
# Risk Management Option Analysis Conclusion Document

**Substance Name:** 2,6-di-tert-butyl-p-cresol
**EC Number:** 204-881-4
**CAS Number:** 128-37-0

**Authority:** France
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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

No ongoing activity other than this RMOA.

Several public agencies such as US-EPA have identified BHA (tert-butyl-hydroxyanisole) – often claimed to be analogue of BHT - as a priority for evaluation, in particular for evaluating if it displays any ED effects. Several international and European assessments have been carried out on the BHA with regard to endocrine disruption:

- The European Commission on Endocrine Disruption (EDC Database) listed BHA as a Category 1 priority substance, based on evidence that it interferes with hormone function.
- SIN List: BHA is included as endocrine disruptor with oestrogenic, thyroid and antiandrogen activity, affecting several body functions including development and reproduction.
- World Wildlife Fund 1996 lists BHA as a suspected endocrine disruptor.
- European Commission priority list 2007: BHA is in category 1 on the priority list of substances for further evaluation of their role in endocrine disruption.
- OCDE, 2010: BHA is in the 2010 list of the high concern substances with evidence or potential evidence of ED effects, which are already regulated or being addressed under existing legislation (Dir 2002/72/EC on food Contact Materials and Dir 95/2/EC on food additives other than colours and sweeteners).
- Substance BHA evaluation has been proposed as the outcome of a French Risk Management Option Analysis Management Option Analysis after an assessment of the toxicological data in the dossier and following a discussion with experts of the ED Expert Group of ECHA after an assessment of the toxicological data in the dossier and following a discussion with experts of the ED Expert Group of ECHA in 2014.
- BHA was proposed to be put under targeted substance evaluation in particular for endocrine disruption properties both in Human Health and Environment. BHA has been included in the CoRAP and evaluated in 2015.

The table below indicates for each known use of BHT which one is already regulated by specific EU legislation.

| **Different uses of BHT** | **Non REACH regulations** | |
|---|---|---|
| Food products or feeding stuffs (food additive) | Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC)) No1333/2008 | BHT is an authorised synthetic antioxidant preservative that was previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the latest in 1996 and the EU Scientific Committee for Food (SCF) in 1987 (European Parliament and Council Directive 95/2/EC (1995) on food additives other than colours or sweetener) then reevaluated by Efsa in 2012.<br>Maximum level of 100 mg BHT (E321)/ kg in oils and fats.<br>BHT is a synthetic antioxidant authorised for use in fats and oils, only for the professional manufacture of heat-treated food, in frying oil and frying fat (excluding olive pomace oil) and in lard, fish oil, beef, poultry and |

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| | | sheep fat. It is permitted alone or in combination with other antioxidants such as gallates, tert-butylhydroquinone (TBHQ) and butylated hydroxyanisole (BHA) in amounts up to 100 mg/kg expressed as fat. |
| Food products or feedingstuffs (food additive) | Regulation (EC) No 95/2/EC | In addition, BHT is permitted in chewing gum alone or in combination with the aforementioned antioxidants at a maximum level of 400 mg/kg chewing gum (Directive No 95/2/EC). |
| Food products in animal nutrition | Regulation (EC) No 1831/2003 | BHT is authorized in feed product for animal nutrition, with a maximal concentration set at 100 mg/kg. |
| Food contact material | Regulation (EC) No. 1935/2004 | BHT is authorized in food contact material (packaging material for fat containing foods). |
| Cosmetics | EU Cosmetic Products Regulation (EC) No 1223/2009 | BHT is listed in the EU database of cosmetic ingredient (CosIng) for its functions as a maskant and antioxidant. |
| Pharmaceuticals | Regulation (EC) No726/2004 | BHT is listed in the list of excipients in medicines with notable effects. |
| Directive on Chemicals Agents at Work | Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work | No SCOEL recommendation regarding indicative OEL values is available.<br>National OEL value at 10 mg/m$^3$ for an 8-hours work day has been adopted by Germany, Finland, France, Austria, UK and Denmark. |
| Waste Framework Directive | Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste | BHT in waste at a concentration that triggers classification of a mixture according to the CLP Regulation will render the waste hazardous. |
| Water Framework Directive | Commission implementing decision (EU) 2015/495 of 20 March 2015 establishing a watch list of | BHT is included in the watch list of the Water Framework Directive containing 10 substances for which Union-wide monitoring data are to be gathered for the purpose of supporting future prioritisation exercises. In fact for these |

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|---|---|---|
| | substances for Union-wide monitoring in the field of water policy pursuant to Directive 200/105/EC | substances the information available indicated that they may pose a significant risk, at Union level, to or via the aquatic compartment, but monitoring data are insufficient to come to a conclusion on the actual risked posed. The analytical methods indicated for BHT are solid-phase extraction (SPE) and gas chromatography-mass spectrometry (GC/MS) and the maximum acceptable method detection limit of 3.16 µg/L. |

## 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

### 3.1 Harmonised classification and labelling

### 3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

### 3.3 Restriction under REACH

### 3.4 Other Union-wide regulatory measures

Regarding the analysis of the full dataset on BHT, we cannot conclude on ED properties of BHT. First, BHT revealed effects on adrenals and thyroid, which biological significance

need to be further evaluated.

Its steric bulk should prevent direct estrogenic and androgenic receptor activation although in vitro data show effect of BHT on estrogenic and androgenic receptor, raising questions on its effect on these pathways. There is no animal data to evaluate this MoA. So no conclusion can be drawn regarding the ED mode of action.

Secondly, BHT demonstrated effects on pup survival and pup weight in rat, behavioural effects in reprotoxicity studies.

BHT induced hypersensitivity by oral (diet) and by dermal contact.

There are limited data on immunotoxicity.

The observed hepatocellular tumors, the effects on lung and thyroid in rodent are to be further evaluated. As a consequence, Anses has proposed BHT as a candidate for substance evaluation process.

Experts from the ED groups agree with France's conclusions based on the current available data (following ED expert group discussions taking place in Helsinki at ECHA the 21-22th of October 2015). Danish EPA supports the testing proposal of an extended one generation (EOGRTS test OECD 443) including B1 cohort, DIT and DNT cohort due to the high sensitivity of sensitive populations such as mothers and children. According to the OECD framework, the EOGRTS is the most appropriate test to determine reprotoxic effects, and conclude on Endocrine Disruptor effects including specific cohorts. The rat model is not the best appropriate model for human (because of the variability in sensitivity of the species to develop tumors of the thyroid). The amphibian test would probably be adapted (LAGDA) to answer environmental challenges and to confirm a possible effect on thyroid in mammals. LAGDA assay (highlighting adverse effects) is prefered to a test on fish as BHT has an activity on thyroid and it has low androgenic or estrogenic activity. HSE UK agency, Danish EPA and AGES Austrian agency confirm that the long-term fish test according to OECD 234 is not relevant. Danish EPA and AGES confirm that LAGDA assay is the most relevant test.

**Therefore, France has decided to perform in 2016 a substance evaluation on BHT.**

## 4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

## 5. NO ACTION NEEDED AT THIS TIME

## 6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

| Follow-up action | Date for follow-up | Actor |
|---|---|---|
| Substance Evaluation | 2016 | France |