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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 June 2022
To:	General Secretariat of the Council
No. Cion doc.:	SEC(2022)251 final
Subject:	*REGULATORY SCRUTINY BOARD OPINION* - Evaluation of the legislation on food contact materials Regulation (EC) No 1935/2004

Delegations will find attached document SEC(2022)251 final.

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Brussels, 9.6.2022
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REGULATORY SCRUTINY BOARD OPINION

Evaluation of the legislation on food contact materials
Regulation (EC) No 1935/2004

{SWD(2022) 163 final}
{SWD(2022) 164 final}

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EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Evaluation of the food contact materials Regulation (EC) No 1935/2004

Overall opinion: POSITIVE

(A) Policy context

The Food Contact Materials (FCM) Regulation ensures the protection of human health for any material or article that comes in contact with food, and allows a smooth functioning of the internal market for these materials. The scope ranges from food packaging and kitchenware materials to items for food manufacturing and processing. The basic act, Regulation (EC) No 1935/2004, accounts for all materials and articles in contact with food, while specific harmonised measures are adopted for example for plastics, including a list of authorised substances. In the absence of harmonised EU rules, Member States can introduce national measures which can be recognised by other Member States by a system of mutual recognition.

The original legal basis dates from 1976 and was not evaluated formally so far. The evaluation addresses the effectiveness, efficiency, coherence, relevance and EU added value of the legal framework for food contact materials. The results of this evaluation can be used for the revision of EU rules on food contact materials.

(B) Summary of findings

The Board notes the complete and genuine evaluation of the food contact materials Regulation. The strengths and shortcomings of the Regulation are described clearly. The Board notes the additional information provided and commitments 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 process of establishing an authorised substance list and possible derogations to it is not well explained. The roles of the different actors (industry, EFSA, Commission) in these processes are not clear.

(2) The effectiveness of the food contact materials legislation for materials other than plastics is not sufficiently clear.

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

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(C) What to improve

(1) The report should explain how lists of authorised substances are established and clarify how derogations can be obtained and justified. It should outline clearly to what extent these lists and exemptions guarantee the safety of these substances. It should also be clear when it is not possible for the evaluation to conclude whether these substances pose a health risk or not.

(2) The report should provide a clear overview of the specific rules and measures in place for the different materials and bring out more clearly how effective the legislation is for materials other than plastics.

(3) The report should improve the clarity of the description of the structure and content of the overall legal framework. The overlap and interplay with other relevant legislation should be presented.

(4) The report is difficult to understand for a non-expert reader. The readability of the report should be improved, e.g. by additional explanations and adding graphical and structured summaries.

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

(D) Conclusion

The DG must take these recommendations into account before launching the interservice consultation.

Full title	Evaluation of legislation on Food Contact Materials - Regulation (EC) No 1935/2004
Reference number	PLAN/2016/436
Submitted to RSB on	2 August 2021
Date ofRSB meeting	Written procedure

Electronically signed on 25/10/202111:37 (UTC+02) in accordance with article 11 of Commission Decision C(2020) 4482