Why Should the Use of Active Substances in Biocidal Products for Leather Be Derogated?

REACH Restriction Proposal on

Skin Sensitisers in Textile and Leather Articles

9 February 2024

Contents

Executive Summary

- The biocidal substances that are used for the preservation of leather are the following: CMK[1], OPP, sodium pyrithione, TCMTB, OIT and IPBC. All of them can be used according to the Biocidal Products Regulation (EU) No 528/2012 (BPR) Product Type 9 – Fibre, leather, rubber and polymerised materials preservatives (PT9).
- The BPR involves a thorough assessment of hazard properties of biocidal active substances and conducts a risk assessment focusing on all endpoints, taking into account exposure and use-specific conditions.
- These biocidal active substances are used to prevent microbial growth and decay of leather intermediates (e.g., hides and skins), ensuring their preservation during production, transportation and storage. To the best of our knowledge, these substances are not used for purposes other than preservation / biocidal effects in leather production.
- All of these biocides for leather preservation are classified as skin sensitisers in Annex VI of CLP.
- Residual amounts of these biocidal active substances are often found in leather articles. Typically, residual concentrations are well above the generic concentration restriction limit of 30 mg/kg proposed for leather articles. Therefore, the deletion of the BPR derogation would lead to severe impact on leather production and to a de facto ban of leather articles in the EU market.
- Based on existing studies, no migration from leather products to human skin is expected under foreseeable conditions of use.
- No alternatives to these biocides exist for preserving the leather intermediates under BPR PT9.
- A derogation for active substances covered under the BPR, as proposed by the Dossier Submitters and supported by RAC and SEAC, seems the most suitable solution, as BPR already addresses all hazard properties of biocidal active substances, including skin sensitisation. Such derogation would be, furthermore, in line with the EU Ecolabel on Footwear[2].
- In the absence of a derogation, the generic limit of 30 mg/kg, which according to the Dossier Submitters is based on generic values 'associated with considerable uncertainty'[3], will apply to leather. However, RAC has not assessed the health benefits that the generic limit could bring for consumers, particularly in comparison with the derogation based on the scope of BPR. Moreover, SEAC did not evaluate the socio-economic impacts of imposing this limit on biocides in leather.
- In practice, such a low limit would mean a ban on the use of biocides in leather production. This would allow the proliferation for bacteria, fungi, and molds that lead to a non-usable leather intermediate material for production of leather articles.
- This will directly affect some 1600 tanneries operating in Europe, which account for approximately 33,000 workers and a turnover of about €7.38 billion. In addition, this will have adverse consequences for customers in leather downstream sectors, which represent 40,000 companies, €125 billion in turnover and 2 million employees.

[1] Also known as PCMC = para- or 4-Chlor-3-methylphenol.

[2] COMMISSION DECISION (EU) 2016/1349 of 5 August 2016 establishing the ecological criteria for the award of the EU Ecolabel for footwear, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02016D1349-20201201.

[3] French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Swedish Chemicals Agency (KeMI), 14 June 2019, 'Annex XV Report on skin sensitising substances in textile, leather, hides and fur articles', https://echa.europa.eu/documents/10162/22a89de7-0d13-8edc-f0f9-05f37dcdaec2, p. 47.

- It can be expected that a ban on biocides would lead to the substitution of leather in both clothing and footwear, as well as in other applications. This is while the majority of leather substitutes rely on plastics derived from fossil fuels which themselves have negative environmental impacts.

1. Introduction

We, key stakeholders in the leather value chain, are concerned about the potential removal of the derogation for active substances in biocidal products in the context of the proposed REACH restriction on skin sensitisers. We understand that the Commission is concerned about the enforceability of this derogation, and that the possibility of removing it has recently been communicated to the Member State experts on the Biocidal Products Regulation (BPR).

The present document introduces the different risk management options that can be used to tackle biocides under this restriction and assesses the associated societal and economic implications. We hope this information helps substantiate the need to maintain the proposed derogation or, at least, underlines the need for a specific impact assessment in the absence thereof.

Contributors to this document include AFIRM (Apparel and Footwear International RSL Management Group), CEC (European Footwear Confederation), COTANCE (Confederation of National Associations of Tanners and Dressers of the European Community), ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers), EUCTL (European Chemistry for Textile and Leather), FESI (Federation of the European Sporting goods Industry) and their members.

2. Risk management options

For the purposes of this restriction proposal, the following risk management options (RMOs) can be used to address active substance in biocidal products:

1) Restriction with a derogation for all active substances in BPR (baseline scenario);
2) Restriction on all active substances in BPR that are classified as skin sensitisers in Annex VI of CLP above the generic limit of 30 mg/kg in leather (non-use scenario); and
3) Restriction on active substances in BPR that are classified as skin sensitisers in Annex VI of CLP with specific substance limits.

2.1. Restriction with a derogation for biocides (baseline scenario)

The Biocidal Products Regulation (BPR) involves a thorough review and assessment of biocidal active substances based on all hazard properties of biocidal active substances, including skin sensitisation, and conducts a risk assessment focusing on all endpoints, taking into account exposure and use-specific conditions. These are evaluated by competent authorities prior to their authorisation. For example, there are restrictions on the authorisation of active substances based on skin sensitising properties, such as the use of C(M)IT/MIT 3:1 in treated articles.[4]

Furthermore, a derogation based on the scope of the BPR would be in line with the EU Ecolabel on Footwear[5]. The text of the EU Ecolabel on Footwear reads as follows:

[4] COMMISSION IMPLEMENTING REGULATION (EU) 2016/131 of 1 February 2016 approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13, eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0131.

[5] COMMISSION DECISION (EU) 2016/1349 of 5 August 2016 establishing the ecological criteria for the award of the EU Ecolabel for footwear, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02016D1349-20201201.

Figure 1 - Extract of EU Ecolabel on Footwear

(e) Biocidal products (within the meaning of Article 3(1)(a) of Regulation (EU) No 528/2012 of the European Parliament and of the Council [1])

Used during transportation or storage of raw and semi-finished materials, final products or final product packaging	(i) Only the following active substances (within the meaning of Article 3(1)(c) Regulation (EU) No 528/2012 shall be allowed: — active substances included in the list drawn up in accordance with Article 9(2) of Regulation (EU) No 528/2012, for the relevant product type (i.e. fibre, leather, rubber and polymerised materials), provided the conditions or restrictions specified therein are met; — active substances included in Annex I of that Regulation provided the conditions or restrictions specified therein are met; — active substances under examination for the relevant product type in the work programme referred to in Article 89(1) of Regulation (EU) No 528/2012.	n/a	*Assessment and verification:* the applicant and material supplier shall provide either declarations of non-use prior to transportation and storage, or evidence that the use of the biocidal active substance is allowed under Regulation (EU) No 528/2012. If used, a list of active substances added during transportation or storage of raw, semi-finished materials or to final product packaging shall be provided, including the related H statements.
	(ii) Biocidal products shall not be incorporated into final products or any part thereof during footwear assembly in order to impart biocidal properties to the final product.	n/a	*Assessment and verification:* the applicant and material supplier shall provide declarations of non-use in the final product or any part thereof.
	(iii) Chlorophenols (their salts and esters), organotin compounds (including TBT, TPhT, DBT and DOT), dimethyl fumarate (DMFu), triclosan and nanosilver shall not be used during the transportation or storage of the product, any article of it and any homogeneous part of it and shall not be incorporated into the final product or product packaging.	Not detectable	*Assessment and verification:* the applicant or material supplier(s) shall provide a declaration of non-use. The declaration shall be supported by the results of final product testing for the presence of the following substances: *Chlorophenols:* leather, EN ISO 17070; textiles, XP G 08-015 (detection limits: leather: 0,1 ppm; textiles: 0,05 ppm); *Dimethyl fumarate:* ISO/TS 16186.

Official Journal of the European Union L 2

2.2. Generic limit of 30 mg/kg of biocides in leather (non-use scenario)

For substances for which no substance specific migration factor or elicitation threshold dose were found, the Dossier Submitters proposed to use generic values 'associated with considerable uncertainty'[6]. Based on these generic values, the Dossier Submitters proposes a concentration limit of 40 mg/kg for these substances in leather – 30 mg/kg in the RAC opinion.

Currently, the application of such a low limit for biocides is not supported by any of the existing certification schemes for leather –e.g., EU Ecolabel, Blue Angel, Nordic Ecolabel, AFIRM, OEKO-TEX® LEATHER STANDARD, bluesign®.

In addition, it should be noted that some of the biocides in scope of this document are included in the list of preservatives allowed for used in cosmetic products –according to Annex V of the Cosmetics Product Regulation (CPR)[7]– under thresholds up to 0.2 % (2,000 mg/kg):

Figure 2 –Limits for OPP in Annex V the Cosmetics Products Regulation

7	Biphenyl-2-ol (19)	o-Phenylphenol	90-43-7	201-993-5	(a) Rinse-off Products (b) Leave-on products	(a) 0,2 % (as phenol) (b) 0,15 % (as phenol)		Avoid contact with eyes

Figure 3 –Limit for CMK Annex V the Cosmetics Products Regulation

24	Chlorocresol	p-Chloro-m-Cresol	59-50-7	200-431-6	Not to be used in products applied on mucuous membranes	0,2 %		

[6] ANSES and KeMI, 14 June 2019, 'Annex XV Report on skin sensitising substances in textile, leather, hides and fur articles', p. 47.

[7] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast), https://eur-lex.europa.eu/eli/reg/2009/1223/oj/eng.

2.3. Specific substance limits of biocides in leather

At present, there are only a few certification schemes that provide specific limits for biocides in leather. The best examples are the German product certification "Blue Angel", which provides a list of biocides that are not classified as strong contact allergens along with specific substance limits based on the availability of detection methods for leather[8], (range of 100-500 mg/kg, depending on the biocide), and OEKO-TEX® LEATHER STANDARD (range of 100-750 mg/kg, depending on the biocide)[9].

3. Risk assessment

3.1. Identification of the substances and hazard assessment

The biocidal substances that are used for the preservation of leather intermediates and currently classified as skin sensitisers in Annex VI of CLP are the following:

Table 2 - List of relevant biocidal substances classified as skin sensitisers in Annex VI of CLP

Active	CAS No.	Legal Classification for Skin Sensitizing effects (acc. to CLP).
CMK	59-50-7	Skin Sens. 1B
OPP	90-43-7	Skin Sens. 1B
Sodium pyrithione	3811-73-2	Skin Sens. 1
TCMTB	21564-17-0	Skin Sens. 1
OIT	26530-20-1	Skin Sens. 1A
IPBC	55406-53-6	Skin Sens. 1

To the best of our knowledge, these substances are not used for other purposes than preservation / biocidal effects in leather production.

3.2. Exposure

3.2.1. Description of the use

The leather-making process relies on the utilisation of biocides –such as CMK, IPBC, OPP, OIT, sodium pyrithione and TCMTB– to protect leather intermediates –like wet blue[10] or wet white[11]– from microbial growth and decay, ensuring their preservation during production, transportation and storage. The required storage stability must be of at least 12 months and often takes place in countries with higher temperatures and a high level of humidity.

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[8] German Federal Government, Blue Angel –Appendix A – Biocidal conservatives for leather, https://produktinfo.blauer-engel.de/uploads/criteriafile/en/DE-UZ%20148-201503-en%20criteria-V5.pdf, p. 17; 19.

[9] OEKO-TEX®, LEATHER STANDARD, https://www.google.com/url?q=https://www.oeko-tex.com/importedmedia/downloadfiles/OEKO-TEX_LEATHER_STANDARD_Standard_EN_DE.pdf&sa=D&source=docs&ust=1707387107809313&usg=AOvVaw0a5cGT8X3pw47vAD_yFVxg, p. 29.

[10] Moist chrome-tanned leather.

[11] Leather tanned using aldehydes, aluminum, zirconium, titanium, or iron salts, or a combination thereof. Like wet blue, wet white is also a semifinished stage.

These substances are not used for other purposes than preservation / biocidal effects in leather production.

3.2.2. Volumes

In the initial stages of leather processing, these substances are used at relatively high concentrations, which is imperative to prevent mold damage swiftly and effectively. When using leather biocidal chemicals typical application rates of biocidal active substances can go up to 2,000 mg/kg in the leather intermediates to preserve these intermediates.

Subsequently, these concentrations are tipically reduced in later processing stages, leaving minimal residual amounts necessary for ongoing preservation efficacy. These residual amounts of biocidal active substances in leather articles are typically well above the proposed generic concentration limit of 30 mg/kg for leather proposed in the RAC final opinion. The residual concentrations can vary in a wide range depending on many factors like the kind and type of original material used for leather production (origin, thickness, structure, etc.), used tanning agent, expected transportation and / or storage time, intended quality of intermediate leather and final leather material, humidity, storage and transportation temperature, and several other parameters.

3.2.3. Migration

A comprehensive migration study was performed by LANXESS Deutschland GmbH to evaluate the extent of biocide migration from leather and assess potential risks to consumers.[12] In this study, four different types of leather were produced: automotive leather, shoe upper leather, garment leather, and furniture leather. The wet blue intermediates were preserved with four common biocides: CMK, OPP, OIT and TCMTB.

CMK and OPP typically require higher amounts because of their distinct modes of action, while OIT and TCMTB are generally applied in lower amounts. The selection of dosages for each specific active ingredient in this investigation deliberately exceeded the standard and recommended application levels. This overuse was intentional to illustrate that, even in a worst-case scenario, no migration occurs. It is crucial to note that these elevated quantities are well beyond what is typically used in commercially available leathers.

In order to simulate real-life conditions that leather products might encounter during their lifecycle, friction tests were conducted following the DIN EN ISO 1 05-X12 standard. The leather samples and cotton fabrics, saturated with an artificial sweat solution of pH 5. 5 according to DIN EN ISO 1 05-E04, were subjected to 1,000 friction cycles with a friction force of 9 ± 0.2 N. Analytical determination of the active ingredient content was carried out on the leather samples and cotton fabrics, according to the DIN EN ISO 13365-1 and DIN EN ISO 13365-2 standards, respectively.

The analysis of the active ingredient content in the leather samples revealed elevated values for all four biocides, attributed to the intentional application of substantial quantities for preservation purposes (refer to Table 3). Subsequent to the friction tests, an investigation into the presence of the

[12] LANXESS Deutschland GmbH, 18 September 2023, 'Exploring biocide residues in leather: a migration study', https://lanxess.com/-/media/Project/Lanxess/Corporate-Internet/Products-and-Solutions/Industries/Microbial-Control/World-leather_Migration-study.pdf.

four biocides in the cotton fabrics immersed in the sweat solution was conducted. Notably, all biocides in the cotton fabrics exhibited levels below the detection limit of 30 mg/kg:

Table 3 - Results of migration study by LANXESS

Active Ingredient Content in mg/kg for the different types of leather				
	OPP	**CMK**	**OIT**	**TCMTB**
	DIN EN ISO 13365 -1 (2020-12) in mg/kg dry weight	*DIN EN ISO 13365 -1 (2020-12) in mg/kg dry weight*	*DIN EN ISO 13365 -1 (2020-12) in mg/kg dry weight*	*DIN EN ISO 13365 -1 (2020-12) in mg/kg dry weight*
Shoe Upper				
Leather sample	3500	1800	1300	1100
Cotton fabric after rubbing (grain side)	not detectable	not detectable	not detectable	not detectable
Cotton fabric after rubbing (flesh side)	not detectable	not detectable	not detectable	not detectable
Garment Leather				
Leather sample	4600	2000	1600	1300
Cotton fabric after rubbing (grain side)	not detectable	not detectable	not detectable	not detectable
Cotton fabric after rubbing (flesh side)	not detectable	not detectable	not detectable	not detectable
Automotive				
Leather sample	3300	1600	1200	990
Cotton fabric after rubbing (grain side)	not detectable	not detectable	not detectable	not detectable
Furniture				
Leather sample	2700	1500	690	545
Cotton fabric after rubbing (grain side)	not detectable	not detectable	not detectable	not detectable
Cotton Fabric				
before rubbing	not detectable	not detectable	not detectable	not detectable

The absence of biocide residues in the cotton fabrics used in the friction tests shows that there is no detectable migration of biocides from the leather. Furthermore, **the study not only proves consumer safety, but invalidates the use of the generic migration factor (10%) to derive limits for biocides**[13].

A separate study was conducted by Buckman Laboratories International, Inc., in 2021 to determine maximum levels of the active ingredient TCMTB that may leach and be transferred from leather treated with TCMTB. The study, which was reviewed by the United States Environmental Protection Agency (US EPA), concluded that the factor associated with the migration of TCMTB from leather articles to human skin was estimated at 0.019%, which is also much lower than the default of 10% [14].

The abovementioned studies are provided in attachment to this document.

4. Assessment of risk management options

4.1. Derogation for active substances in BPR (baseline scenario)

4.1.1. Human health impacts

The leather-making process employs biocides to protect leather intermediates from microbial growth and deterioration, ensuring leather is produced, transported and stored under safe conditions for the benefit of both professionals and consumers. While residues may exist in final leather products, the provided migration study indicates no health risks associated with residues of these substances in the leather.[15]

4.1.2. Environmental impacts

As this is the baseline scenario, there are no expected environmental impacts associated with this measure.

4.1.3. Economic impacts

As this is the baseline scenario, there are no expected economic impacts associated with this measure.

4.2. Generic limit of 30 mg/kg (non-use scenario)

4.2.1. Human health impacts

As explained in section 1.3.1, residual amounts of biocides are often found in leather articles. These residual amounts of biocidal active substances in leather articles are typically well above the proposed generic concentration limit of 30 mg/kg for leather proposed in the RAC final opinion. The residual concentrations can vary in a wide range depending on many factors like the kind and type of original material used for leather production (origin, thickness, structure, etc.), used tanning agent, expected

[13] French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and the Swedish Chemicals Agency (KeMI), 11 June 2020, 'Background document to the Opinion on the Annex XV dossier proposing restrictions on skin sensitising substances in textile, leather, hides and fur articles', https://echa.europa.eu/documents/10162/82d6f20a-af6c-9a42-3cc5-77649900f348, p. 40.

[14] Buckman Laboratories International, Inc., June 2021, 'Study: Recoverability of TCMTB Residues from the Surface of Leather Treated with Busan 30WB'.

[15] LANXESS Deutschland GmbH, 18 September 2023, 'Exploring biocide residues in leather: a migration study'.

transportation and / or storage time, intended quality of intermediate leather and final leather material, humidity, storage and transportation temperature, and several other parameters.

Therefore, the generic limit of 30 mg/kg would mean a de facto ban on the use of biocides in leather. This would allow the proliferation for bacteria, fungi, and molds that lead to a non-durable leather intermediate material for production of leather articles.

4.2.2. Environmental impacts

- Substitution of leather

We expect that a ban on biocides would mean that EU consumers will not be supplied with leather products any longer, leading to its substitution in both clothing and footwear, as well as other applications.

In this regard, we would like to note that leather makes use of animal skin byproducts from the meat and dairy industries that would otherwise be disposed of, and as a biobased material it can be produced regeneratively by meat processors using best practices and technologies.

The majority of leather substitutes, such as synthetic leather, i.e. polymer-coated textiles, rely heavily on plastics derived from fossil fuels which have their own environmental impacts including the potential shedding of microplastics. This is also valid for so-called 'vegan leather' in which non-animal biobased material is incorporated in the synthetic polymer layer of the synthetic leather material.

In addition, products of genuine leather are characterised by their longevity and often have several lifecycles, passing from hand to hand, from generation to generation within families or via second hand market, minimising the environmental impact of their production and contributing to tackling fast fashion. Leather is highly durable and sought after material for innumerable products.

Moreover, leather products can be recovered, reused or repurposed and biodegrade at the end of their lifecycle.[16]

- Recycling of leather

The impact on the repurposing of leather should also be considered. At present, there are a number of innovative leather processes for pre-consumer leather residues or post-consumer leather products discarded at end of life. For instance, the British company ELeather has developed a patented process for converting wet-blue splits (Chrome-tanned splits), which would not be processed further to split leather, into a composite material, where the tanned leather fibres are engineered into a new material that has found its way into heavy-duty public transport upholstered seatings[17]. In addition, the German company Salamander, leader in the production of leather fibre board for reinforcements in footwear, developed solutions for the recycling of leather residues that are already being implemented during production[18].

In the absence of a derogation with respect to BPR, existing leather articles used in various recycling processes will likely contain residual biocide active substances in concentrations above or well above

[16] La Conceria, April 2022, *Mileage and leather: miles and miles of circularity,* https://www.laconceria.it/en/leather-goods/mileage-and-leather-miles-and-miles-of-circularity.
[17] eLeather Group, 'What is Engineered Leather and How to Work with It?', https://www.eleathergroup.com/what-is-engineered-leather-and-how-to-work-with-it/.
[18] Salamander, 'Loop Concepts', https://salamanderps.com/en/solutions/loop-concepts/.

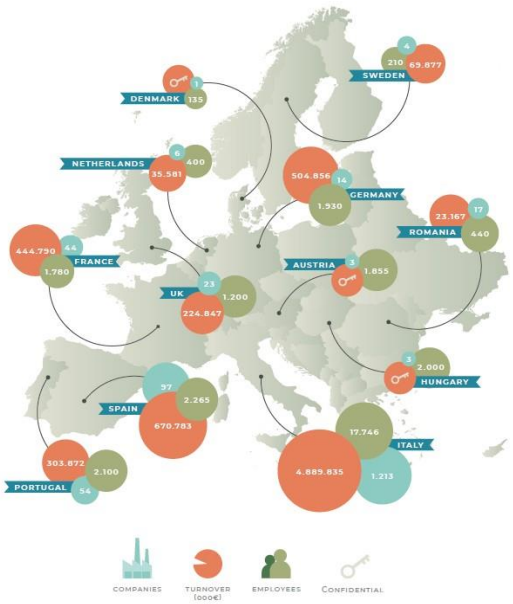
the proposed 30 mg/kg limit value, preventing their use in the mechanical recycling process, i.e. they will become waste.

4.2.3. Economic impacts

The generic limit will prevent the safe and efficient production, transport and storage of leather intermediates. This will affect the about 1600 tanneries currently operating in Europe, which account for 33,000 workers and a turnover of €7.38 billion.

In addition, this will have adverse consequences for leather downstream sectors, which represent 40,000 companies, €125 billion in turnover and 2 million employees.

Moreover, having regard to the size of the EU market for leather articles, applying the 30 mg/kg limit of biocides in leather would affect the global trade of leather and constitute a significant trade barrier.



4.2.4. Legal impacts

Exemptions based on the BPR are common derogations in restriction entries of REACH Annex XVII. Removing the proposed derogation in the context of the REACH restriction proposal on skin sensitisers would put in question the exemptions envisioned in the already adopted restrictions, potentially setting a precedent for reevaluation.

4.3. Specific substance limits[19]

4.3.1. Human health impacts

Given that the migration study indicates no health risks associated with biocide residues in the leather, it seems unnecessary from the health standpoint to derive specific limits for these substances.

However, we can anticipate that reducing the quantities of biocides used in leather intermediates could make them more susceptible to mold and microbial growth, especially in humid environments. This could increase the probabilities of uncontrolled contamination of leather, potentially posing health risks.

If specific substance limits were to be proposed, we recommend that their health benefits, particularly in comparison with restriction option (1), are carefully examined.

4.3.2. Environmental impacts

Overall, reducing the quantities of biocides used in leather intermediates could lead to microbial degradation, compromising the structural integrity of leather and making it more prone to tearing, cracking, or other forms of damage.

[19] Please note that in absence of reference values, it is not possible to provide concrete proof of health, environmental and economic impacts.

4.3.3. Economic impacts

We expect that compliance with specific substance limits will bring additional testing and certification requirements for economic operators, the extent of which cannot be derived in the absence of reference limits.

5. Conclusions

The present document has evaluated the risk from human exposure to residues of biocides in leather based on different exposure parameters. In addition, three risk management measures have been evaluated based on the associated health, environmental, societal and economic impacts.

The assessment revealed that the derogation proposed by the Dossier Submitters is substantiated by the comprehensive and thorough hazard and risk evaluations of biocidal active substances conducted in the context of the Biocidal Products Regulation (EU) No 528/2012 (BPR), which address specific applications and take into account, among other aspects, exposure and use-specific conditions. This is also referred to in the Ecolabel on Footwear.

In contrast, the alternative of applying a generic limit of 30 mg/kg could effectively ban biocides in leather. Such a low limit would carry profound consequences, potentially rendering leather non-usable for production due to bacterial and fungal proliferation.

The impact on the European leather industry would be substantial, affecting 1600 tanneries, 33,000 workers, and a €7.38 billion turnover. The ripple effect would extend to downstream sectors, impacting 40,000 companies, €125 billion in turnover, and 2 million employees. Beyond economic implications, a ban on biocides will lead to the potential substitution of leather with alternatives. This substitution would, furthermore, introduce environmental concerns, as many substitutes rely on plastics.

On the other hand, the absence of health risks associated with biocide residues in leather suggests that it is unnecessary to derive specific limits for these substances. This is underpinned by the fact that only a few certification schemes provide specific limits for certain biocides in leather, and these limits were set based on technical feasibility and the fact that they do not migrate out of leather during simulated ordinary use.

Based on all the above, we advocate for the maintenance of the proposed derogation, which will only apply to substances used for biocidal purposes and is necessary for the safe and efficient production of leather. Alternatively, we believe that the implementation of generic or specific substance limits for these substances should be subject to a specific risk assessment and a targeted evaluation of the expected socio-economic impacts.

We remain at the Commission’s disposal in case any further clarification is required.