



Brussels, 22.05.2008

**ORIENTATION NOTE**  
**ELECTRONIC CIGARETTES AND THE EC LEGISLATION**

*Legal disclaimer:*

*The opinions presented in this document are not an official position of the European Commission.  
It is for the European Court of Justice to give authoritative interpretations on Community law.*

**Conclusions:**

- **Electronic cigarette not containing tobacco is not a tobacco product under the Tobacco Products Directive.**
- **Whether the electronic cigarette falls under Directive 2001/83 on human medicinal products depends on whether it can be characterised as human medicine by presentation or by function:**
  - **The electronic cigarette can be regarded as a human medicine by presentation if it is presented as a remedy to get rid of nicotine addiction.**
  - **The electronic cigarette can be regarded as a human medicine by function in so far as it qualifies as "restoring, correcting or modifying physiological functions" in a significant manner.**
- **Whether the electronic cigarette could be regarded as falling under Directive 93/42/EEC on medical devices depends on the claimed intended use and whether this intended use has a medical purpose or not.**
- **The Directive 2001/95 on general product safety applies in so far as there are no specific provisions with the same objective in other Community law. This Directive enables the withdrawal of the product from the market if the regulator can show that it is dangerous to the health and safety of consumers.**

**1. PURPOSE**

This paper has been produced on the request of the Council Health Working Party. In its meeting of 21 January 2008 electronic cigarettes were discussed under "any other business" on the initiative of the Netherlands.

Several Member States reported a significant increase of the sale of electronic cigarettes having introduced smoking bans earlier this year. Many Member States said that they were examining whether this product could be classified as a human medicine.

Member States expressed an urgent need for orientation from the Commission as to which EC legislation applies to such electronic cigarettes.

## **2. WHAT IS AN ELECTRONIC CIGARETTE?**

"Electronic cigarette" looks like a cigarette, but is actually a nicotine inhalator. It contains pure nicotine to be inhaled. It normally does not contain tobacco. However, there are many types of "electronic cigarettes".

Nicotine is delivered through replaceable cartridges that are available in various concentrations (e.g. 16 mg, 11 mg, 6 mg and 0 mg). Thus, the device can be adjusted to various levels of nicotine as per the needs of the user. A battery and charger is included.

Information on how many cigarettes does one cartridge correspond to varies between 15 and 20. Nevertheless, some manufacturers claim that the nicotine content is many times lower to that of a classic cigarette.

The presentation of the product varies between manufacturers and retail sellers.

## **3. TOBACCO PRODUCTS DIRECTIVE (2001/37/EC)**

### **Scope**

Under the Tobacco Products Directive (2001/37/EC) 'tobacco products' means "products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not".

### **Regime**

The Tobacco Products Directive lays down maximum TNCO limits and regulates their labelling and verification (Articles 3 and 4). Health warnings are required for each unit packet of tobacco products (Article 5). Member States must report ingredients to competent authorities (Article 6). Misleading safety claims are banned (Article 7)

### **Orientation**

E-cigarettes may fall under the Tobacco Products Directive only if they contain tobacco (even a marginal amount is enough).

However, these kinds of products have the potential of undermining the smoking cessation policies, since they keep the smoking addiction. In order to facilitate information exchange between the Member States on emerging tobacco and nicotine products, the Commission has made this issue a regular information point in the Regulatory Committee under the Tobacco Products Directive.

Member States are invited to report about their national experiences and processes in the Regulatory Committee.

#### 4. PHARMACEUTICAL PRODUCTS DIRECTIVE (DIRECTIVE 2001/83/EC)

##### Scope

Article 1(2) of Directive 2001/83/EC gives the following definition of a medicinal product:

- a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;
- or
- b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Therefore, a substance can fall under the definition of a medicinal product either by its presentation or by its function.

According to Article 2(2) of the Directive:

In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

##### *Human medicine by presentation*

According to settled case-law, the term presentation of a product must be interpreted broadly. In this regard, a product is presented for treating or preventing disease when it is expressly indicated or recommended as such, possibly by means of labels, leaflets or oral representation. Furthermore, a product is also presented as a medicinal product whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties for treating or preventing disease in human beings.<sup>1</sup> Reference to research by pharmaceutical laboratories or to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product in question can lead to the classification of the product as medicinal.

##### *Human medicine by function*

The EU definition of human medicine includes all substances endowed with pharmacological properties with a view to making a medical diagnosis or to restoring, correcting or **modifying physiological functions**.

---

<sup>1</sup> Case C-319/05, Commission v Germany (garlic capsules), paragraphs 43-47. According to settled case-law, the term 'presentation' of a product must be interpreted broadly. It must be recalled, in that connection, that by basing its arguments on the criterion of the 'presentation' of the product, Directive 2001/83 intends to cover not only medicinal products having a genuine therapeutic or medical effect, but also those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented. The Directive thereby intends to protect the consumer not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies (van Bennekom, paragraph 17). In that regard, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the 'form' must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product (see, to that effect, van Bennekom, paragraph 19, and Monteil and Samanni, paragraph 24).

Following the case-law of the European Court of Justice, for the purposes of determining whether a product falls within the definition of a medicinal product by function, the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.<sup>2</sup>

The risk to health is an autonomous factor which must be taken into consideration in the classification of a product as a medicinal product by function (see for instance C-211/03 etc. – HLH Warenvertriebs GmbH and Ortica, paragraph 53).

On the other hand, however, the risk to health is only one of the factors to be taken into consideration in the classification. In order to classify a product as medicinal product by function, the definition set out in Article 1(2)(b) of Directive 2001/83/EC must be fulfilled: a medicinal product by function is “any substance ... which may be used ... either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”

If a product does not have therapeutic effects, in the recommended dose, it cannot be used with a view to restoring, correcting or modifying physiological functions and hence does not fall under the definition of Article 1(2)(b) of the Directive. The mere fact that it poses a risk to health cannot alter that conclusion and cannot be the only factor to lead to the classification of the product as medicinal.

This view is also in line with the ruling of the European Court of Justice of 15 November 2007 (C-319/05 - Garlic), where the Court goes a step further and sets out that the definition of medicinal product by function covers products which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions; the product under assessment must have the function of treating or preventing disease (see paragraphs 61, 64 of that judgment). This requirement of the product being designed to restore, correct or modify physiological functions is certainly not fulfilled by products which are incapable of producing therapeutic effects in the recommended dose.

In this regard, the ECJ has referred to the meaning of “restoring, correcting or modifying physiological functions” contained in the pharmaceutical *acquis* in the following terms:

*“As regards the meaning of “restoring, correcting or modifying physiological functions”, it is clear from the aim of health protection pursued by the Community legislature that the phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body. However, that criterion does not serve to include substances such as certain cosmetics which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions”<sup>3</sup>*

## **Regime**

### *Putting on the market*

No medicinal product may be placed on the market of a Member State unless an authorization has been issued by the competent authorities of that Member State, or by the Commission in the centralized authorization procedure under Regulation 726/2004/EC, on the basis of the scientific

---

<sup>2</sup> Case C-319/05, paragraph 55.

<sup>3</sup> Case C-112/89, Upjohn, paragraphs 21-22.

opinion of the [European Agency for the Evaluation of Medicinal Products](#) ("the Agency"). Only applicants established in the Community may be granted a marketing authorization.

Certain particulars and documents must be included with the authorization request: constituents of the medicinal product, manufacturing method, therapeutic indications, contra-indications and adverse reactions, posology, method and route of administration, expected shelf life, precautionary and safety measures (storage, administration, disposal of waste, risk to the environment), description of control tests employed by the manufacturer, results of the tests (analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products are set out in Annex I) and, finally, a copy of the marketing authorisation obtained in another Member State or non-member country.

When examining a marketing application for a medicinal product, the competent authority of the Member State:

- must verify whether all the particulars and documents required have been supplied;
- may have the medicinal product, its raw materials and, if necessary, intermediate products or other constituents, tested by a laboratory.<sup>4</sup>

When the marketing authorisation is issued, the competent authority of the Member State concerned must inform the holder of the summary of the product characteristics as approved by it.

In exceptional circumstances and following consultation with the applicant, an authorisation may be granted subject to certain specific obligations (carrying out of further studies following the granting of the authorization, notification of adverse reactions to the medicinal product).<sup>5</sup>

The authorization is valid for five years and is renewable. After issuance of the authorisation the holder must take account of scientific and technical progress and ensure that the medicinal product is manufactured and checked by means of generally accepted scientific methods.

The marketing authorization is refused if it proves that:

- the medicinal product is harmful in normal conditions of use (safety criterion);
- its therapeutic effect is lacking or is insufficiently substantiated (this criterion of efficacy does not apply to homeopathic medicinal products);
- its qualitative and quantitative composition is not as declared (criterion of quality);
- the particulars and documents which should accompany the application have not been provided.

The duration of the procedure for granting an authorization to place a medicinal product (homeopathic or otherwise) on the market may not exceed 210 days.

### *Advertising*

---

<sup>4</sup> See Article 19 of Directive 2001/83/EC for more details.

<sup>5</sup> This is laid down in Article 22 of Directive 2001/83/EC: "In exceptional circumstances and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to meet certain conditions, in particular concerning the safety of the medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. This authorisation may be granted only for objective, verifiable reasons and must be based on one of the grounds set out in Annex I. Continuation of the authorisation shall be linked to the annual reassessment of these conditions. The list of these conditions shall be made publicly accessible without delay, together with deadlines and dates of fulfilment."

The Directive defines "advertising of medicinal products" as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (e.g. advertising to the general public and advertising to persons qualified to prescribe or supply medicinal products, visits by medical sales representatives, supply of samples, sponsorship of promotional meetings and scientific congresses attended by persons qualified to prescribe or supply medicinal products, etc.).

Member States must prohibit any advertising of a medicinal product for which a marketing authorization has not been granted.

The advertising of a medicinal product must encourage the rational use of the product and may not be misleading.

The Directive distinguishes between advertising to the general public and advertising to persons qualified to prescribe or supply medicinal products.

Member States shall prohibit the advertising to the general public of medicinal products which: are available on medical prescription only or contain psychotropic or narcotic substances.<sup>6</sup>

Medicinal products may be advertised to the general public which, by virtue of their composition and purpose, are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.<sup>7</sup>

Member States must prohibit the direct distribution of medicinal products to the public for promotional purposes. They may also prohibit, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

Without prejudice to Article 88, all advertising to the general public of a medicinal product shall:

(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;

(b) include the following minimum information:

- the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance,
- the information necessary for correct use of the medicinal product,
- an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.<sup>8</sup>

All advertising to the general public of a medicinal product must be clearly identifiable as such and must include the following minimum information:

- name of the medicinal product.
- the information necessary for correct use of the medicinal product;

---

<sup>6</sup> Article 88(1) of Directive 2001/83/EC.

<sup>7</sup> Article 88(2) of Directive 2001/83/EC.

<sup>8</sup> Article 89 of Directive 2001/83/EC.

- an express, legible invitation to read carefully the instructions on the package leaflet.

The advertising of a medicinal product to the general public shall not contain any material which:

- (a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
- (b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
- (c) suggests that the health of the subject can be enhanced by taking the medicine;
- (d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 88(4);
- (e) is directed exclusively or principally at children;
- (f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
- (g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- (h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- (i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- (j) refers, in improper, alarming or misleading terms, to claims of recovery;
- (k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.<sup>9</sup>

## **Orientation**

### *Competence*

It is for each national authority to decide, account being taken of all the characteristics of the product, whether it falls within the definition of a medicinal product by its function or presentation. Evaluation by EMEA is excluded.

### *Human medicine by presentation?*

The manufacturers often describe their product as an alternative cigarette. Marketing may also refer to use as cessation aid. For example one manufacturer states: "Our cut back sets have specifically been designed for people who want to cut back smoking habit (100 days plan)." People are advised to start with high cartridges and gradually switch to lighter ones, ending up to zero level of nicotine. They state that it "has been proven to be successful".

Therefore, it is obvious that the marketing of electronic cigarettes may include references to how to get rid of nicotine addiction. Tobacco dependence syndrome has been classified as a disease in the International Classification of Diseases (ICD)<sup>10</sup>.

---

<sup>9</sup> Article 90 of Directive 2001/83/EC.

The question is whether an averagely well-informed consumer gains the impression that the product in question should have the properties for treating or preventing disease in human beings.

#### *Human medicine by function?*

The electronic cigarette is normally a device whose only purpose is to administer nicotine into the human body through inhalation. Nicotine is a substance that has a strong effect on central nervous system with properties similar to those of amphetamine and cocaine. Nicotine causes strong physical addiction and withdrawal symptoms. It presents a danger to health in large quantities (40-60 mg can be lethal dosage for adult human beings).

Some manufacturers claim that the content of nicotine is many times lower than that of a classic cigarette. If this is the case, it would appear doubtful that the definition of medicinal product by function, as interpreted by the ECJ, is fulfilled.

On the other hand, one cartridge may include different intensities of nicotine content, for example either 0 mg, 6 mg, 11 mg or 16 mg of nicotine according to user's choice. One cartridge is said to correspond to 15-20 cigarettes.

This means that the electronic cigarette - with the most intense cartridge - gives about the same yield of nicotine as one cigarette (1 mg). Therefore, the statement that the product includes "many times less" nicotine than cigarettes would seem to be misleading.

It is for each national authority to decide, account being taken of all the characteristics of the product, whether it falls within the definition of a medicinal product by its function.

## **5. MEDICAL DEVICES DIRECTIVE (DIRECTIVE 93/42/EEC)**

### **Scope**

Article 1 (2)a of Directive 93/42/EEC gives the following definition of a medical device:

*'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

*and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means<sup>11</sup>*

---

<sup>10</sup> See <http://www.who.int/classifications/icd/en/>. Point F17.-Mental and behavioural disorders due to use of tobacco.

<sup>11</sup> 03 L 169, 12.07.1993 P. 0001 — 0043, Directive as last amended by Directive 2007/47/EC (03 L247; 21.9.2007, p.21)



Therefore, Article 1 (2)a of Directive 93/42/EEC requires that, in order for a product to be qualified as a medical device, it is to have a medical purpose.

The Medical Devices Guidance document MEDDEV 2. 1/1 states that: *‘Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines through the label, the instruction for use and the promotional material related to a given device its specific medical purpose.’*

The medical purpose as a pre-condition for the applicability of the medical devices Directives and the performance of the device are intrinsically linked; the intended performance must be of medical utility. There must be data that supports the claimed medical purpose.

## **Regime**

### *Placing on the market*

Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in Directive 93/42/EEC when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

### *Essential requirements*

The devices must meet the essential requirements set out in Annex I of Directive 93/42/EEC which apply to them, taking account of the intended purpose of the devices concerned.

### *Free movement and Safeguard Clause*

Once a manufacturer has satisfied the requirements of the Directive 93/42/EEC, he can CE mark his product and place it on the market.

Where a Member State ascertains that devices referred to in Article 4 (1) and (2) second indent of Directive 93/42/EEC, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service.

## **Orientation**

As per Article 1 (2)a of Directive 93/42/EEC one key criteria that has to be met for a product to be qualified as a medical device is that **it must have a medical purpose**, *i.e.* it must relate to (...) *diagnosis, prevention, monitoring, treatment or alleviation of disease,... diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap... investigation, replacement or modification of the anatomy or of a physiological process,... control of conception, (...).*

The medical purpose has to be supported by data on the label, in the instructions and/or in promotional materials.

All e-cig manufacturers do not claim a medical purpose. Instead, they may say that the product can be used as *“an alternative for cigarettes in places and/or during occasions where smoking is*

*prohibited*". This claim clearly does not relate to a medical purpose as described above and for that reason the product cannot be a medical device.

One manufacturer makes a claim that the product has been specifically "*designed for people who want to cut back on their smoking habit*". This claim would need to be further assessed taking into account all product characteristics to determine whether such a claim can constitute a medical purpose in the sense of Directive 93/42/EEC.

At this point, it must be noted that, defining a given product as a medical device or not remains within the competence of the Competent Authorities of the Member States where the product is on the market. This has to be done on a **case by case basis**, taking all product characteristics into account, and in particular, any claim made by the manufacturer as well as the intended use of the product.

**If a medical purpose can be established**, and assuming that nicotine can be regarded as a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, two possibilities may arise:

(i) Where the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable: that single product shall be governed by Directive 2001/83/EC (article 1(3), second subparagraph of Directive 93/42/EEC). The relevant essential requirements of Annex I to Directive 93/42/EEC shall apply as far as safety and performance-related device features are concerned. However, from the information provided, we understand that this possibility cannot apply as the product is reusable.

(ii) In other cases, the electronic part may be seen as a medical device which is intended to administer a medicinal product. In such cases, that device shall be governed by the Directive 93/42/EEC, without prejudice to the provisions of Directive 2001/83/EC with regard to the medicinal product. (article 1(3), first subparagraph of Directive 93/42/EEC)

If the electronic device would be qualified as a medical device then the charger might be considered as an accessory to this medical device, *i.e.* an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

## 6. GENERAL PRODUCT SAFETY DIRECTIVE

### Scope

The General Product Safety Directive 2001/95/EC (GPSD) applies to consumer products. This includes both products which are intended for consumers and products which are likely, under reasonably foreseeable conditions, to be used by consumers.

The GPSD applies in so far as there are no specific provisions with the same objective in other Community law. Moreover, where a product is subject to specific safety requirements imposed by sectoral Community legislation, the GPSD applies to risks or categories of risks not covered by those requirements. Therefore, the GPSD does not, for example, cover food and medicinal products and applies only in a complementary manner to medical devices.

### Regime

The GPSD provides for the following key obligations and possibilities:

- obligation for producers and distributors to market only safe products and to take the necessary corrective actions and to inform the relevant national authorities if they have put on the market an unsafe product (Articles 3 and 5);
- obligation for national authorities to carry out market surveillance and enforcement activities to ensure that only safe products are put on the market (Articles 6-9);
- obligation for national authorities to notify each other and the Commission via the RAPEX system of measures taken in order to restrict the marketing or use of dangerous products (Articles 11-12);
- possibility for the Commission under specific circumstances to take temporary, urgent measures to restrict the marketing or use of products posing a serious risk to the health and safety of consumers (Article 13);

The GPSD contains a list of conformity assessment criteria in Article 3(2) and (3). These are relevant also in the risk assessment and guide the thinking as to what could be considered as dangerous under this Directive. It is noteworthy that the GPSD does not subject products in a general manner to prior safety assessment and marketing authorisation by the national authorities before they are placed on the market. However, if it is considered that a certain product could pose a risk or be dangerous, national authorities can make its marketing subject to prior conditions so as to make it safe or suspend the marketing of a product for the period needed for safety evaluations.

### Orientation

E-cigarettes are consumer products and their safety risk assessment (and management) can in theory fall under the GPSD to the extent they are not covered by other Community legislation setting forth more specific provisions with the same objective. However, restrictive measures available to the Member States under the GPSD only concern products that could pose a risk to the health and safety of consumers or are dangerous/pose a serious risk in case of more far-reaching measures. The GPSD does not establish any general prior marketing authorisation system as it is the case, for example, with medicinal products.

It is for the Member States to establish that a particular product is dangerous taking due account of the relevant safety rules, standards and codes. The main factor to take into account is how to ensure the intake of nicotine is not unsafe within the meaning and under the conformity assessment criteria of the GPSD.

## 7. SUMMARY OF THE EC LEGISLATIVE FRAMEWORKS

	Prior authorisation	Safety tests	Advertising restrictions	Other requirements
Pharmaceutical Products (Directive 2001/83)	Yes.	Yes.	Yes.	Effectiveness tests
Medical Devices (Directive	No.		No.	Conformity assesment, CE

1993/42)				marking.
Tobacco Products (Directive 2001/37)	No.	No.	Yes.	Warning labelling, ingredients reporting.
General Product Safety (Directive 2001/95)	No.	Yes.	No.	