is to ensure a **high level of protection** of both human and animal health and the environment.

The provisions of the BPR are underpinned by the **precautionary principle**, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

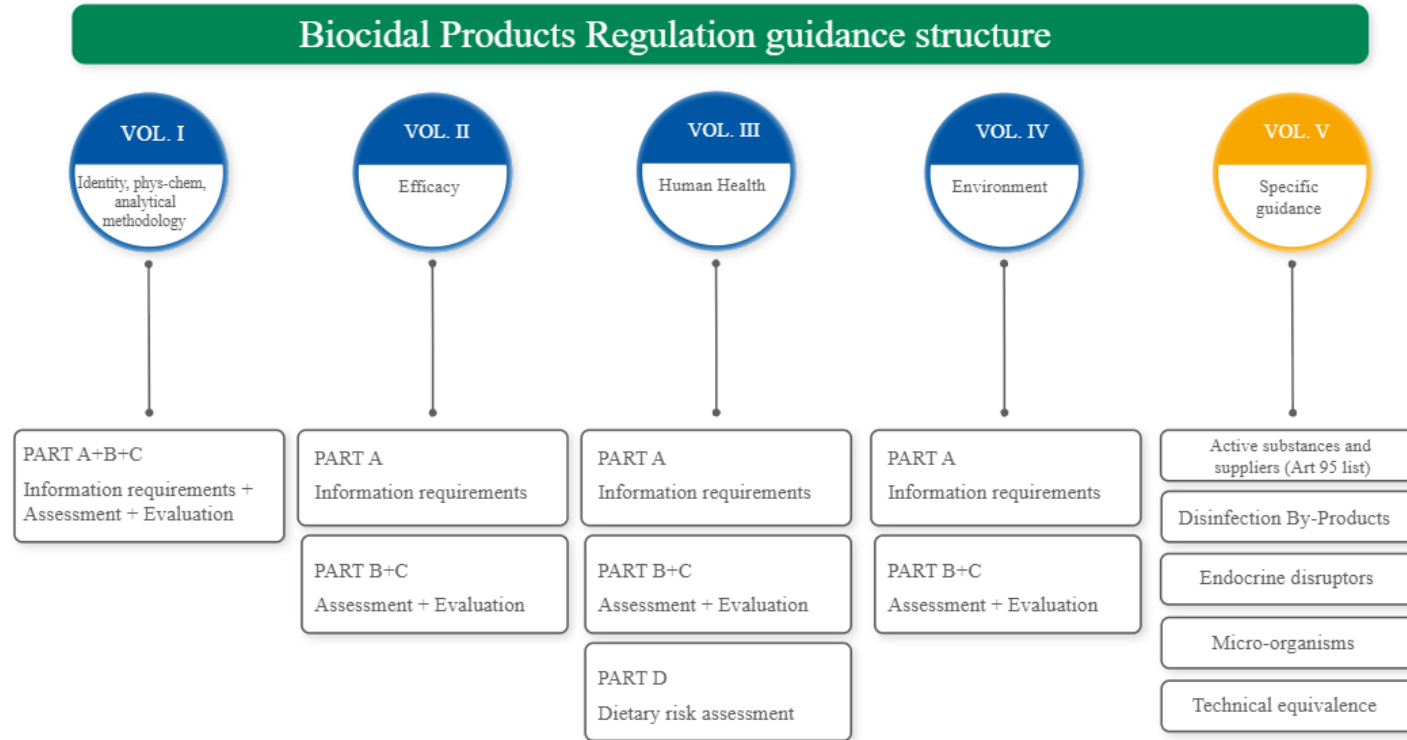
Submission of applications and dossier in line with the Regulation's requirements must be done through ECHA's online platform **R4BP** (European Chemicals Agency's Register for Biocidal Products).

<https://echa.europa.eu/support/dossier-submission-tools/r4bp>

<https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

# Authorisation procedures of Biocidal products

It is the responsibility of the applicant to generate sufficient data that fulfils the requirements in support of their biocidal product's safety and efficacy.



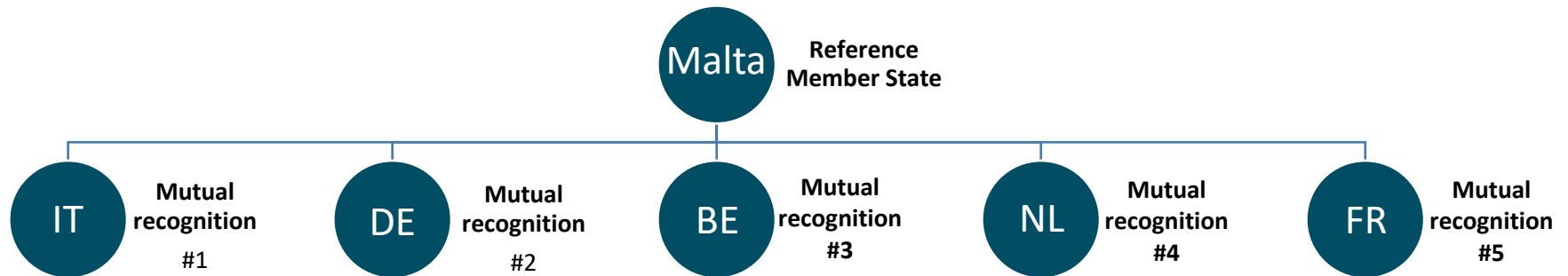
The ECHA Guidance on biocides legislation also describes how to perform the required assessments and explains the guiding principles for the evaluation of the applications to be performed by the EU competent authorities.

# Authorisation procedures of Biocidal products

The choice of EU competent authority is left up to companies.

The EU competent authority appointed by a company to conduct the first and complete evaluation of the biocidal product is known as the **Reference Member State**.

Once first approval is granted by the Reference Member State, then the same authorisation can be extended to other Member States (**concerned Member States**) by **mutual recognition processes** which allow **quicker access** to the market for companies and ensures **harmonisation** within the EU.



## Authorisation procedures of Biocidal products

Companies can choose between several alternative processes, depending on their product and the number of countries where they wish to sell it.

Companies have the possibility to apply for an authorisation at Union level (**Union authorisation**), which allows companies to place their biocidal products on the market throughout the entire Union via a single application, without the need to submit additional mutual recognition applications.

Companies may also group several similar biocidal products under a single authorisation application (**Biocidal Product Family**), provided that the difference in the composition among the "members" of the family remains within a specified range.

## Transitional Authorisation procedures of Biocidal products

The approval of active substances is an ongoing process and the evaluation is still ongoing for many other active substances.

What is the applicable registration procedure for a biocidal product containing 'under review' active substances?

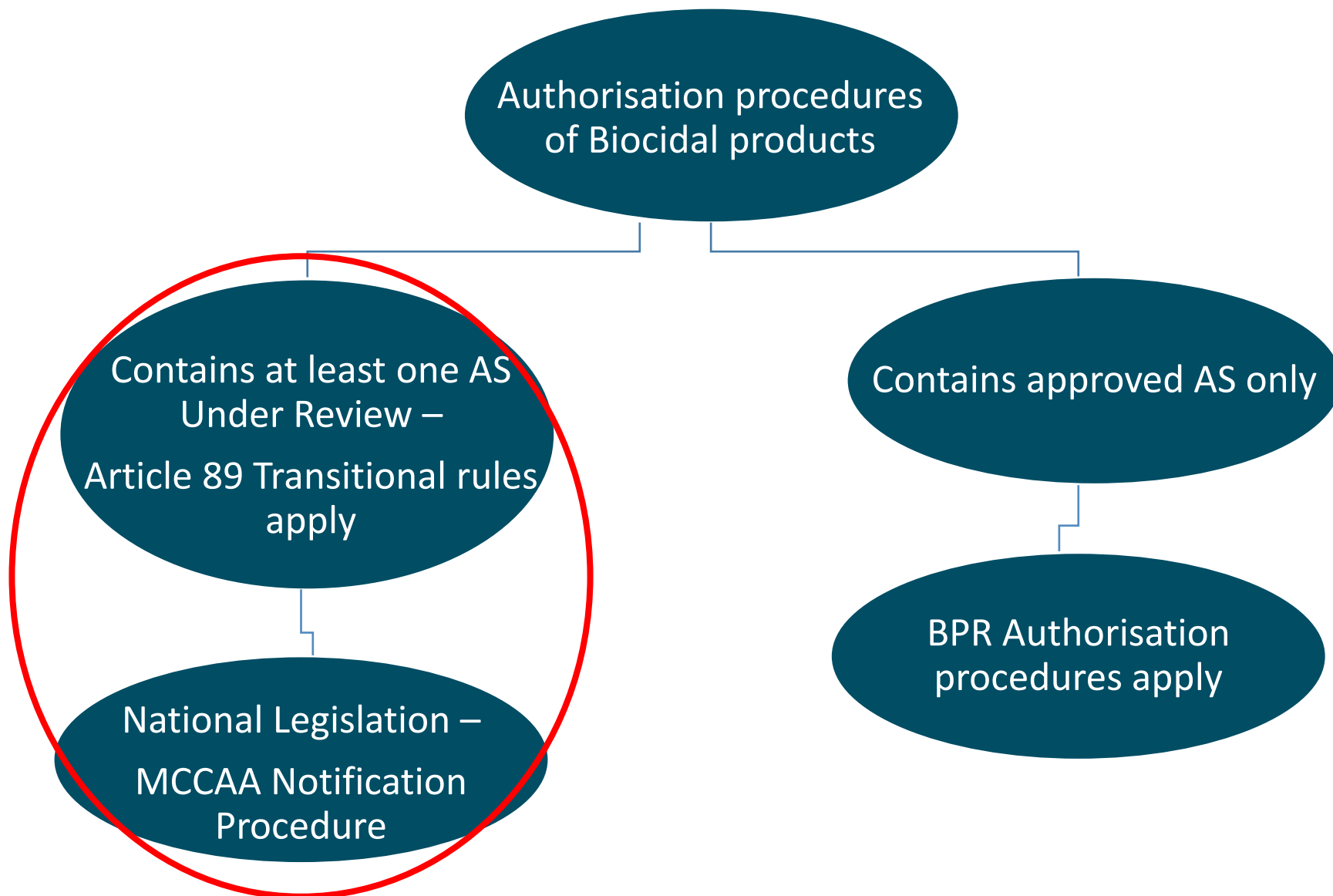
Commission deadline has been recently extended to the 31<sup>st</sup> December 2030.

In the interim Article 89 of the BPR allows each Member State to authorise the making available on the market or use in its territory of a biocidal product in accordance with its national rules.

The BPR transitional measures are implemented in Malta through the MCCAAs Notification process.

<https://forms.mccaa.org.mt/index.php?r=survey/index&sid=165836&newtest=Y&lang=en>

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## MCCAA Notification Procedure (temporary)

APPLICATION  
+ supporting  
documentation

Through e-form on MCCAA website

APPLICANT  
IDENTITY

Local importer or foreign  
supplier/manufacture may both  
act as the registrants

TIMEFRAME  
OF  
FINALISATION

Few days/weeks (depending on  
submission of compliant  
documentation by applicant)

FEES

€ 100 (€ 50 for a renewal)

	MCCAA Notification Procedure (temporary)	BPR Authorisation procedures
APPLICATION + supporting documentation	Through e-form on MCCAA website	Through ECHA's online platform R4BP (European Chemicals Agency's Register for Biocidal Products)
APPLICANT IDENTITY	Local importer or foreign supplier/manufacturer may both act as the registrants	Must be submitted and managed by the foreign supplier/manufacturer obo the local importer
TIMEFRAME OF FINALISATION	Few days/weeks (depending on submission of compliant documentation by applicant)	Lengthy procedures (depends on whether product is already registered in another EU Country or not)
FEES	€ 100 (€ 50 for a renewal)	Starts at € 500 for a Mutual Recognition (when product is already registered in another EU Country)



# Insecticide


#1


Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
Tetramethrin	231-711-6	7696-12-0	PT18	UNDER REVIEW		Germany	Initial application for approval in progress Competent authority evaluation

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
(RS)- $\alpha$ -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	257-842-9	52315-07-8	PT18	01/06/2020	31/05/2030	Belgium	Approved

National Legislation –  
MCCAA Notification  
Procedure

## Insecticide #2

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
deltamethrin	258-256-6	52918-63-5	 PT18	01/10/2013	31/03/2028	Sweden	<b>Approved - Renewal in progress</b> Competent authority evaluation

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
(RS)- $\alpha$ -cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	257-842-9	<b>52315-07-8</b>	 PT18	01/06/2020	31/05/2030	Belgium	<b>Approved</b>

BPR Authorisation  
procedure via  
ECHA's R4BP

## Insecticide #3

As the BPR Authorisation procedure is a lengthy procedure necessitating months/years until completion by the Reference Member State

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
2-methyl-4-oxo-3-(prop-2-ynyl)cyclopent-2-en-1-yl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate (Prallethrin)	245-387-9	23031-36-9	PT18	01/03/2026	29/02/2036	Greece	Approved

(the last approval date for an AS in the product)

Substance name	EC /List no	CAS no	Product-type	Approval start date	Approval end date	Evaluating competent authority	Approval/Assessment status
(RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (Cypermethrin)	257-842-9	52315-07-8	PT18	01/06/2020	31/05/2030	Belgium	Approved

BPR Authorisation procedure via ECHA's R4BP must be submitted before 01/03/2026

MCCAA Notification application must also be submitted in parallel before 01/03/2026 to ensure continued placing on the market while the BPR Authorisation is under assessment

# What are the most common issues we encounter as a Competent Authority?

## Minor

- Incomplete information on labelling
- For certain PTs labelling must be compiled in both English and Maltese languages
- Safety Data Sheets submitted are not the latest versions and require minor updates

**The MCCAА requests for document revisions  
These can be relatively easily rectified**

## Major

- Contains non-approved AS or a banned co-formulant
- AS not compliant with Article 95
- Products authorised for professional use only are imported by individuals for personal use
- Safety Data Sheets submitted are not compliant with EU REACH/CLP Regulations

**These products are not allowed on the  
Maltese/EU market.**

## Conclusions / Recommendations

Keep updated with regards to the assessment status of the active substance/s in your product/s, as different routes of registration may be applicable and not all registration timeframes are under the MCCA's control.

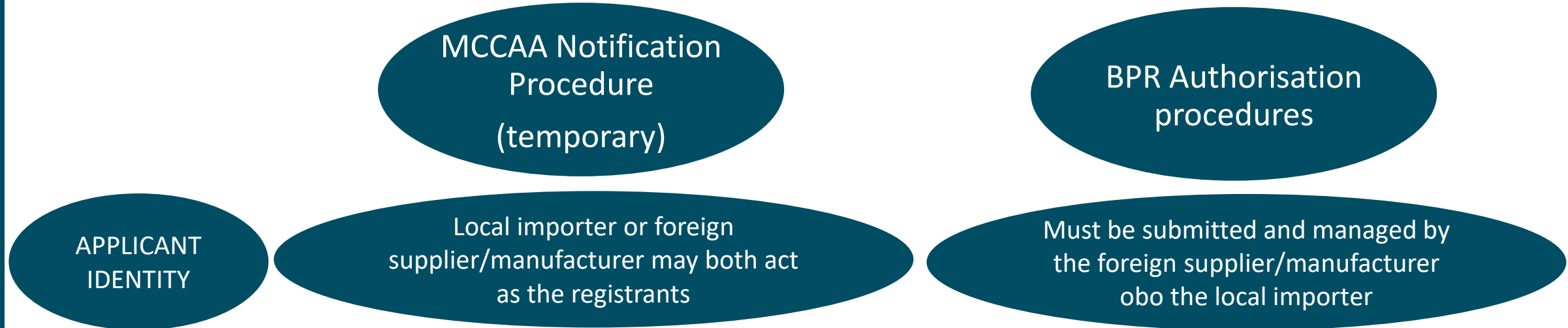
Ensure you have direct and constant communication with the foreign product manufacturer/supplier. (distributors and intermediaries may not be as knowledgeable about the BPR (EU) requirements, especially if you purchase from third countries)

Borderline products; sometimes proper categorisation of a product is not clear-cut. Is it a Biocide? Cosmetic? Detergent? Medical Device? Is a double registration under different EU Regulations required?

If following consultation with your suppliers you are still in doubt about proper categorisation of a product, please do contact us before confirming purchase of consignment. Send us the product label and Safety Data Sheet.

If a consignment containing unregistered biocidal product/s arrives in Malta, the MCCA cannot support its release by Customs.

## Conclusions / Recommendations



Certain registration procedures may be done by the local importer. Other registration procedures must be taken care of directly by the foreign product suppliers / manufacturers.

In any case, we recommend that you liaise with the foreign supplier/manufacturer of the products to take care of the respective regulatory registration requirements on your behalf.

This is because while they should be more familiar with the regulatory requirements, all the necessary documentation should also be available at their end.

Contact details;  
[biocides@mccaa.org.mt](mailto:biocides@mccaa.org.mt)

Further information (inc. publicly available database of Registered Biocidal Products in Malta);  
<https://mccaa.org.mt/Section/Content?contentId=1131>

THANK YOU !