Under the Biocidal Products Regulation (BPR), ECHA risks unintentionally restricting every PT 9 biocidal product the leather industry relies on

Executive Summary

The PT 9 biocidal active substances currently undergoing approval under the Biocidal Products Regulation (BPR) risk being restricted in silos. Each evaluation proceeds on the assumption that another active substance will remain available, while that other substance is subject to the same evaluation process, on the same grounds, at the same time. Such parallel evaluations in silos risk jeopardising the minimum availability of biocide active substances required for the European leather industry to operate.

The European Competent Authorities (Member States, ECHA/BPC and the European Commission) should therefore undertake a comprehensive risk assessment of all PT 9 biocidial active substances used by the leather industry currently undergoing BPR approval, rather than assessing each substance in isolation.

The leather and chemical industries have been pointing out for some time now that, in the biocides sector, a shortage of technically suitable active substances is becoming apparent due to regulatory activities within the EU biocidal products regulation (BPR). Therefore, the signatories of this position paper urge the European Competent Authorities to ensure a comprehensive assessment, taking into account practical conditions of use and the availability of technically suitable alternatives. To make sure that enough active substances that are on the market today will remain available, for the future viability of the European leather industry. Details are explained in the following sections of this paper.

If their use were restricted in Europe, the hides and skins produced from slaughter of meat and milk animals could increasingly be exported outside of Europe, processed to leather in non-EU countries, including the use of possibly “non-regulated” biocides and without being subject to or adhering the same high level standards of the EU Biocidal Product Regulation, and then imported as leather or leather articles into the European market. This could lead to severe effects on European consumers, who will use articles possibly containing substantial amounts of unknown and uncontrolled biocidal active substances. This poses a significant risk, as only a very small proportion of imported goods are inspected.

At the same time, European tanneries and the whole leather value chain would face a breakdown, including downstream industries such as footwear, leather-goods, furniture, and automotive industries because the leather production – and as a consequence the production of leather articles would shift to locations outside of Europe. Moreover, this

shift of production would weaken the competitiveness and sustainability of the European leather value chain.

We would therefore like to emphasize once again the importance of adopting a balanced approach. We trust our aspects mentioned above will be carefully considered to ensure that regulatory decisions continue to support both a high level of protection and the long-term availability of effective biocidal products.

Relevance of biocides in leather production

While leather, and consumer articles made out of leather, are long-lasting and resistant against mechanical as well as biological stresses, hides and all intermediates used during leather production are prone to quick biological decomposition. The collagen that makes up most of the hide structure is a perfect culture medium for bacteria, mould and yeast when enough moisture is present, which is the case for the majority of leather production steps.

a.) *BPR Product-type 9 (PT9): Fibre, leather, rubber and polymerised materials preservatives*

As a consequence, a number of biocide active substances are applied in the leather manufacturing process to safeguard the material and the quality of the final product. By protecting hides and all leather intermediates against bacteria, mould and yeast, the health of the workers is protected too, as operators do not risk of being in contact with them.

During the first step of leather production - the so-called beamhouse - bacteria are the main issue, as they are the fastest growing microorganism. Bactericides need to be added into the process float, or the hides would be destroyed before the process ends.

In the following leather production steps - tanning and crusting - the acidic pH takes mould to the forefront. This requires the usage of fungicides to make sure that leather intermediates can be sorted, stored and shipped – usually whilst wet. After that the last steps in leather production include drying, which makes leather resistant against further microbiological attack.

b.) *Product-type 6 (PT6): Preservatives for products during storage*

Process chemicals for leather production are usually supplied to tanneries in unit sizes that are not consumed by a single leather production batch. Once the packaging has been opened many of the process chemicals are subject to microbiological attack and need protection. This is even more true for the types that are based on renewable, biological raw materials or where organic solvents have been replaced by water as matrix to increase sustainability and make the product more circular.

Current situation: Availability of biocidal active substances in the European leather industry

In Europe and some other regions, the use of biocides is governed by a strict legal framework that does involve approval of the various biocidal active substances. Efficiency, risk and benefit have to be demonstrated to the authorities before an active substance is approved and can be used in a biocidal product or product formulation. In the EU, these must be approved through the **Biocidal Product Regulation EU 528/2012 (BPR)**. Regulatory hurdles and prohibitive associated costs have led to a number of biocidal active substances being withdrawn has already resulted in a number of biocidal active substances being withdrawn from the market, reducing the choice of active substances available for leather production to the minimum.

In addition, the currently available fungicides for leather production have different actions and varying degrees of efficiency - based on the type of mould. While the threat profile at the facility level varies depending on the region, location, temperature and season.

Consequently, it is crucial to use different mixes of biocidal active substances, allowing effective preservation at the lowest suitable does. Moreover, regular changes of active substances - or different percentage combinations of active substances - are necessary to prevent the adaptation of mould strains as well as to avoid resistance to active substances. In a nutshell, to produce leather and reduce total usage of active substances, it is necessary that more than one biocidal active substance is available.

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As for fungicides to be used in leather production within BPR PT9, currently only one biocidal active substance has completed the assessment process and is approved by the EU Competent Authorities. A low number of additional active biocidal substances – in total only about eight additional biocides for leather application (five fungicides and three bactericides) – are at different stages of the evaluation process (see Annex I, below). Most of these active substances in evaluation are at risk of not being approved or being approved with extremely stringent conditions. Investigations already have been carried out demonstrating that no other alternatives exist for the leather industry sector.

Furthermore, from a regulatory point of view, each active substance should not be solely evaluated individually by different countries. An integrated view based on specific interested industries (such as the leather industry) must be considered. Therefore, the current approach makes the use of these active biocidal substances impossible, because they are being evaluated as stand-alone biocidal substance, without taking into consideration the whole industrial context. Therefore, in our opinion, the existing public

consultation process might not be sufficient to guarantee approval of sufficient active substance.

Signatories

Confederation of National Associations of Tanners and Dressers of the European Community **(COTANCE)**

European Chemistry for Textile and Leather **(EUCTL)**

Federation of the European Sporting Goods Industry **(FESI)**

European Confederation of the Footwear Industry **(CEC)**

Annex I – Overview of active biocidal substances relevant for leather application being currently assessed for approval under the Biocidal Products Regulation

Fungicides

- **chlorocresol (PCMC or CMK)** – EC 200-431-6; CAS 59-50-7
  - *Status PT9*: **approved** for PT9
  - *CA*: France
  - *Notes*: currently the **only approved biocide for PT9** which is used in **leather** application
- **OPP** (Biphenyl-2-ol) – EC 201-993-5; CAS 90-43-7
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Spain
  - *Notes*: approved in several other PTs

- **OIT** (2-octyl-2H-isothiazol-3-one) – EC 247-761-7; CAS 26530-20-1
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: France
  - *Notes: Risk of non-approval or at least very strict use restrictions due to an extremely conservative and unrealistic approach to derive PNEC. Therefore, industry is asking for a weight-of- evidence assessment using the full scientific data package and realistic use and exposure conditions.*

- **TCMTB** ((benzothiazol-2-ylthio)methyl thiocyanate) – EC 244-445-0; CAS 21564-17-0
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Norway
  - *Notes*: Assessment as a candidate for substitution for PT9 and PT12 is ongoing, with a public consultation open until 5 October 2026.

- **IPBC** (3-iodo-2-propynylbutylcarbamate) – EC 259-627-5; CAS 55406-53-6
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Denmark
  - *Notes*: IPBC is already identified as candidate for substitution for PT6, PT8 and PT10. Its assessment for PT9 may therefore result in a similar substitution status or in restrictive conditions of use, further reducing the range of fungicidal active substances available to the leather industry.

Bactericides

- **Sodium dimethyldithiocarbamate (SDDC)** – EC 204-876-7; CAS 128-04-1
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Sweden
  - *Notes*: --
- **zinc pyrithione** – EC 236-671-3; CAS 13463-41-7
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Sweden
  - *Notes*:
    - Already candidate for substitution for PT2, PT10 and PT21 → risk that zinc pyrithione will be proposed for substitution also for PT9
    - No longer supported for PT2 and PT10, maybe as a consequence as substitution candidate
- **sodium pyrithione** – EC 223-296-5; CAS 3811-73-2
  - *Status PT9*: **Initial application for approval in progress** - Competent authority evaluation
  - *CA*: Sweden
  - *Notes*:
    - Due to structural similarities no "alternative" to zinc pyrithione

Already phased out / Never phased in

- **Propiconazole** (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole) – EC 262-104-4; CAS 60207-90-1
  - *Status PT9*: **expired** since 31/05/2025
  - *CA*: Finland
  - *Notes*:

- **DIMTS** p-[(diiodomethyl)sulphonyl]toluene - EC / List no.: 243-468-3; CAS no.: 20018-09-1
  - *Status PT9*: no longer supported
  - *CA*: United Kingdom
  - Notes: Common Active Substance in the US

- **MBT** MethyleneBis (thiocayanate) CAS no 6317-18-6
  - *Status PT12*: not approved
  - *CA*: France

- **Carbendazim** EC / List no.: 234-232-0; CAS no.: 10605-21-7
  - *Status PT9*: not approved
  - *CA*: Germany

- **OPP-Na**: Sodium [1, 1'-biphenyl]-2-ol salt – EC / List no. 205-055-6; CAS Number: 132-27-4
  - *No longer supported in Europe*

- **CHED** S-Hexyl-S'-Chloromethyl-cyanodithiocarbimate; CAS no.: 125744-11-2
  - *Status*: new development, not notified in Europe due to cost hurdle