National Health Surveillance Agency

www.anvisa.gov.br

Public Consultation No 41 of 23 June 2009.

D.O.U (Official Gazette of the Union) of 24/06/09

The Board of the National Health Surveillance Agency (ANVISA), in the exercise of the powers granted by Article 11(IV) and Article 35 of ANVISA's Regulations, approved by Decree No. 3029 of 16 April 1999, and having regard to the provisions of Article 54, indent (V) and paragraphs (1) and (3) of the Internal Regulations approved in accordance with Annex I of ANVISA Administrative Ruling No. 354 of 11 August 2006, republished in the Official Gazette of the Union of 21 August 2006, at a meeting held on 16 June 2009,

hereby approves the following Public Consultation, and I, the Director-President, order its publication:

Article 1. Criticism and suggestions concerning the draft Resolution prohibiting the sale of Electronic Smoking Devices (ESD) may be submitted up to 30 (thirty) days from the date of publication of this Public Consultation.

Article 2. The full text of the draft Resolution will be available on Anvisa's website, http://www.anvisa.gov.br. Suggestions should be submitted in writing, using the dedicated form available on Anvisa's website at: http://www.anvisa.gov.br/divulga/consulta/formulario.doc, to one of the following addresses: Avenida Graça Aranha 206 - 2º andar - Centro - Rio de Janeiro - RJ, CEP 20030-001, or by e-mail to: controle.tabaco@anvisa.gov.br.

Article 3. At the end of the period specified in Art. 1, the National Health Surveillance Agency will talk to the Bodies and Entities involved and other parties with an interest in the matter, and ask them to nominate representatives for subsequent discussions, in order to arrive at a final wording.

DIRCEU RAPOSO DE MELLO

ANNEX A

Form for submission of contributions as part of a Public Consultation

National Health Surveillance Agency	FORM FOR SUBMISSION OF CONTRIBUTIONS AS PART OF A PUBLIC CONSULTATION

Introduction and guidelines

This form is intended to enable members of the public to send their contributions to aid in the process of making a decision on a Public Consultation organised by Anvisa.

When completing the form, please note the instructions below:

- Completed forms can be returned to Anvisa by e-mail, fax or post, using the addresses given in the Public Consultation.
- Complete all sections of this Form and send your comments within the period during which the Public Consultation is open for contributions.

- Any contributions received outside this period or not sent using this Form will not be taken into consideration for the preparation of the final text of the regulation.
- If the information provided on this Form is incomplete or imprecise Anvisa may not be able to use it.
- The contributions received by Anvisa will be published and will remain available to the public on Anvisa's website.
- This process will help to increase transparency and public participation, and will help Anvisa to prepare the final text of the proposed regulation.

Thank you for your contribution!

National Health Surveillance Agency	FORM FOR SUBMISSION OF CONTRIBUTIONS AS PART OF A PUBLIC CONSULTATION

Public consultation: No_____/ year _____

I. Identification of the participant

Full name:		
Address :		
Town:		**Federal Unit:**
Telephone: ( )	**Fax: ( )**	**E-mail:**

1. Please tick the one that applies to you. *(Choose one only)*

( ) Consumer (natural person)
( ) Consumer protection association or body
( ) Health professional (natural person)
( ) Body or organisation of health professionals
( ) Entrepreneur or owner of business establishment
( ) Association or body representative of the regulated sector
( ) Academia or teaching and research institution
( ) Federal, State or Local Government body or entity
( ) Other. Please specify:

2. How did you hear of this Public Consultation? *(More than one reply possible)*

( ) Official Gazette of the Union
( ) Anvisa website
( ) Circular or letter from Anvisa
( ) Other websites
( ) Television
( ) Radio
( ) Newspapers and magazines
( ) Association, body or institution representative of your category or sector of civil society
( ) Friends, colleagues or work professionals
( ) Other. Please specify:

3. In general terms, what is your opinion on the proposal under discussion? *(Choose one only)*

( ) Strongly approve
( ) Approve
( ) Somewhat approve
( ) Somewhat disapprove
( ) Disapprove
( ) Strongly disapprove

II. Contributions to the Public Consultation	
Existing published text (if any)	**Proposal (addition, deletion or rewording)**
Reasons:	

Existing published text (if any)	**Proposal (addition, deletion or rewording)**
Reasons:	

Existing published text (if any)	**Proposal (addition, deletion or rewording)**
Reasons:	

Existing published text (if any)	**Proposal (addition, deletion or rewording)**
Reasons:	

Appendix I

Rules governing the Public Consultation

1. Participation in the public consultation procedure shall take place by identification of the interested parties and use of the dedicated form.

2. The form for the submission of contributions shall be available on Anvisa's website at the address www.anvisa.gov.br and can also be obtained from the Agency's head office in Brasilia or by fax on request of the interested party to the sector responsible for the public consultation as indicated on the relevant call for contributions.

3. Contributions delivered in person to the Agency's head office in Brasilia or sent by e-mail, fax or post, according to the guidelines laid down in the call for contributions to the public consultation, will be accepted.

4. All contributions received will be examined by Anvisa and will remain available to the public on the Agency's website at www.anvisa.gov.br.

5. Contributions sent after the deadline, unidentified contributions and contributions not sent on the corresponding form will not be accepted.

6. At the end of the consultation period, and following discussions by the Board, a report containing an analysis of the contributions and giving reasons for the institutional position will be made public.

7. The result of the analysis of the contributions may include replies consolidated into blocs.

8. The Report of the Analysis of the Contributions shall be available on Anvisa's website at the address www.anvisa.gov.br and can also be obtained from the Agency's head office in Brasilia or by fax on request of the interested party to the sector responsible for the public consultation as indicated on the relevant call for contributions.

9. After discussions of the Board the consolidated version of the draft regulatory instrument put to public consultation will also be made available.

10.Responsibility for clarifying any queries related to the public consultation rests with the sector responsible for the consultation as indicated on the relevant call for contributions.

ANNEX B

RESOLUTION OF THE BOARD (RDC) No … OF … … 2009

The Board of the National Health Surveillance Agency, in the exercise of the powers granted by Article 11(IV) of the Regulation approved by Decree No. 3029 of 16 April 1999, and having regard to the provisions of Article 54, indent (II) and paragraphs (1) and (3) of the Internal Regulations approved in accordance with Annex I of ANVISA Administrative Ruling No. 354 of 11 August 2006, republished in the Official Gazette of the Union of 21 August 2006, at a meeting held on xxxx xxxxx 2009, and

having regard to the provisions of RDC Resolution No 90 of 27 December 2007 and amendments thereto;

hereby adopts the following Resolution of the Board and I, the Director-President, order its publication:

Article 1. The sale of any electronic smoking devices, known as electronic cigarettes, e-cigarettes, e-ciggy, e-pipe, e-cigar, among others, intended as a replacement for cigarettes, cigarillos, cigars, pipes and similar in the smoking habit or as an alternative anti-smoking treatment, is hereby prohibited in the absence of any scientific data demonstrating their efficiency and effectiveness and the safety of the use and handling thereof.

Sole paragraph. The prohibition laid down in Article 1 extends to all accessories and refills intended for use in any electronic smoking device.

Article 2. Any applications to register for trading purposes any electronic device intended to replace cigarettes, cigarillos, cigars, pipes or similar in the smoking habit will only be accepted by Anvisa if toxicological studies and specific scientific tests demonstrating all of the alleged purposes are provided.

1. The toxicological study and tests mentioned in this Article must be conducted in accordance with internationally recognised and accepted scientific protocols and methods, accompanied by an assessment of the risk of damage to the user's health and proof that they do not contaminate the environment with toxic compounds.

2. All of the results of the toxicological studies and tests mentioned in this Article shall be subject to expert analysis.

Article 3. Any type of incitement to use the devices listed in Article 1, by means of advertising, publicity, promotion or information, including on the Internet, is hereby prohibited.

Article 4. This Resolution shall enter into force on the date of its publication.

DIRCEU RAPOSO DE MELLO