►B REGULATION (EC) No 1920/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 December 2006

on the European Monitoring Centre for Drugs and Drug Addiction (recast)

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on the European Monitoring Centre for Drugs and Drug Addiction (recast)

Article 1

Objective

1. This Regulation provides for the European Monitoring Centre for Drugs and Drug Addiction ('the Centre').

2. The Centre's objective is to provide, in the areas referred to in Article 3, the Community and its Member States with factual, objective, reliable and comparable information at European level concerning drugs and drug addiction and their consequences.

3. The statistical, documentary and technical information processed or produced is intended to help provide the Community and the Member States with an overall view of the drug and drug addiction situation when, in their respective areas of competence, they take measures or decide on action. The statistical element of this information shall be developed, in collaboration with the relevant statistical authorities, using as necessary the Community Statistical Programme to promote synergy and avoid duplication. Account shall be taken of further data from the World Health Organisation and the United Nations Organisation (the 'UN') available worldwide.

4. Without prejudice to Article 2(d)(v), the Centre may not take any measure which goes beyond the sphere of information and the processing thereof.

5. The Centre shall not collect any data making it possible to identify individuals or small groups of individuals. It shall refrain from any transmission of information relating to specific named cases.

Article 2

Tasks

In order to achieve the objective set out in Article 1, the Centre shall perform the following tasks within its areas of activity:

(a) **Collection and analysis of existing data**

(i) collecting, registering and analysing information, including data resulting from research, communicated by Member States and data emanating from Community, non-governmental national sources and competent international organisations, including the European Police Office (Europol); providing information on best practices in the Member States and facilitating the exchange of such practices among them; this collection, registration, analysis and information work shall also cover data on emerging trends in poly-drug use, including the combined use of licit and illicit psychoactive substances;

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(ii) carrying out surveys, preparatory studies and feasibility studies, together with any pilot projects necessary to accomplish its tasks; organising meetings of experts and, whenever necessary, setting up ad hoc working parties for the purpose; setting up and making available open scientific documentation resources and assisting in the promotion of information activities;

(iii) providing an organisational and technical system capable of supplying information on similar or complementary programmes or action pursued by the Member States;

(iv) establishing and coordinating, in consultation and in cooperation with the competent authorities and organisations in the Member States, the network referred to in Article 5;

(v) facilitating exchanges of information between decision-makers, researchers, specialists and those involved in drugs-related issues in governmental and non-governmental organisations;

(b) **Improvement of data-comparison methods**

(i) ensuring improved comparability, objectivity and reliability of data at European level by establishing indicators and common criteria of a non-binding nature, compliance with which may be recommended by the Centre, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Community; in particular, the Centre shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies;

(ii) facilitating and structuring information exchange in terms of both quality and quantity (databases);

(c) **Dissemination of data**

(i) making the information produced by it available to the Community, the Member States and competent organisations;

(ii) ensuring wide dissemination of work done in each Member State and by the Community itself, and, where appropriate, by third countries or international organisations;

(iii) ensuring wide dissemination of reliable non-confidential data, publishing on the basis of data which it gathers, a yearly report on the state of the drugs problem, including data on emerging trends;

(d) **Cooperation with European and international bodies and organisations and with third countries**

(i) contributing to improving coordination between national and Community action in its areas of activity;

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(ii) without prejudice to Member States' obligations with regard to transmission of information under the provisions of the United Nations Conventions on drugs, promoting the incorporation of data on drugs and drug addiction gathered in the Member States or emanating from the Community into international monitoring and drug-control programmes, particularly those established by the UN and its specialised agencies;

(iii) cooperating actively with Europol to attain maximum efficiency in monitoring the drugs problem;

(iv) cooperating actively with the organisations and bodies referred to in Article 20;

(v) transferring, at the request of the Commission and with the approval of the Management Board referred to in Article 9, its know-how to certain third countries such as candidate countries or the countries of the western Balkans and assist in the creation and strengthening of structural links with the network referred to in Article 5 and the setting-up and consolidation of the national focal points referred to in that Article;

(e) **Information obligations**

In principle, the Centre shall, if it identifies new developments and changing trends, inform the competent authorities of the Member States thereof;

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(f) **Exchange of information on, early warning system for, and risk assessment of, new psychoactive substances**

(i) collecting, collating, analysing and assessing the available information from the national focal points referred to in Article 5 and the Europol national units on new psychoactive substances as defined in point 4 of Article 1 of Council Framework Decision 2004/757/JHA [1] and communicating that information to the national focal points and the Europol national units as well as to the Commission without undue delay;

(ii) drawing up the initial report or combined initial report in accordance with Article 5b;

(iii) organising the risk assessment procedure in accordance with Articles 5c and 5d;

(iv) monitoring, in cooperation with Europol and with the support of the national focal points referred to in Article 5 and the Europol national units, all new psychoactive substances that have been reported by Member States.

[1] Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

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Article 3

Priority areas of activity

The objective and tasks of the Centre, as set out in Articles 1 and 2, shall be implemented following the order of priorities indicated in Annex I.

Article 4

Working method

1. The Centre shall progressively carry out its tasks in the light of the objectives adopted in the three-year and annual work programmes referred to in Article 9(4) and (5) and with due regard to the available resources.

2. In pursuing its activities, the Centre shall, in order to avoid duplication, take account of activities already carried out by other existing or future institutions and agencies, notably Europol, and shall ensure that it adds to their value.

Article 5

European Information Network on Drugs and Drug Addiction (Reitox)

1. The Centre shall have at its disposal the European Information Network on Drugs and Drug Addiction (Reitox). The network shall consist of one focal point for each Member State and each country which has concluded an agreement pursuant to Article 21 and a focal point for the Commission. The designation of the national focal points shall be the exclusive responsibility of the countries concerned.

2. The national focal points shall form an interface between the participating countries and the Centre. They shall contribute to the establishment of key indicators and data, including guidelines for their implementation with a view to obtaining reliable and comparable information at European Union level. They shall collect and analyse in an objective manner at national level, bringing together experience from different sectors – health, justice, law enforcement – in cooperation with experts and national organisations active in the field of drugs policy, all relevant information on drugs and drug addiction, as well as on policies and solutions applied. In particular, they shall provide data for the five epidemiological indicators specified by the Centre.

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The national focal points may also provide the Centre with information on new trends in the use of existing psychoactive substances and/or new combinations of psychoactive substances which pose a potential risk to public health as well as information on possible measures related to public health.

3. The national authorities shall ensure the operation of their focal point for the collection and analysis of data at national level on the basis of guidelines adopted with the Centre.

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4. The specific tasks allocated to the national focal points shall appear in the Centre's three-year programme as referred to in Article 9(4).

5. While fully respecting the primacy of the national focal points, and in close cooperation with them, the Centre may have recourse to additional expertise and sources of information in the field of drugs and drug addiction.

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Article 5a

Information exchange on, and early warning system for, new psychoactive substances

Each Member State shall ensure that its national focal point, as referred to in Article 5, and its Europol national unit provide the Centre and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay. The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.

The Centre, in cooperation with Europol, shall collect, collate, analyse and assess the information and communicate it in a timely manner to the national focal points and the Europol national units as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report or the combined initial report pursuant to Article 5b.

Article 5b

Initial report

1. Where the Centre, the Commission or a majority of the Member States considers that information shared on a new psychoactive substance collected pursuant to Article 5a in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.

For the purpose of this paragraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Centre accordingly and shall inform the Member States thereof.

2. The initial report shall contain a first indication of:

(a) the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;

(b) the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;

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(c) the pharmacological and toxicological description of the new psychoactive substance;

(d) the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance.

The initial report shall also contain:

(a) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;

(b) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;

(c) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;

(d) information on whether the new psychoactive substance is currently or has been under assessment within the system established by the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 Convention on Psychotropic Substances ('United Nations system');

(e) other relevant information, where available.

3. For the purpose of the initial report, the Centre shall use information which is at its disposal.

4. Where the Centre considers it necessary, it shall request the national focal points referred to in Article 5 to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request.

5. The Centre shall, without undue delay, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:

(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council ([1]), Directive 2001/82/EC of the European Parliament and of the Council ([2]) or Regulation (EC) No 726/2004 of the European Parliament and of the Council ([3]);

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([2]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([3]) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;

(d) an unauthorised medicinal product for human use in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with point (c) of Article 10(1) of Directive 2001/82/EC;

(e) an investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC of the European Parliament and of the Council ([1]).

Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.

6. The Centre shall, without undue delay, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.

7. The Centre shall, without undue delay, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

8. The details of the cooperation between the Centre and the bodies and agencies referred to in paragraphs 5, 6 and 7 of this Article shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with the second paragraph of Article 20.

9. The Centre shall respect the conditions on use of the information, which are communicated to the Centre, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information.

10. The Centre shall submit the initial report to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

([1]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

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11. Where the Centre collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

Article 5c

Risk assessment procedure and report

1. Within two weeks of receipt of an initial report as referred to in Article 5b(10), the Commission may request the Centre to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.

2. Within two weeks of receipt of a combined initial report as referred to in Article 5b(11), the Commission may request the Centre to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

3. The risk assessment report or combined risk assessment report shall contain:

(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;

(b) available information on the pharmacological and toxicological properties of the new psychoactive substance;

(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects;

(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;

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(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;

(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;

(g) other relevant information, where available.

4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances. The Scientific Committee may be extended as deemed necessary by the Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance. The Director shall designate those experts from a list of experts. The Management Board shall approve the list of experts every three years.

The Commission, the Centre, Europol and the European Medicines Agency shall each have the right to nominate two observers.

5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Centre shall organise the risk assessment procedure, including identifying future information needs and relevant studies.

6. The Centre shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report.

7. Upon receipt of a duly reasoned request of the Centre, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.

Article 5d

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.

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2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.

3. No risk assessment shall be carried out where the new psychoactive substance is an active substance in:

(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation;

(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;

(d) an investigational medicinal product as defined in point (d) of Article 2 of Directive 2001/20/EC.

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Article 6

Protection and confidentiality of data

1. Data on drugs and drug addiction provided to or by the Centre may be published subject to compliance with Community and national rules on the dissemination and confidentiality of information. Personal data may not be published or made accessible to the public.

Member States and the national focal points shall be under no obligation to provide information classified as confidential under their national law.

2. Regulation (EC) No 45/2001 shall apply to the Centre.

Article 7

Access to documents

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Centre.

2. The Management Board referred to in Article 9 shall adopt the arrangements for implementing Regulation (EC) No 1049/2001.

3. Decisions taken by the Centre pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint to the Ombudsman or form the subject of an action before the Court of Justice of the European Communities, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

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Article 8

Legal capacity and location

1. The Centre shall have legal personality. In each of the Member States, it shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property and may be a party to legal proceedings.

2. The seat of the Centre shall be located in Lisbon.

Article 9

Management Board

1. The Centre shall have a Management Board consisting of one representative from each Member State, two representatives from the Commission, two independent experts particularly knowledgeable in the field of drugs designated by the European Parliament and one representative from each country which has concluded an agreement pursuant to Article 21.

Each member of the Management Board shall have one vote, except for the representatives of the countries which have concluded agreements pursuant to Article 21, who shall not have the right to vote.

The decisions of the Management Board shall be taken by a two-thirds majority of the members with a right to vote, except in the cases provided for in paragraph 6 of this Article and in Article 20.

Each member of the Management Board may be assisted or represented by a substitute. Where a full member who has the right to vote is absent, his or her substitute may exercise that right.

The Management Board may invite as non-voting observers representatives of international organisations with which the Centre cooperates in accordance with Article 20.

2. The Chairperson and Vice-Chairperson of the Management Board shall be elected from amongst and by its members for a three-year period. Their terms of office shall be renewable once.

The Chairperson and Vice-Chairperson shall have the right to take part in the voting.

The Management Board shall draw up its own rules of procedure.

3. The meetings of the Management Board shall be convened by its Chairperson. It shall hold an ordinary meeting at least once a year. The Centre's Director, as referred to in Article 11, shall take part in the meetings of the Management Board, without voting rights, and shall, under Article 11(3), provide for the Board's Secretariat.

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4. The Management Board shall adopt a three-year work programme on the basis of a draft submitted by the Director, after consulting the Scientific Committee referred to in Article 13 and obtaining the opinion of the Commission, and shall forward it to the European Parliament, the Council and the Commission.

5. Under the three-year work programme, the Management Board shall adopt each year the Centre's annual work programme on the basis of a draft submitted by the Director, after consulting the Scientific Committee and obtaining the opinion of the Commission. The work programme shall be forwarded to the European Parliament, the Council and the Commission. It may be adjusted in the course of the year in accordance with the same procedure.

6. Where the Commission expresses its disagreement with the three-year or annual work programme, those programmes shall be adopted by the Management Board by a three-fourths majority of the members with a right to vote.

7. The Management Board shall adopt the annual report on the Centre's activities and forward it by 15 June to the European Parliament, the Council, the Commission, the Court of Auditors and the Member States.

8. The Centre shall forward annually to the budgetary authority any information relevant to the outcome of the evaluation procedures.

Article 10

Executive Committee

1. The Management Board shall be assisted by an Executive Committee. The Executive Committee shall be made up of the Chairperson and the Vice-Chairperson of the Management Board, two other members of the Management Board representing the Member States and appointed by the Management Board and two Commission representatives. The Director shall take part in meetings of the Executive Committee.

2. The Executive Committee shall meet at least twice a year and whenever necessary to prepare the decisions of the Management Board and to assist and advise the Director. It shall decide on behalf of the Management Board on those matters provided for in the financial rules adopted pursuant to Article 15(10) that are not reserved to the Management Board by this Regulation. Decisions shall be adopted by consensus.

Article 11

Director

1. The Centre shall be headed by a Director appointed by the Management Board on a proposal from the Commission for a five-year term, which shall be renewable.

2. Before appointment to a first term, out of a maximum of two terms, the candidate selected by the Management Board for the post of Director shall be invited without delay to make a statement before the European Parliament and answer questions put by members of that institution.

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3. The Director shall be responsible for:

(a) preparing and implementing the decisions and programmes adopted by the Management Board,

(b) day-to-day administration,

(c) preparing the Centre's work programmes,

(d) the preparation of the draft estimate of the Centre's revenue and expenditure and the implementation of the budget,

(e) the preparation and publication of the reports provided for in this Regulation,

(f) managing all staff-related matters, and in particular exercising the powers which are devolved on the appointing authority,

(g) defining the Centre's organisational structure and submitting it to the Management Board for approval,

(h) the performance of the tasks referred to in Articles 1 and 2,

(i) carrying out a regular assessment of the Centre's work.

4. The Director shall be accountable for his activities to the Management Board.

5. The Director shall be the Centre's legal representative.

Article 12

Hearing of the Director and of the Chairperson of the Management Board before the European Parliament

Each year the Director shall submit to the European Parliament the general report on the Centre's activities. The European Parliament may also ask for a hearing with the Director and the Chairperson of the Management Board on any subject related to the Centre's activities.

Article 13

Scientific Committee

1. The Management Board and the Director shall be assisted by a Scientific Committee which shall deliver an opinion where provided for in this Regulation on any scientific matter concerning the Centre's activities which the Management Board or the Director may submit to it.

The opinions of the Scientific Committee shall be published.

2. The Scientific Committee shall consist of at most fifteen well-known scientists appointed in view of their scientific excellence and their independence by the Management Board, following the publication of a call for expressions of interest in the *Official Journal of the European Union*. The selection procedure shall ensure that the specialist fields of the members of the Scientific Committee cover the most relevant scientific fields linked to the problems of drugs and drug addiction.

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The members of the Scientific Committee shall be appointed in a personal capacity and shall give their opinions completely independently of the Member States and the Community Institutions.

The Scientific Committee shall take into account the various positions expressed in national expert opinions, if available, before delivering any opinion.

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For the purpose of assessing the risks posed by the new psychoactive substance or group of new psychoactive substances, the Scientific Committee may be extended following the procedure laid down in Article 5c(4).

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3. Members shall serve on the Scientific Committee for a three-year period, which shall be renewable.

4. The Scientific Committee shall elect its chairperson for a three-year period. It shall be convened by its chairperson at least once a year.

Article 14

Drawing up of the budget

1. Estimates of all the revenue and expenditure of the Centre shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Centre.

2. The revenue and expenditure shown in the budget shall be in balance.

3. The Centre's revenue shall, without prejudice to other resources, consist of a subsidy from the Community entered in the general budget of the European Union (Commission Section), payments for services rendered and any financial contributions from the organisations and bodies and third countries referred to in Articles 20 and 21 respectively.

4. The Centre's expenditure shall include:

(a) staff remuneration, administrative and infrastructure expenses, and operating costs;

(b) expenditure in support of the Reitox focal points.

5. Each year the Management Board, on the basis of a draft drawn up by the Director, shall produce an estimate of revenue and expenditure for the Centre for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March, together with the Centre's work programme. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the ‘budgetary authority’) together with the preliminary draft general budget of the European Union.

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6. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

7. The budgetary authority shall authorise the appropriations for the subsidy to the Centre and shall adopt the establishment plan for the Centre.

8. The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.

9. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of the budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

Article 15

Implementation of the budget

1. The Director shall implement the Centre's budget.

2. By 1 March following each financial year, the Centre's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities ([1]) (hereinafter referred to as 'the general Financial Regulation').

3. By 31 March following each financial year, the Commission's accounting officer shall forward the Centre's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for the financial year shall also be forwarded to the European Parliament and to the Council.

4. On receipt of the Court of Auditors' observations on the Centre's provisional accounts, pursuant to Article 129 of the general Financial Regulation, the Director shall draw up the Centre's final accounts under his own responsibility and submit them to the Management Board for an opinion.

([1]) OJ L 248, 16.9.2002, p. 1.

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5. The Management Board shall deliver an opinion on the Centre's final accounts.

6. The Director shall, by 1 July following each financial year, forward the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

The final accounts shall be published.

7. The Director shall send the Court of Auditors a reply to its observations by 30 September. He shall also send this reply to the Management Board.

8. The Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, as laid down in Article 146(3) of the general Financial Regulation.

9. The European Parliament, on a recommendation from the Council acting by a qualified majority, shall, before 30 April of year N + 2, give a discharge to the Director in respect of the implementation of the budget for year N.

10. The financial rules applicable to the Centre shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 ([1]) on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 unless specifically required for the Centre's operation and with the Commission's prior consent.

Article 16

Combating fraud

1. In order to combat fraud, corruption and any other illegal activities affecting the Communities' financial interests, the provisions of Regulation (EC) No 1073/1999 shall apply without restriction to the Centre.

2. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks at the premises of the recipients of the Centre's funding.

Article 17

Privileges and immunities

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Centre.

([1]) OJ L 357, 31.12.2002, p. 72.

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Article 18

Staff Regulations

The Staff Regulations of officials of the European Communities and the Conditions of Employment of other servants of the European Communities and the rules adopted jointly by the Community Institutions for the purpose of applying those Staff Regulations and Conditions of Employment shall apply to the staff of the Centre.

Where it engages staff from third countries following the conclusion of the agreements referred to in Article 21, the Centre shall, in any event, comply with the Staff Regulations and Conditions of Employment referred to in paragraph 1 of this Article.

The Centre shall exercise in respect of its staff the powers devolved to the appointing authority.

The Management Board shall, in agreement with the Commission, adopt the appropriate implementing rules in accordance with the Staff Regulations, Article 110, and the Conditions of Employment referred to in paragraph 1.

The Management Board may adopt provisions to allow national experts from other Member States to be employed on secondment at the Centre.

Article 19

Liability

1. The contractual liability of the Centre shall be governed by the law applicable to the contract in question. The Court of Justice shall have jurisdiction pursuant to an arbitration clause contained in a contract concluded by the Centre.

2. In the case of non-contractual liability, the Centre shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by the Centre or its staff in the performance of their duties. The Court of Justice shall have jurisdiction in disputes relating to the compensation of any such damage.

3. The personal liability of its staff towards the Centre shall be governed by the provisions applying to the staff of the Centre.

Article 20

Cooperation with other organisations and bodies

Without prejudice to relations which the Commission may maintain pursuant to Article 302 of the Treaty, the Centre shall actively seek to cooperate with international organisations and other, particularly European, governmental and non-governmental bodies competent in the sector of drugs.

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Such cooperation shall be based on working arrangements concluded with the organisations and bodies referred to in the first paragraph. Those arrangements shall be adopted by the Management Board on the basis of a draft submitted by the Director and after the Commission has delivered an opinion. Where the Commission expresses its disagreement with these arrangements, the Management Board shall adopt them by a three-fourths majority of the members with a right to vote.

Article 21

Participation of third countries

The Centre shall be open to the participation of any third country that shares the interest of the Community and of its Member States in the Centre's objectives and work, on the basis of agreements entered into between such third countries and the Community on the basis of Article 300 of the Treaty.

Article 22

Jurisdiction of the Court of Justice

The Court of Justice shall have jurisdiction in actions brought against the Centre under Article 230 of the Treaty.

Article 23

Evaluation report

The Commission shall initiate an external evaluation of the Centre every six years to coincide with the completion of two of the Centre's three-year work programmes. Such evaluations shall also include the Reitox system. The Commission shall forward the evaluation report to the European Parliament, the Council and the Management Board.

In that context, the Commission shall, if appropriate, present a proposal for revision of the provisions of this Regulation in the light of developments in respect of regulatory agencies, in accordance with the procedure laid down in Article 251 of the Treaty.

Article 24

Repeal

Regulation (EEC) No 302/93 is hereby repealed.

References made to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex III.

Article 25

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

A. The work of the Centre shall be carried out with due regard to the respective powers of the Community and its Member States in the area of drugs, as those powers are defined by the Treaty. It shall cover the various facets of the drugs and drug addiction phenomenon, and the solutions applied. In doing so, the Centre shall be guided by the Drugs Strategies and Action Plans adopted by the European Union.

The Centre shall focus on the following priority areas:

1) monitoring the state of the drugs problem, in particular using epidemiological or other indicators, and monitoring emerging trends, in particular those involving poly-drug use;

2) monitoring the solutions applied to drug-related problems; providing information on best practices in the Member States and facilitating the exchange of such practices among them;

3) assessing the risks of new psychoactive substances and maintaining a rapid information system with regard to their use and also regarding new methods of using existing psychoactive substances;

4) developing tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate European Union policies.

B. The Commission shall make available to the Centre, for dissemination, the information and statistical data which it possesses pursuant to its powers.

▼B

ANNEX II

REPEALED REGULATION AND SUCCESSIVE AMENDMENTS

Council Regulation (EEC) No 302/93	OJ L 36, 12.2.1993, p. 1.
Council Regulation (EC) No 3294/94	OJ L 341, 30.12.1994, p. 7.
Council Regulation (EC) No 2220/2000	OJ L 253, 7.10.2000, p. 1.
Council Regulation (EC) No 1651/2003	OJ L 245, 29.9.2003, p. 30.

▼B

ANNEX III

CORRELATION TABLE

Council Regulation (EEC) No 302/93	This Regulation
Article 1	Article 1
—	Article 1(3), second and third sentences
Article 2(A), sub-heading	Article 2(a), sub-heading
Article 2(A)(1)	Article 2(a)(i), first phrase
—	Article 2(a)(i), second and third phrases
Article 2(A)(2) to (5)	Article 2(a)(ii) to (v)
Article 2(B), sub-heading	Article 2(b), sub-heading
Article 2(B)(6), first phrase	Article 2(b)(i), first phrase
—	Article 2(b)(i), second phrase
Article 2(B)(7)	Article 2(b)(ii)
Article 2(C), sub-heading	Article 2(c), sub-heading
Article 2(C)(8) to (10)	Article 2(c)(i) to (iii)
Article 2(D), sub-heading	Article 2(d), sub-heading
Article 2(D)(11) to (13)	Article 2(d)(i), (ii) and (iv)
—	Article 2(d)(iii) and (v)
—	Article 2(e)
Article 3	Article 4
Article 4	Article 3
Article 5(1)	Article 5(1)
—	Article 5(2), (3) and (4)
Article 5(4)	Article 5(5)
Article 6(2) and (3)	Article 6(1)
—	Article 6(2)
Article 6a	Article 7
Article 7	Article 8
—	Article 8, heading
—	Article 8 (2)

▼B

Council Regulation (EEC) No 302/93	This Regulation
Article 8(1)	Article 9(1), first, fourth and fifth subparagraphs
Article 8(2)	Article 9(1), second and third subparagraphs; Article 9(2); Article 9(3), second sentence
—	Article 9(3), first and third sentences
Article 8(3)	Article 9(4)
Article 8(4)	Article 9(5), first and third sentences
—	Article 9(5), second sentence
—	Article 9(6)
Article 8(5) and (6)	Article 9(7) and (8)
—	Article 10
Article 9(1), first subparagraph	Article 11(1)
—	Article 11(2)
Article 9(1), second subparagraph	Article 11(3)
Article 9(1), second subparagraph, first to sixth indent	Article 11(3)(a) to (f), first phrase
—	Article 11(3)(f), second phrase
—	Article 11(3)(g)
Article 9(1), second subparagraph, seventh indent	Article 11(3)(h)
—	Article 11(3)(i)
Article 9(2) and (3)	Article 11(4) and (5)
—	Article 12
Article 10(1)	Article 13(1)
Article 10(2)	Article 13(2), first and fourth subparagraphs
—	Article 13(2), second and third subparagraphs
Article 10(3), (4) and (5)	Article 13(3) and (4)
Article 11(1) to (6)	Article 14(1) to (5)
Article 11(7) to (10)	Article 14(6) to (9)

▼B

Council Regulation (EEC) No 302/93	This Regulation
Article 11a(1) to (5)	Article 15(1) to (5)
Article 11a(6) and (7)	Article 15(6)
Article 11a(8) to (11)	Article 15(7) to (10)
—	Article 16
Article 12	Article 20
—	Article 20, second subparagraph
Article 13(1)	Article 21
Article 13(2)	—
Article 14	Article 17
Article 15	Article 18, first, third and fourth subparagraphs
—	Article 18, second and fifth subparagraphs
Article 16	Article 19
Article 17	Article 22
Article 18	Article 23, first subparagraph, first and third sentences
—	Article 23, first subparagraph, second sentence
—	Article 23, second subparagraph
—	Article 24
Article 19	Article 25
Annex, paragraph A, first subparagraph	Annex I, paragraph A, first subparagraph, first sentence
—	Annex I, paragraph A, first subparagraph, second and third sentences
—	Annex I, paragraph A, second subparagraph, points (1) to (4)
Annex, paragraph A, second subparagraph, points 1 to 5	—
Annex, paragraph B	Annex I, paragraph B
Annex, paragraph C	—
—	Annex II
—	Annex III