AN BILLE UM SHUBSTAINTÍ NEAMHLEIGHEASACHA SÍCIGHNÍOMHACHA 2010

NON-MEDICINAL PSYCHOACTIVE SUBSTANCES BILL 2010

Mar a tionscnaíodh
As initiated

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[No. 18 of 2010]

Acts Referred to

Garda Síochána Act 2005	2005, No. 20
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Irish Medicines Board Act 1995	1995, No. 29
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Misuse of Drugs Acts 1977 and 1984	
Pharmacy Act 2007	2007, No. 20

AN BILLE UM SHUBSTAINTÍ NEAMHLEIGHEASACHA SÍCIGHNÍOMHACHA 2010

NON-MEDICINAL PSYCHOACTIVE SUBSTANCES BILL 2010

BILL

entitled

AN ACT TO MAKE NEW PROVISION FOR THE REGULATION, REGISTRATION AND LICENSING OF THE SALE, IMPORTATION, DISTRIBUTION AND PRODUCTION OF NON-MEDICINAL PSYCHOACTIVE SUBSTANCES AND THE ESTABLISHMENT OF A BODY KNOWN AS AN tÚDARÁS RIALÁLA UM SHUBSTAINTÍ NEAMHLEIGHEASACHA SÍCIGHNÍOMHACHA ("AN tÚDARÁS") AND IN ENGLISH AS THE NON-MEDICINAL PSYCHOACTIVE SUBSTANCES REGULATORY AUTHORITY ("THE AUTHORITY") AND TO PROVIDE FOR RELATED MATTERS.

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

PART 1

Preliminary and General

Short Title.

1.—This Act may be cited as the Non-Medicinal Psychoactive Substances Act 2010.

Interpretation.

2.—In this Act—

"the Authority" refers to An tÚdarás Rialála um Shubstaintí Neamhleigheasacha Sícighníomhacha translated into English as the Non-Medicinal Psychoactive Substances Regulatory Authority;

"child" is a person below the age of 18 years;

"distribution" means the practice of making substances or products available for use;

"Health Services Executive" or "HSE" is that which is established under the Health Act 2004;

"importation" means the act of bringing substances and products into Ireland;

"Ireland" means both jurisdictions on the island;

"Irish Medicines Board" is that which is established under the Irish Medicines Board Act 1995;

"Joint Policing Committees" having the meaning assigned by the Garda Síochána Act 2005;

"Licensee" means the holder of a license applied for under s*ection 18;*

"Licensing Agreements" means the Licensing Agreements referred to in *section 12* of this Act;

"The Minister" refers to the Minister for Health and Children unless specified otherwise;

"national" or "nationally" means covering both jurisdictions on the island;

"non-medicinal psychoactive substance" means any product or substance that has a psychoactive effect, that is recognised by the Authority as falling within its remit, and that is not covered under the Irish Medicines Board (Miscellaneous Provisions) Act 2006, the Pharmacy Act 2007, The Misuse of Drugs Acts 1977 and 1984 as amended or the Intoxicating Liquor Act 2003;

"production" means the manufacture of substances or products;

"Register of those involved in the sale, importation, distribution and production of non-medicinal psychoactive substances" has the meaning assigned to it by *section 19*;

"Register of Non-Medicinal Psychoactive Substances" has the meaning assigned to it by *section 14*; and

"sale" includes to offer for sale or to sell or to supply through retail outlet or at any other place, home delivery or internet sale whether or not for profit.

Expenses.

3.—The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Finance, be paid out of money provided by the Oireachtas and through licensing fees referred to in *section 16(2)(e)* of this Act.

Commencement.

4.—The Minister shall by order appoint a day to be the establishment day for the purposes of this Act and the day will be no more than two months following the passage of the Act.

Making Orders.

5.—Where an order is proposed to be made under this Act, a draft of the order shall be laid before both Houses of the Oireachtas, and the order shall not be made until a resolution approving the draft has been passed by each such House.

PART 2

Non-Medicinal Psychoactive Substances Regulatory Authority

6.—(1) There shall be established a body known as An tÚdarás Rialála um Shubstaintí Neamhleigheasacha Sícighníomhacha translated into English as the Non-Medicinal Psychoactive Substances Regulatory Authority (in this Act referred to as "the Authority").

An tÚdarás Rialála um Shubstaintí Neamhleigheasacha Sícighníomhacha (translated in English to the Non-Medicinal Psychoactive Substances Regulatory Authority).

(2) The Authority shall consist of ten members appointed by the Minister, with the approval of the Oireachtas Joint Committee on Health and Children and reflecting equal representation of each gender.

(3) Of those ten—

(*a*) one shall be nominated by the Irish Medicines Board (IMB) as a representative of that body and to coordinate regulation between that body and the Authority,

(*b*) one shall be nominated by the Food Safety Authority as a representative of that body and to coordinate regulation between that body and the Authority,

(*c*) one shall be nominated by the Pharmaceutical Society of Ireland as having particular knowledge and experience of the dispensing of controlled substances,

(*d*) one shall be nominated by the Garda Síochána as having particular experience and knowledge on the subject of drug enforcement to provide information and be of assistance to the Authority,

(*e*) one shall be nominated by the Alcohol and Drug Research Unit of the Health Research Board as having expertise in drugs research,

(*f*) one shall be nominated by the National Advisory Committee on Drugs to ensure coherence between the work of the Authority and the National Drugs Strategy,

(*g*) two shall be nominated as having such qualifications, skills and experience as is deemed to be helpful to advise the Authority on scientific issues,

(*h*) two shall be nominated as having sufficient qualifications, skills and experience as is deemed to be helpful to advise the Authority on issues of drugs and harm reduction one of whom will be nominated by the community drugs services sector and one by the voluntary drugs services sector.

(4) The Authority shall be a Body Corporate.

(5) The Authority may sue and may be sued in its corporate name.

(6) The Authority may acquire, hold and transfer land and other property.

(7) The Authority will meet at regular intervals or on any other occasion as may be necessary to carry out its functions under this Act.

(8) The Authority will be provided with a permanent secretariat to process applications, maintain registers, provide information to the Authority and undertake any administrative duties as may be necessary.

(9) The Minister, when appointing a member under *subsection (3)(g)* and *(h)*, shall fix such member's period of membership which shall not exceed 5 years.

(10) A member of the Authority may at any time resign his or her membership by letter addressed to the Minister and the resignation shall take effect from the date specified therein or upon receipt of the letter by the Minister, whichever is the later.

(11) A member of the Authority may at any time be removed from membership of the Authority by the Minister if, in the Minister's and the Oireachtas Joint Committee on Health and Children's opinion, the member has become incapable through ill-health of performing his or her functions, or has committed stated misbehaviour, or his or her removal appears to the Minister and the Oireachtas Joint Committee on Health and Children to be necessary for the effective performance by the Authority of the functions of the Authority.

(12) If a member of the Authority dies, resigns, retires, becomes disqualified or is removed from office, the Minister may appoint a person to be a member of the Authority to fill the casual vacancy so occasioned and the person so appointed shall be appointed in the same manner as the member of the Authority who occasioned the casual vacancy. The person so appointed shall be appointed within 2 months of the Minister being notified of the vacancy.

(13) A member of the Authority whose period of membership expires by the effluxion of time shall be eligible for re-appointment as a member of the Authority.

Independence of the Authority.

7.—The Authority shall, subject to this Act, be independent in the exercise of its functions.

Procedural Rules.

8.—(1) The Authority shall issue a set of Procedural Rules for the purpose of regulating and prescribing the practice and procedure to be followed—

(*a*) by the Authority in exercising the functions under *section 9* of this Act,

(*b*) by other persons or bodies in their dealings with the Authority in connection with the exercise of the functions referred to in *section 9* of this Act.

(2) The Authority—

(*a*) shall keep the Procedural Rules under review, and

(*b*) may from time to time revise the whole or any part of the Procedural Rules and shall issue the revised Procedural Rules.

PART 3

Functions and Powers

9.—(1) The principle functions of the Authority shall be— Functions of the Authority.

(*a*) to identify substances and products that the Authority considers to be within its remit as non-medicinal psychoactive substances,

(*b*) to gather information and liaise with other bodies both nationally and internationally to encourage a consistent approach to non-medicinal psychoactive substances regulation and control based on international best practice,

(*c*) to classify substances and products that are identified as being non-medicinal psychoactive substances under the process referred to in *paragraph (a)* based on considerations and procedures outlined in s*ection 12* of this Act with regard to potential harm to individual health and well-being, or harm to society when consumed or otherwise used by persons,

(*d*) to establish a register of non-medicinal psychoactive substances as provided for in *section 14* of this Act,

(*e*) to regulate the availability, restriction or prohibition of non-medicinal psychoactive substances not covered by the Irish Medicines Board (Miscellaneous Provisions) Act 2006, the Pharmacy Act 2007, the Misuse of Drugs Acts 1977 and 1984 as amended or the Intoxicating Liquor Act 2003 by way of the identification of relevant categories of license and the formulation and publication of Licensing Agreements pertaining to each based on the classifications under *paragraph (c)* and considerations outlined in *section 12* of this Act,

(*f*) to formulate and publish rules for the issuing of licenses provided for under *section 18* of this Act setting out the standards required for the issuing of licenses to those involved in the retail, distribution, import and production of non-medicinal psychoactive substances, and the procedure to be followed to apply for a license, or to appeal a negative decision, suspension or withdrawal of a license,

(*g*) to process and make decisions on applications for licenses based on the rules outlined in *section 18* of this Act, and issue or refuse to issue licenses accordingly,

(*h*) to establish and maintain a publicly available register of those licensed to engage in the sale, importation, distribution and production of non-medicinal psychoactive substances as referred to in *section 19* of this Act, including a record of any breaches of Licensing Agreements,

(*i*) to conduct or otherwise instigate inspections of licensees' premises, products and any property connected to the sale, distribution, importation and production of non-medicinal psychoactive substances, as provided for in *section 20* of this Act, and to report any suspected criminal offences to the relevant authority, and

(*j*) to establish and enforce sanctions as referred to in *section 21* of this Act, for breaches of Licensing Agreements referred to in *paragraph (e)* and make decisions on the suspension or withdrawal of licenses,

(*k*) to cooperate with the Food Safety Authority, Health and Safety Authority, An Garda Síochána, Joint Policing Committees, Customs and Excise, the PSNI, INTERPOL and EUROPOL where appropriate in the conduct of its functions.

(2) The Authority shall conduct its functions under *paragraphs (a)* to *(k)* based on an imperative to reduce harm to individuals and society.

Conferral of additional functions on the Authority.

10.—(1) The Minister may, if he or she so thinks fit and if so requested by the Oireachtas Joint Committee on Health and Children, by order—

(*a*) confer on the Authority such additional functions connected with its functions or activities that the Authority is authorised to undertake (including functions for the purpose of enforcing any directive, regulation or other act adopted by an institution of the European Communities in relation to non-medicinal psychoactive substances and products) as he or she considers appropriate, and

(*b*) make such provision as he or she considers necessary or expedient in relation to matters ancillary to or arising out of the conferral on the Authority of functions under this section or the performance by the Authority of functions so conferred.

(2) The Minister may by order amend or revoke an order under this section (including an order under this subsection).

Powers of the Authority.

11.—The Authority shall have all such powers that are necessary for or incidental to the performance of its functions under this Act.

PART 4

Non-Medicinal Psychoactive Substances

Identification and classification of substances and products.

12.—(1) The Authority shall perform the function outlined in s*ection 9(1)(a)* and *(c)* of this Act by taking into account the following factors—

(*a*) the effect on perception, health and wellbeing of any manner of use of a substance or product by persons,

(*b*) the social effect of any manner of usage of a substance or product by persons, and

(*c*) individual and social harm-reduction imperatives.

(2) The decisions of the Authority will be considered authoritative and shall be based on—

(*a*) available scientific and statistical evidence of the effects of any manner of use of substances or products when consumed or otherwise used by persons,

(*b*) qualitative evidence and other credible information from users of substances or products as to their effect on individual perception, health and wellbeing when consumed or otherwise used by persons,

(*c*) qualitative evidence and other credible information from members of an Garda Síochána, Joint Policing Committees, Customs and Excise, PSNI, INTERPOL and EUROPOL as to the effect of the use of substances or products on individual behaviour and on society, when consumed or otherwise used by persons,

(*d*) quantitative and qualitative information including testimony from health staff and the HSE on the effect of the use of substances or products on perception, health and wellbeing when consumed or otherwise used by persons, and

(*e*) an assessment of information and testimony from such other sources as the Authority deems appropriate with regards to the effects of the use of substances or products on society or on the perception, health and wellbeing of persons.

Application for a decision of the Authority on the classification of a product or substance.

13.—(1) In any case where there is doubt about the status of a substance or product as a non-medicinal psychoactive substance or its classification or where a new product or substance is introduced into Ireland that could fall under the remit of the Authority, any person including a licensee or potential licensee may apply for a decision of the Authority as to the classification of the product or substance.

(2) An application under *subsection (1)* should be submitted in writing and include—

(*a*) the name of the product or substance,

(*b*) the origins of the product or substance,

(*c*) any information that can be reasonably expected to be provided as to the ingredients or chemical make-up of the product or substance, and

(*d*) any information that can be reasonably expected to be provided relating to the effects of the product or substance on perception, health and wellbeing when consumed or otherwise used by persons.

(3) This application should also be accompanied by a physical sample of the product or substance.

(4) The Authority shall decide whether the substance is a non-medicinal psychoactive substance and if so whether to—

(*a*) impose a full prohibition on it, or

(*b*) regulate it by way of an appropriate Licensing Agreement.

(5) It shall be an offense under the law to engage in the sale, importation, distribution, marketing or production of a product before a decision is made by the Authority on the application referred to in *subsection (1)*.

Register of Non-Medicinal Psychoactive Substances.

14.—(1) The Authority shall perform the function referred to in *section 9(1)(d)* of this Act by—

(*a*) setting up as soon as practicable after the establishment of the Authority a register for substances and products deemed to be within the remit of the Authority in accordance with its function referred to in s*ection 9(1)(a)* of this Act,

(*b*) entering on to the register under *paragraph (a)* all substances and products entitled to be registered there,

(*c*) entering on to the register under *paragraph (a)*—

(i) the name of the substances or products that the Authority deems to be within its remit in accordance with its function under *section 9(1)(a)* of this Act,

(ii) any other relevant information relating to the substances or products that the Authority deems necessary to fulfill its function under *section 9(1)(d)* of this Act, including any decision pending or taken by the Authority under *section 13* of this Act regarding its regulatory status,

(*d*) otherwise maintaining and updating the register as new decisions are made, and

(*e*) ensuring that the information in the Non-Medicinal Psychoactive Substances Register is available without charge, to the public at all times.

(2) Without prejudice to the generality of *subsection (1)(e)* the Authority shall publish the information on the substances register by means of—

(*a*) a dedicated website on the internet, updated as new decisions are made under *sections 9(1)(c)*, *12* and *13*, and

(*b*) at least one other method of publication nationally, as soon as possible after the setting up of the substances register and thereafter at intervals of not more than 3 months.

Power to ban certain substances and products.

15.—(1) Without prejudice to the generality of *section 11* the Authority shall have the power to prohibit the sale, importation, distribution and production of any non-medicinal psychoactive substance or product where it deems that it is in the public interest to do so.

(2) Without prejudice to the generality of *subsection (1)*, where there are sufficient public health concerns the Authority shall have the power to impose a provisional prohibition on the sale, importation, distribution and production of any non-medicinal psychoactive substance or product to allow for the conduct of further research into the effects of the substance in question.

(3) A provisional prohibition under *subsection (2)* shall have effect until such time as a final decision is made by the Authority as to the substance's classification under *sections 9(1)(c), 12* and *13*.

(4) The Authority shall also have the power to impose a provisional prohibition on the sale, importation, distribution and production of any non-medicinal psychoactive substance or product to have effect for the duration of compliance procedures in relation to relevant legislative provisions such as the EU Technical Standards Directive.

(5) It shall be an offence under the law to engage in the sale, importation, distribution and production of any non-medicinal psychoactive substance which is the subject of a prohibition under this section.

Regulation of non-medicinal psychoactive substances and products through Licensing Agreements.

16.—(1) The Authority shall fulfill its role referred to in *section 9(1)(e)* of this Act by formulating any categories and conditions of license that the Authority deems necessary that will serve as Licensing Agreements to apply to the sale, importation, distribution and production of non-medicinal psychoactive substances which the Authority decides not to prohibit under *section 15* having considered the factors under *section 12*.

(2) Such Licensing Agreements shall—

(*a*) regulate the sale, importation, distribution and production of non-medicinal psychoactive substances which the Authority decides not to prohibit under *section 15,*

(*b*) outline the conditions of practice and conduct, reporting, transparency and compliance and any other requirements deemed necessary by the Authority that those licensed to sell, import, distribute or produce non-medicinal psychoactive substances must adhere to in order to satisfy the requirements of their Licensing Agreements,

(*c*) outline the obligations of licensees with appropriate regard for relevant considerations including those outlined in *section 12* and in particular the harm reduction imperative,

(*d*) outline any fees relating to obtaining a license with respect to the Licensing Agreements set at a level to cover the operational expenses of the Authority, and

(*e*) outline penalties and sanctions for breaches of the Licensing Agreements.

(3) Without prejudice to the generality of *subsection (2)(c),* the various Licensing Agreements applicable to the relevant non-medicinal psychoactive substances may include but shall not be limited to provisions—

(*a*) prohibiting sale to intoxicated persons,

(*b*) restricting the locations and hours of sale of licensee's operations,

(*c*) prohibiting marketing of the substances in any form,

(*d*) requiring appropriate standards of packaging, including packaging information, and specific health warnings,

(*e*) requiring full traceability of goods,

(*f*) requiring training and accreditation of Licensees and their staff,

(*g*) controlling the dosages, volume or quantities of particular substances that may be sold,

(*h*) requiring certain physical conditions aimed at limiting the accessibility of substances, and

(*i*) establishing price controls.

(4) The Licensing Agreements developed and introduced by the Authority shall be based on considerations evaluated under *section 12* including in particular the harm reduction imperative.

(5) The Authority—

(*a*) shall keep the Licensing Agreements under review; and

(*b*) may from time to time revise the whole or any part of the Licensing Agreements and issue revised Licensing Agreements.

Protection of children.

17.—(1) It shall be an offence for a person to sell, offer or make available any substance or product to a person under the age of eighteen years or to a person acting on behalf of that person if he or she knows or has reasonable cause to believe that the substance or product is likely to be used by the person under the age of eighteen years for the purpose of causing intoxication.

(2) In proceedings against any person for an offence under *subsection (1)*, it shall be a defence for him or her to prove that at the time he or she sold, offered or made available the substance he or she was under the age of eighteen years and was acting otherwise than in the course of or furtherance of a business.

(3) In proceedings against any person for an offence under *subsection (1)* it shall be a defence for him or her to prove that he or she took reasonable steps to assure himself or herself that the person to whom the substance was sold, offered or made available, or any person on whose behalf that person was acting, was not under the age of eighteen years.

(4) A person who is guilty of an offence under *subsection (1)* shall be liable—

(*a*) on summary conviction to imprisonment for a term not exceeding twelve months or to a fine not exceeding €3,000 or to both, or

(*b*) on conviction on indictment to a fine not exceeding €1,000,000 or to imprisonment for a term not exceeding 10 years or to both.

(5) In determining the appropriate sentence the judge shall consider all the relevant circumstances including the personal circumstances of the person convicted, the social impact of the offence or

offences and where the commission of the offence is related to the conduct of the convicted person's business this shall be considered an aggravating factor.

(6) A Court by which a person is convicted of an offence under this section may order anything shown to the satisfaction of the court to relate to the offence to be forfeited and either destroyed or dealt with in such other manner as the court thinks fit.

(7) A member of the Garda Síochána may seize any substance or product which is in the possession of a child in any public place and which the member has reasonable cause to believe is being used by that child in a manner likely to cause him or her to be intoxicated. Any substance so seized may be destroyed or otherwise disposed of in such a manner as a member of the Garda Síochána not below the rank of Superintendent may direct.

(8) This section is without prejudice to the provisions of the Misuse of Drugs Acts 1977 and 1984 as amended.

PART 5

Licensing

Rules for issuing licenses.

18.—(1) The Authority will formulate and publish rules, fulfilling the function under *section 9(1)(f)* of this Act, that outline the requirements an applicant must satisfy in order to obtain a license.

(2) These rules should reflect international best practice and ensure that the relevant applicant—

(*a*) meets a suitable standard of responsibility, accountability and compliance in order to fulfill their role under the Licensing Agreements in *section 16* of this Act, and

(*b*) has no historical infringements which would warrant the Authority to refuse their application.

(3) The Authority—

(*a*) shall keep the rules under review, and

(*b*) may from time to time revise the whole or any part of the rules and issue revised rules.

(4) The Authority shall issue licenses to those who are successful in their application under the rules by virtue of meeting all applicable criteria under *subsections (1)* and *(2)*.

The NMPS Licensees' and Applicants' Register.

19.—(1) The Authority shall perform the registration function referred to in *section 9(1)(h)* of this Act by—

(*a*) setting up as soon as practicable after the establishment of the Authority a register of those engaged in the sale, importation, distribution and production of non-medicinal psychoactive substances,

(*b*) entering onto the register under *paragraph (a)* the name of and other prescribed information concerning every applicant and licensee entitled to be registered there,

(*c*) entering onto the register under *paragraph (a)*—

(i) the name of the person or persons who have legal responsibility for the relevant license,

(ii) the name under which the operation is to be carried on,

(iii) the address of the premises from which the licensee is operating, or in the case of a website, the address of the person who has legal responsibility for its operation,

(iv) such other details of the applicant or licensee as the Authority deems necessary to fulfill its function under *section 9(1)(h)* of this Act,

and

(*d*) publishing via a dedicated website on the internet and by publication in full of the register at least annually by at least one other method of publication nationally, and

(*e*) otherwise maintaining the register.

PART 6

Enforcement

Inspection of Licensees and Non-Licensees.

20.—(1) As part of the Licensing Agreements under *section 16* of this Act, a licensee or license applicant will give their consent to allow the Authority to inspect any product, premises or other property that may be reasonably considered to be involved in their operation with relation to non-medicinal psychoactive substances in order to allow the Authority to fulfill its role as outlined in *section 9(1)(i)* of this Act.

(2) The Authority shall have the power to appoint suitably trained persons in order to carry out inspections under *subsection (1)*.

(3) The appointed inspectors referred to in *subsection (2)* must carry and produce appropriate identification to confirm that they are authorised to carry out inspections on behalf of the Authority.

(4) The Authority may enlist the assistance of members of An Garda Síochána for the purpose of carrying out inspections or request that An Garda Síochána conduct any inspection on its behalf.

(5) Licensees need not be notified in advance of inspections carried out on behalf of the Authority.

(6) Any suspected criminal offence shall be reported to the relevant prosecuting authority.

(7) The Authority will consult and cooperate as necessary with An Garda Síochána, local Joint Policing Committees and Revenue Customs Service to develop effective ways to monitor the operations of those involved in the sale, importation, distribution and production of non-medicinal psychoactive substances who are not licensed under *section 18* of this Act, in a manner consistent with existing law.

21.—(1) It shall be an offense under the law to sell, import, distribute or produce non-medicinal psychoactive substances without an appropriate license or on a suspended license. Offences and breaches of licensing conditions.

(2) A person guilty of an offence under this section shall be liable—

(*a*) on summary conviction to imprisonment for a term not exceeding twelve months or to a fine not exceeding €3,000 or to both, or

(*b*) on conviction on indictment to a fine not exceeding €1,000,000 or to imprisonment for a term not exceeding 10 years or to both.

(3) The Authority will fulfill its function under *section 9(1)(j)* of this Act by—

(*a*) establishing and publishing a range of acts or omissions which would constitute a breach of the Licensing Agreements, and

(*b*) establishing appropriate and proportionate sanctions for each act or omission based on the severity of the potential harm to individual health, well-being and society.

(4) Without prejudice to the generality of *subsection (3)(b)* the Authority shall have the power to suspend or withdraw licenses for breaches of Licensing Agreements.

(5) The Authority shall have the authority to issue fines to licensees for breaches of the Licensing Agreements of not more than €500,000. Non-payment of fines may be considered grounds to undertake further sanctions including the suspension or withdrawal of licenses under *subsection (4)*.

PART 7

Appeals

22.—(1) Decisions of the Authority may be appealed to the Minister, however the Minister may only overturn a decision of the Authority on the basis of clear evidence that to do so would be in the public interest and a decision of the Authority shall stand until such time as it may be overturned. Appeals.

(2) Appeals may be taken on grounds such as the existence of new scientific or qualitative evidence with regard to the potential harm of a substance or any other grounds as may be established by way of Ministerial Order.

(3) All decisions by the Minister under this section shall be underpinned by a presumption in favour of the protection of public health against other considerations.

(4) The Minister shall provide the rationale for his or her decisions in written form.

(5) The appeals procedure shall be established by way of Ministerial Order.

PART 8

Reports

Reports.

23.—(1) As soon as may be after the end of the financial year of the Authority in which the establishment day falls and of each subsequent financial year of the Authority, but not later than 6 months thereafter, the Authority shall make a report which may be referred to the Oireachtas Joint Committee on Health and Children and the Minister of its activities during that year.

(2) Each report under *subsection (1)* shall include information in such form and regarding such matters as the Oireachtas Joint Committee on Health and Children or the Minister may request.

(3) The Authority shall, whenever so requested by the Oireachtas Joint Committee on Health and Children or the Minister, furnish to the Oireachtas Joint Committee on Health and Children and the Minister information in relation to such matters as the requesting party may specify concerning or relating to the scope of the Authority's activities generally, or in respect of any account prepared by the Authority or any report specified in *subsection (1)* or the policy or activities, other than day to day activities, of the Authority.

(4) The Authority may publish such other reports on matters related to its activities and functions, as may from time to time be considered relevant and appropriate by the Authority.