Amendment 57
S&D-Greens/Efa-GUE/NGL
Consolidated amendment replacing Amendments: 1146 to 1248, 1360, JURI 65, IMCO 59, INTA 55, AGRI 69, ITRE 64-65
Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
1. ***The following*** nicotine-containing products may only be placed on the market if they ***were*** authorised pursuant to Directive 2001/83/EC***:***	1. Nicotine-containing products may only be placed on the market if they ***are*** authorised pursuant to Directive 2001/83/EC***, taking into account the well-established use of nicotine.***
a) products with a nicotine level exceeding 2 mg per unit, or	***deleted***
b) products with a nicotine concentration exceeding 4 mg per ml or	***deleted***
c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml.	***deleted***
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to update the nicotine quantities set out in paragraph 1 taking into account scientific developments and marketing authorisations granted to nicotine- containing products pursuant to Directive 2001/83/EC.	***deleted***
3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:	***deleted***
This product contains nicotine and can damage your health.	
4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:	***deleted***
(a) be printed on the two largest surfaces of the unit packet and any outside packaging;	

(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.	
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings.	***deleted***

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