Risk Management Option Analysis Conclusion Document

Substance Name: triclocarban

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Authority: FR

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☒ CoRAP and Substance Evaluation Triclocarban is on the CoRAP list for an evaluation by France in 2020.
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☒ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments[2]	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	

[2] COMMISSION DECISION of 14 October 2008 concerning the non-inclusion of certain substances in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (notified under document number C(2008) 5894) (2008/809/EC) - http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32008D0809&rid=12

Other processes/ EU legislation	☐ Other (provide further details below)

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	x
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Triclocarban (TCC) is used in the following products: coating products, cosmetics and personal care products, fillers, putties, plasters, modelling clay, finger paints, inks and toners, pharmaceuticals, washing & cleaning products and air care products. In the framework on the French National Strategy on Endocrine Disruptors in 2016, the French Competent Authority requested ANSES to evaluate its toxicological and ecotoxicological profile and verify whether risk management measures should be necessary for this substance.

Based on the metabolisation and on the elimination of TCC, the bio-accumulation of TCC is likely to be low.

Concerning the TCC, toxicological data shows that TCC is nontoxic to Wistar albino rats acutely exposed to the dose level of 2000 mg/kg body weight by oral or dermal route. TCC was therefore considered to be not irritating to the rabbit eye and not irritating to the skin of human, rabbits and guinea pigs. TCC is considered as not sensitizing to the skin of human.

Concerning the genotoxicity, no evidence of genotoxicity was found in Ames test using S. typhimurium strains TA 100, TA 1535, TA 1537 and TA 98 with or without metabolic activation for TCC. No evidence of genotoxicity was found in in vitro mammalian chromosome aberration test was performed using Chinese hamster ovary with different doses of TCC (31, 3, 62,5, 125, 250, 500, 1000, 1500, 2000 µg/ml).

This study shows an effect of TCC on the activity of the NIS (Sodium-iodine symporter) on a thyroid cellular lineage with a good level of evidence and suggests that TCC could alter the biosynthesis of the TH by modulating the contribution in iodine in thyreocytes in certain conditions.

Regarding the activation of the receptors ER, AR, AhR, CAR, TCC activates luciferase expression through the androgen receptor, and not through the glucocorticoid receptor. TCC did not compete with the AR binding but amplified the AR-mediated activity. TCC has no agonistic activity alone but enhance the DHT-induced activity. TCC also promotes ERα activity with similar potency as estradiol. TCC is a CAR activator but not an agonist ligand for either mouse or human CAR. TCC can induce significant up regulation of pS2 and down regulation of ERα meaning that Triclocarban have estrogenic properties. TCC has the capacity of interfering with the receptor AhR, and to modify interelations AhR-RE in the regulation of the genic expression. TCC has the capacity of interfering with the receptor AhR and can enhance testosterone dependent induction of luciferase gene expression and have weak estrogenic activities.

Regarding the modulation of the expression of the enzymes of xenobiotic and steroid metabolism, TCC may induce activation of the CAR receptor, with induction of CYP2B10 and UGT1A, and / or activation of AhR with induction of CYP1A1 and CYPIB1.

Regarding the activation of thyroidian hormones, TCC could alter the biosynthesis of the thyroidian hormones by modulating the contribution in iodine in thyreocytes in certain conditions.

Environmental and ecotoxicological data show that TCC could be considered fulfilling the P/vP criteria based on predicted and experimental degradation half-life in water, sediment or soil compartment, as well as the T criteria with the lowest NOEC value reported at 0.005 mg/L for fish (*Pimephales promelas).* The highest value of BCF, issued from prediction, is 800, leading to the conclusion that TCC is not expected to bioaccumulate in the food chain.

Regarding The ED potential in the environmental organisms, one study indicates that TCC could have a potential androgenic activity on fish as it enhances AR-mediated response to a well-known androgen (Trenbolone). Other studies suggest that TCC has both estrogenic and androgenic activity through regulation of *vtg* and *ar* gene expression and might impact steroidogenesis through decline in cholesterol levels and inhibition of *star* gene expression in fish. Finally, it is demonstrated a chronic effect on reproduction (increased number of embryos) of New Zealand mudsail after TCC treatment. This significant increase of number of embryos has been previously found in experiments with exogenous estrogenic ED compounds (BPA, octylphenol, nonylphenol, ethynylestradiol).

However, concerning the environmental ED potential, supplementary data with recognized guidelines would allow to confirm or invalidate the proposed assumptions.

In the current state of the knowledge and with regard to the guidelines of the OECD (OECD, on 2012) for the evaluation of PE, it is considered that on the basis of the supplied toxicological and ecotoxicological data, there is no enough data to identify potential ED effects. The result suggests that TCC has an endocrine disruptor character with an important level of evidence. Nevertheless, due to the lack of information and in the absence of known adverse effects, it is not possible to conclude on the ED properties of this substance.

In order to have information to link the mode of action observed *in vitro* with adverse effects, a reprotoxicity assay could be recommended to clarify uncertainties about ED properties. We also recommend to clarify the promoting effect of TCC on the bacterial resistance.

A substance evaluation on TCC is therefore considered as the most suitable option.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor
Substance Evaluation	2020	France