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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 October 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	D(2025) 109574 annex
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Regulation (EC) No 1333/2008 of the European Parliament and the Council and Commission Regulation (EU) No 231/2012 as regards the use of shellac (E 904) in food for special medical purposes in tablet and coated tablet forms

Delegations will find attached document D(2025) 109574 annex.

Encl.: D(2025) 109574 annex



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2025/781 ANNEX
(POOL/E2/2025/781/781 EN
ANNEX.docx) D109574/02
[...](2025) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION

**amending Regulation (EC) No 1333/2008 of the European Parliament and the Council
and Commission Regulation (EU) No 231/2012 as regards the use of shellac (E 904) in
food for special medical purposes in tablet and coated tablet forms**

ANNEX I

In Part E of Annex II, in food category 13.2 ‘Foods for special medical purposes as defined by Regulation (EU) No 609/2013 (excluding products from food category 13.1.5)’, the following entry is inserted between the entries for food additives E 491-495 Sorbitan esters and E 950 Acesulfame K:

	E 904	Shellac	46 000		only in tablet and coated tablet forms
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ANNEX II

In the Annex, the entry for 'E 904 Shellac' is amended as follows:

(1) The specification 'Definition' is replaced by the following:

'Definition	Shellac is the purified and bleached lac, the resinous secretion of the insect <i>Laccifer (Tachardia) lacca</i> Kerr (Fam. <i>Coccidae</i>). The wax is removed by filtration.'
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(2) the specification 'Description' is replaced by the following:

'Description	Wax-free bleached shellac — off-white to light yellow, amorphous, granular resin'
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(3) the specification 'Wax' is replaced by the following:

'Wax	not more than 0,2 %'
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