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From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 28 April 2023

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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No. Cion doc.: SEC(2023) 170 final

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Subject: Opinion of the Regulatory Scrutiny Board on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004

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Delegations will find attached document SEC(2023) 170 final.

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Encl.: SEC(2023) 170 final



EUROPEAN COMMISSION

Brussels, 16.09.2022  
SEC(2023) 170 final

**REGULATORY SCRUTINY BOARD OPINION**

**Proposal for a Regulation of the European Parliament and of the Council  
on detergents and surfactants, amending Regulation (EU) No 2019/1020 and repealing  
Regulation (EC) No 648/2004**

{COM(2023) 217 final}

{SWD(2023) 113 final}

{SWD(2023) 114 final}

{SWD(2023) 115 final}



EUROPEAN COMMISSION  
Regulatory Scrutiny Board

Brussels,  
RSB

### **Opinion**

#### **Title: Impact assessment / Revision of the Detergents Regulation**

**Overall opinion: POSITIVE**

##### **(A) Policy context**

The Detergents Regulation provides for the free movement of detergents and surfactants on the internal market. It aims to ensure a high level of protection of the environment and human health and covers both consumer and industrial detergents. The Regulation applies in all EU Member States and countries of the European Economic Area (i.e. Iceland, Lichtenstein, Norway). Since its entry into force in 2004, the Regulation has been amended multiple times to reflect market innovations and safety concerns including in 2008 to align with the Regulation on classification, labelling and packaging of substances and mixtures.

This initiative aims to revise the Detergents Regulation to reflect new challenges including new market developments and simplification opportunities. The impact assessment explores options to cover refill sales as a sustainable new practice and microbial cleaning products as innovative products. It also posits changes to labelling requirements and ingredient data sheets by reaping the benefits of digital solutions

##### **(B) Summary of findings**

The Board notes the additional information provided in advance of the meeting and commitment to make changes to the report. The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

- (1) The report does not sufficiently explain the scope of the initiative for refills and microbial detergents. The analysis does not provide a sufficient explanation of what success would look like.
- (2) The report lacks clarity on the impacts on SMEs. In particular, it does not provide a clear description of the evidence of the acceptability of costs to fulfil the risk management requirements for microbial products.

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This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 08/010. E-mail: regulatory-scrutiny-board@ec.europa.eu

**(C) What to improve**

(1) The report should clarify the scope of the initiative for refills and microbial detergents. The analysis should better elaborate how serious the problems related to refill sales and microbial products are, and whether facilitation of refill sales is a primary or secondary objective. The report should clarify upfront that the overarching aims of the intervention are safety for citizens and the environment, as well as the level playing field for EU businesses.

(2) The report should better explain what success would look like. The analysis should include necessary benchmarks to measure the accomplishment of the objectives. The report should reflect these in the monitoring and evaluation arrangements, the operational objectives and the monitoring indicators.

(3) The report should better explain the impacts of each option on SMEs. Given that most of the producers of microbial detergents are SMEs, the report should analyse the impacts on different categories of them, especially microenterprises. The report should better explain why and how the SMEs would 'strongly benefit' from digital labelling.

(4) The report needs better reasoning behind the 'acceptability' of EUR 200,000 costs for SMEs to fulfil the risk management requirements for microbial products. It should further detail what this cost includes and why it may vary from one company to another. It should better present the evidence to support this assumption and clarify the uncertainty of the calculations.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

*Some more technical comments have been sent directly to the author DG.*

**(D) Conclusion**

**The DG may proceed with the initiative.**

**If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.**

Full title	Proposal for a regulation of the European Parliament and the Council Amending Regulation (EC) No 648/2004 of the European Parliament and the Council of 31 March 2004 on detergents
Reference number	PLAN/2021/10270
Submitted to RSB on	20 July 2022
Date of RSB meeting	Written procedure

**ANNEX – Quantification tables extracted from the draft impact assessment report**

*The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.*

*If the draft report has been revised in line with the Board’s recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.*

<b>I. Overview of Benefits (total for all provisions) – Preferred Option</b>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<b>Direct benefits</b>		
Reduced administrative burden for manufacturers of detergents due to elimination of duplications, digital labelling and abolitionment of ingredient data sheets	€7 million - abolishment of ingredient data sheets for hazardous detergents  Savings due to elimination of duplications in the labelling requirements and digital labelling - non quantifiable.  Digital labels are easier to update and less costly compared to physical labels. Moving certain information to the digital labels allows for less relabelling.	The introduction of digital labelling is on a voluntary basis and manufacturers of detergents are already required to maintain a website with a full ingredient list.
Users enjoying greater ease of use and increased awareness of key information (e.g. ingredients, safety information).	Non-monetary benefit	Evidence from the consultations highlights that increased awareness about product information on labels and more informed decision-making is likely to reduce risks to health and safety.  Public authorities also benefit from simplified labels and digital labels render enforcement easier (information online will be easy to navigate and searchable).
Improved functioning of the internal market	Non-monetary benefit	Legal clarity and certainty for microbial cleaning products and refill sales. Harmonised requirements for microbial cleaning products and facilitation of refill sales also through (optional) digital labelling.
Reduced risks to health and safety of users	Non-monetary benefit	Improved label readability would lead to increased consumer safety. Consumers receive complete information on refilled detergents and are allowed to make informed

		choices for their health and the environment. Ingredient data sheet for non-hazardous detergents is maintained.
Optimised protection of the environment	Non-monetary benefit	Simplified dosage instructions and detailed information on e-labels ensures proper use and prevents overdosing. Consumers receive information on use of refilled detergents and microbial cleaning products.
<b><i>Indirect benefits</i></b>		
Reduced disposal of plastic waste (refill sales)	Impact not quantified; the baseline savings estimated at €3.3 million	The facilitation of refill sales would lead to a reduction of disposed plastic waste and consequent cost savings. These savings could increase based on the expected growth of refill sales.
Potential reduction in the disposal of unused labels due to digital labelling	Not quantifiable	Digital labels are easier to update and less costly compared to physical labels. Moving certain information to the digital labels allows for less relabelling.
<b><i>Administrative cost savings related to the 'one in, one out' approach *</i></b>		
Annual direct administrative savings - abolishment of ingredient data sheets for hazardous detergents	€7 million	
Potential additional administrative costs savings due to voluntary digitalisation of labels	Not quantifiable	The benefits would stem from the digitalisation of some information compared with the current physical-only labelling requirements. Given the voluntary nature of the preferred option, no costs would be imposed on businesses. Businesses would only provide digital labelling if they perceive the potential to enjoy reduced costs (or if they perceived sufficient other business benefits to justify any cost increase). Cost savings would arise through reducing the frequency of disposing of and redesigning

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		physical labels. There would also be economies of scale in that more languages could fit on physical labels. All types of firms (SMEs and large enterprises) would be able to benefit from digitalisation.
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II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs	Not relevant	Not relevant	€72,000 Total familiarisation costs (€25.7/h, 4 man hours per company)	€200.000* (tests for microbial cleaning products)	Not relevant	Not relevant
	Direct administrative costs	Not relevant	Not relevant	voluntary digital labelling - minor costs for updating websites	Not relevant	Not relevant	Not relevant
	Direct regulatory fees and charges	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	Direct enforcement costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Possible slight increase of enforcement costs – not quantifiable
	Indirect costs	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
<i>Costs related to the 'one in, one out' approach</i>							
<b>Total</b>	Direct adjustment	Not relevant	Not relevant	Not relevant	Not relevant		

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	costs						
	Indirect adjustment costs	Not relevant	Not relevant	Not relevant	Not relevant		
	Administrative costs (for offsetting)	Not relevant	Not relevant	Not relevant	Not relevant		

\* It should be noted that this an upper bound estimate, taking into account the highest number of batches reported by stakeholders during the interviews. The costs related to proving the lack of antibiotic resistance can range from €0 (in cases where the relevant data is already available in EUCAST<sup>1</sup>) to €335 per strain of microorganism used (in cases where this needs

<sup>1</sup> European Committee on Antimicrobial Susceptibility Testing