

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

[<sup>XI</sup>TITLE X U.K.]

## AGENCY

*Article 75* U.K.

### Establishment and review

- 1 A European Chemicals Agency is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this Regulation and to ensure consistency at Community level in relation to these aspects.
- 2 The Agency shall be subject to a review by 1 June 2012.

*Article 76* U.K.

### Composition

- 1 The Agency shall comprise:
  - a a Management Board, which shall exercise the responsibilities set out in Article 78;
  - b an Executive Director, who shall exercise the responsibilities set out in Article 83;
  - c a Committee for Risk Assessment, which shall be responsible for preparing the opinion of the Agency on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling under Title XI and any other questions that arise from the operation of this Regulation relating to risks to human health or the environment;
  - d a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;
  - e a Member State Committee, which shall be responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States under Title VI and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;
  - f a Forum for Exchange of Information on Enforcement (hereinafter referred to as the Forum) which shall coordinate a network of Member States authorities responsible for enforcement of this Regulation;
  - g a Secretariat, which shall work under the leadership of the Executive Director and provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate coordination between them. It shall also undertake the

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work required of the Agency under the procedures for pre-registration, registration and evaluation as well as preparation of guidance, database maintenance and information provision;

h a Board of Appeal, which shall decide on appeals against decisions taken by the Agency.

2 The Committees referred to in points (c), (d) and (e) of paragraph 1 (hereinafter referred to as the Committees) and the Forum may each establish working groups. For this purpose they shall adopt, in accordance with their rules of procedure, precise arrangements for delegating certain tasks to these working groups.

3 The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

## Article 77 **U.K.**

### Tasks

1 The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2 The Secretariat shall undertake the following tasks:

- a performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the Community's international trading obligations towards third countries;
- b performing the tasks allotted to it under Title III;
- c performing the tasks allotted to it under Title VI;
- d performing the tasks allotted to it under Title VIII;
- e establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list. It shall make the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 118;
- f making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 119(1);
- g providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;
- h providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII;
- i providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in preparations or in articles;

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- j providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);
  - k preparing explanatory information on this Regulation for other stakeholders;
  - l at the Commission's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
  - m keeping a Manual of Decisions and Opinions based on conclusions from the Member State Committee regarding interpretation and implementation of this Regulation;
  - n notification of decisions taken by the Agency;
  - o provision of formats for submission of information to the Agency.
- 3 The Committees shall undertake the following tasks:
- a performing the tasks allotted to them under Titles VI to XI;
  - b at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
  - c at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles.
- 4 The Forum shall undertake the following tasks:
- a spreading good practice and highlighting problems at Community level;
  - b proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
  - c coordinating exchange of inspectors;
  - d identifying enforcement strategies, as well as best practice in enforcement;
  - e developing working methods and tools of use to local inspectors;
  - f developing an electronic information exchange procedure;
  - g liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;
  - h examining proposals for restrictions with a view to advising on enforceability.

Article 78 **U.K.**

### **Powers of the Management Board**

The Management Board shall appoint the Executive Director pursuant to Article 84 and an accounting officer in accordance with Article 43 of Regulation (EC, Euratom) No 2343/2002.

It shall adopt:

- (a) by 30 April each year, the general report of the Agency for the previous year;
- (b) by 31 October each year the work programme of the Agency for the coming year;
- (c) the final budget of the Agency pursuant to Article 96 before the beginning of the financial year, adjusting it, where necessary, according to the Community contribution and any other revenue of the Agency;

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(d) a multiannual work programme, which shall be regularly revised.

It shall adopt the internal rules and procedures of the Agency. These rules shall be made public.

It shall perform its duties in relation to the Agency's budget pursuant to Articles 96, 97 and 103.

It shall exercise disciplinary authority over the Executive Director.

It shall adopt its rules of procedure.

It shall appoint the Chairman, the members and alternates of the Board of Appeal in accordance with Article 89.

It shall appoint the members of the Agency committees as set out in Article 85.

It shall forward annually any information relevant to the outcome of the evaluation procedures in accordance with Article 96(6).

#### Article 79 **U.K.**

### **Composition of the Management Board**

1 The Management Board shall be composed of one representative from each Member State and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights and in addition two independent persons appointed by the European Parliament.

Each Member State shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.

2 Members shall be appointed on the basis of their relevant experience and expertise in the field of chemical safety or the regulation of chemicals whilst ensuring there is relevant expertise amongst the board members in the fields of general, financial and legal matters.

3 The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission shall identify half of its appointees, and the Council shall identify 12 of its appointees, for whom this period shall be six years.

#### Article 80 **U.K.**

### **Chairmanship of the Management Board**

1 The Management Board shall elect a Chairman and a Deputy-Chairman from among the members with voting rights. The Deputy-Chairman shall automatically take the place of the Chairman if he is prevented from attending to his duties.

2 The terms of office of the Chairman and the Deputy-Chairman shall be two years and shall expire when they cease to be members of the Management Board. The term of office shall be renewable once.

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## Article 81 **U.K.**

### **Meetings of the Management Board**

1 The meetings of the Management Board shall be convened by invitation of its Chairman or at the request of at least one third of the Board members.

2 The Executive Director shall take part in the meetings of the Management Board, without voting rights.

3 The Chairmen of the Committees and the Chairman of the Forum, as referred to in Article 76(1)(c) to (f), are entitled to attend the meetings of the Management Board without voting rights.

## Article 82 **U.K.**

### **Voting of the Management Board**

The Management Board shall adopt rules of procedure for voting, including the conditions for a member to vote on behalf of another member. The Management Board shall act by a two-thirds majority of all members with the right to vote.

## Article 83 **U.K.**

### **Duties and powers of the Executive Director**

1 The Agency shall be managed by its Executive Director, who shall perform his duties in the interests of the Community, and independently of any specific interests.

2 The Executive Director shall be the legal representative of the Agency. He shall be responsible for:

- a the day-to-day administration of the Agency;
- b managing all the Agency resources necessary for carrying out its tasks;
- c ensuring that the time-limits laid down in Community legislation for the adoption of opinions by the Agency are complied with;
- d ensuring appropriate and timely coordination between the Committees and the Forum;
- e concluding and managing necessary contracts with service providers;
- f the preparation of the statement of revenue and expenditure and the implementation of the budget of the Agency pursuant to Articles 96 and 97;
- g all staff matters;
- h providing the secretariat for the Management Board;
- i preparing draft opinions of the Management Board concerning the proposed rules of procedure of the Committees and of the Forum;
- j making arrangements, upon request from the Management Board, for the execution of any further function(s) (within the remit of Article 77) allotted to the Agency by delegation from the Commission;
- k establishing and maintaining a regular dialogue with the European Parliament;
- l determining the terms and conditions for use of software packages;

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m rectifying a decision made by the Agency following an appeal and after consulting the Chairman of the Board of Appeal.

3 Each year, the Executive Director shall submit the following to the Management Board for approval:

- a a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction received by the Agency and opined upon, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; complaints received and the action taken; an overview of the activities of the Forum;
- b a draft work-programme for the coming year;
- c the draft annual accounts;
- d the draft forecast budget for the coming year;
- e a draft multiannual work programme.

The Executive Director shall, following approval by the Management Board, forward the work programme for the coming year and the multiannual work programme to the Member States, the European Parliament, the Council and the Commission, and shall have them published.

The Executive Director shall, following approval by the Management Board, forward the Agency's general report to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors, and shall have it published.

#### Article 84 **U.K.**

### **Appointment of the Executive Director**

1 The Executive Director of the Agency shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on Internet sites.

The Executive Director shall be appointed on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

Power to dismiss the Executive Director shall lie with the Management Board, in accordance with the same procedure.

Before being appointed, the candidate selected by the Management Board shall be invited as soon as possible to make a statement before the European Parliament and to answer questions from Members of Parliament.

2 The term of the office of the Executive Director shall be five years. It may be prolonged by the Management Board once for another period of up to five years.

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## Article 85 **U.K.**

### Establishment of the Committees

1 Each Member State may nominate candidates to membership of the Committee for Risk Assessment. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3).

2 Each Member State may nominate candidates to membership of the Committee for Socio-economic Analysis. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3).

3 Each Member State shall appoint one member to the Member State Committee.

4 The Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.

Members of the Committees shall be appointed for a term of three years which shall be renewable.

The members of the Management Board may not be members of the Committees.

The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

The Executive Director or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees as observers. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board.

5 The members of each Committee appointed following nomination by a Member State shall ensure that there is appropriate coordination between the tasks of the Agency and the work of their Member State competent authority.

6 The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.

7 The Member States shall refrain from giving the members of the Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.

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8 When preparing an opinion, each Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members, including their grounds. The minority position(s), including their grounds, shall also be published.

9 Each Committee shall draft a proposal for its own rules of procedure, to be approved by the Management Board, within six months of the Committees first being appointed.

These rules shall in particular lay down the procedures for replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions. The Chairman of each Committee shall be an employee of the Agency.

#### Article 86 **U.K.**

### Establishment of the Forum

1 Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.

The Forum shall aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable. Members of the Management Board may not be members of the Forum.

The members of the Forum may be accompanied by scientific and technical advisers.

The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board.

2 The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority.

3 The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.

4 The Forum shall draft a proposal for its own rules of procedure, to be adopted by the Management Board, within six months of the Forum first being appointed.

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members and the procedures for delegating certain tasks to working groups.



## Article 87 **U.K.**

### **Rapporteurs of Committees and use of experts**

1 Where, in accordance with Article 77, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

2 Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3 The provision of services by Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4 The provision of services for which there are several potential providers may require a call for an expression of interest:

- a if the scientific and technical context allows; and
- b if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5 The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible.

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## Article 88 **U.K.**

### Qualification and interests

1 The membership of the Committees and of the Forum shall be made public. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When each appointment is published, the professional qualifications of each member shall be specified.

2 Members of the Management Board, the Executive Director and members of the Committees and of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing and, without prejudice to paragraph 1, be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.

3 At each of their meetings, members of the Management Board, the Executive Director, members of the Committees and of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point.

## Article 89 **U.K.**

### Establishment of the Board of Appeal

1 The Board of Appeal shall consist of a Chairman and two other members.

2 The Chairman and the two members shall have alternates who shall represent them in their absence.

3 The Chairman, the other members and the alternates shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on Internet sites. They shall be appointed on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission.

The Management Board may appoint additional members and their alternates, on recommendation by the Executive Director, following the same procedure, if this is necessary to ensure that the appeals can be processed at a satisfactory rate.

4 The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 133(3).

5 The Chairman and the members shall have equal voting rights.

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## Article 90 **U.K.**

### Members of the Board of Appeal

1 The term of office of the members of the Board of Appeal, including the Chairman and the alternates shall be five years. It may be prolonged once.

2 The members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.

3 The members of the Board of Appeal may not perform any other duties in the Agency.

4 The members of the Board of Appeal may not be removed either from office or from the list during their respective terms, unless there are serious grounds for such removal and the Commission, after obtaining the opinion of the Management Board, takes a decision to this effect.

5 Members of the Board of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal.

6 If a member of the Board of Appeal considers for reasons mentioned in paragraph 5 that he must not take part in a specific appeal proceedings, he shall inform the Board of Appeal accordingly. Members of the Board may be objected to by any party to the appeal proceedings on any of the grounds mentioned in paragraph 5, or if suspected of partiality. No objection may be based on the nationality of members.

7 The Board of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 5 and 6 without the participation of the member concerned. For the purposes of taking this decision, the member concerned shall be replaced on the Board of Appeal by an alternate.

## Article 91 **U.K.**

### Decisions subject to appeal

1 An appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51.

2 An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

## Article 92 **U.K.**

### Persons entitled to appeal, time-limits, fees and form

1 Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.

2 The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.

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3 A fee may be payable by persons bringing an appeal against an Agency decision, in accordance with Title IX.

*Article 93* **U.K.**

**Examination and decisions on appeal**

1 If, after consultation with the Chairman of the Board of Appeal, the Executive Director considers the appeal to be admissible and well founded he may rectify the decision within 30 days of the appeal being filed in accordance with Article 92(2).

2 In cases other than those referred to in paragraph 1 of this Article, the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed in accordance with Article 92(2). In the affirmative, the appeal shall be remitted to the Board of Appeal for examination of the grounds. Parties to the appeal proceedings shall be entitled to make an oral presentation during the procedure.

3 The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

4 The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 133(3).

*Article 94* **U.K.**

**Actions before the Court of First Instance and the Court of Justice**

1 An action may be brought before the Court of First Instance or the Court of Justice, in accordance with Article 230 of the Treaty, contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency.

2 Should the Agency fail to take a decision, proceedings for failure to act may be brought before the Court of First Instance or the Court of Justice in accordance with Article 232 of the Treaty.

3 The Agency shall be required to take the necessary measures to comply with the judgment of the Court of First Instance or the Court of Justice.

*Article 95* **U.K.**

**Conflicts of opinion with other bodies**

1 The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other bodies established under Community law, including Community Agencies, carrying out a similar task in relation to issues of common concern.

2 Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.

3 Where there is a fundamental conflict over scientific or technical points and the body concerned is a Community Agency or a scientific committee, the Agency and the body

concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

Article 96 **U.K.**

**The budget of the Agency**

- 1 The revenues of the Agency shall consist of:
    - a a subsidy from the Community, entered in the general budget of the European Communities (Commission Section);
    - b the fees paid by undertakings;
    - c any voluntary contribution from the Member States.
  - 2 The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses.
  - 3 By 15 February of each year at the latest, the Executive Director shall draw up a preliminary draft budget covering the operational expenditure and the programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board together with an establishment plan accompanied by a provisional list of posts.
  - 4 Revenue and expenditure shall be in balance.
  - 5 Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency 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 at the latest.
  - 6 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 budget of the European Communities.
  - 7 On the basis of the estimate, the Commission shall enter in the preliminary draft budget of the European Communities the estimates it considers 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.
  - 8 The budgetary authority shall authorise the appropriations for the subsidy to the Agency.
- The budgetary authority shall adopt the establishment plan for the Agency.
- 9 The budget of the Agency shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Communities. Where appropriate, it shall be adjusted accordingly.
  - 10 Any modification to the budget, including the establishment plan, shall follow the procedure referred to above.
  - 11 The Management Board shall, without delay, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

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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 97 **U.K.**

**Implementation of the budget of the Agency**

1 The Executive Director shall perform the duties of authorising officer and shall implement the Agency's budget.

2 Monitoring of the commitment and payment of all the Agency's expenditure and of the establishment and recovery of all the Agency's revenue shall be carried out by the Accounting Officer of the Agency.

3 By 1 March at the latest following each financial year, the Agency'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<sup>(1)</sup>.

4 By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Agency'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 that financial year shall also be forwarded to the European Parliament and the Council.

5 On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of Regulation (EC, Euratom) No 1605/2002, the Executive Director shall draw up the Agency's final accounts under his own responsibility and forward them to the Management Board for an opinion.

6 The Management Board shall deliver an opinion on the Agency's final accounts.

7 By 1 July of the following year at the latest, the Executive Director shall send the final accounts, together with the opinion of the Management Board, to the European Parliament, the Council, the Commission and the Court of Auditors.

8 The final accounts shall be published.

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

10 The European Parliament, upon a recommendation from the Council, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 98 **U.K.**

**Combating fraud**

1 In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999

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concerning investigations conducted by the European Anti-Fraud Office (OLAF)<sup>(2)</sup> shall apply without restrictions to the Agency.

2 The Agency shall be bound by the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office (OLAF)<sup>(3)</sup> and shall issue, without delay, the appropriate provisions applicable to all of its staff.

3 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 of the recipients of the Agency's funding and the agents responsible for allocating it.

*Article 99* **U.K.**

#### **Financial rules**

The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Regulation (EC, Euratom) No 2343/2002 unless specifically necessary for the Agency's operation and with the Commission's prior consent.

*Article 100* **U.K.**

#### **Legal personality of the Agency**

1 The Agency shall be a body of the Community and shall have legal personality. In each Member State it shall enjoy the most extensive legal capacity accorded to legal persons under their laws. In particular it may acquire and dispose of movable and immovable property and may be a party to legal proceedings.

2 The Agency shall be represented by its Executive Director.

*Article 101* **U.K.**

#### **Liability of the Agency**

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

2 In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its servants in the performance of their duties.

The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damages.

3 The personal financial and disciplinary liability of its servants towards the Agency shall be governed by the relevant rules applying to the staff of the Agency.

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Article 102 **U.K.**

**Privileges and immunities of the Agency**

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

Article 103 **U.K.**

**Staff rules and regulations**

1 The staff of the Agency shall be subject to the Regulations and Rules applicable to officials and other servants of the European Communities. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.

2 The Management Board shall, in agreement with the Commission, adopt the necessary implementing provisions.

3 The Agency's staff shall consist of officials assigned or seconded by the Commission or Member States on a temporary basis and of other servants recruited by the Agency as necessary to carry out its tasks. The Agency shall recruit its personnel on the basis of a staffing plan to be included in the multiannual work programme referred to in Article 78(d).

Article 104 **U.K.**

**Languages**

1 Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community<sup>(4)</sup> shall apply to the Agency.

2 The translation services required for the functioning of the Agency shall be provided by the Translation Centre of the bodies of the European Union.

Article 105 **U.K.**

**Duty of confidentiality**

Members of the Management Board, members of the Committees and of the Forum, experts and officials and other servants of the Agency, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the duty of professional secrecy.

Article 106 **U.K.**

**Participation of third countries**

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of third countries to participate in the work of the Agency.



*Article 107* **U.K.****Participation of international organisations**

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of international organisations with interests in the field of chemicals regulation to participate as observers in the work of the Agency.

*Article 108* **U.K.****Contacts with stakeholder organisations**

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and relevant stakeholder organisations.

*Article 109* **U.K.****Rules on transparency**

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles which is not of a confidential nature.

*Article 110* **U.K.****Relations with relevant Community bodies**

1 The Agency shall cooperate with other Community bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.

2 The Executive Director, having consulted the Committee on Risk Assessment and the European Food Safety Authority, shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not otherwise affect the competences vested in the European Food Safety Authority.

3 This Title shall not affect the competences vested in the European Medicines Agency.

4 The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.

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### Article 111 **U.K.**

#### **Formats and software for submission of information to the Agency**

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1).

For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.]

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#### **Editorial Information**

- X1** Substituted by [Corrigendum to Regulation \(EC\) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals \(REACH\), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation \(EEC\) No 793/93 and Commission Regulation \(EC\) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC \(Official Journal of the European Union L 396 of 30 December 2006\).](#)

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- (1) [<sup>X1</sup>OJ L 248, 16.9.2002, p. 1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p. 1).]
- (2) [<sup>X1</sup>OJ L 136, 31.5.1999, p. 1.]
- (3) [<sup>X1</sup>OJ L 136, 31.5.1999, p. 15.]
- (4) [<sup>X1</sup>OJ 17, 6.10.1958, p. 385/58. Regulation as last amended by Council Regulation (EC) No 920/2005 (OJ L 156, 18.6.2005, p. 3).]

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