

# **Constitution of the International Alliance for Biological Standardization (IABS)**

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## **I. NAME, LOCATION, OBJECTIVES**

### **Article 1**

The International Alliance for Biological Standardization (referred to herein as the "Alliance" or the "IABS") is a nonprofit-making association governed by Articles 60 - 79 of the Swiss Civil Code and by the present Articles of Association (hereinafter the "Constitution").

The former names of the association were International Association for Biological Standardization and subsequently the International Association for Biologicals, both also known under the acronym "IABS". The first Statutes of the IABS were adopted by the General Assembly meeting on 20th September 1959, in Tel Aviv.

In order to further promote the federative intent of its worldwide activities in the field of Biologicals, the General Assembly of the IABS decided, at its 28<sup>th</sup> meeting in Langen, Germany, to include the term "Alliance" in its name and to revise its Constitution accordingly.

For-profit entities shall not have voting rights at the General Assembly, but representatives of such entities may be elected to the Board of Directors (the "Board"), be elected to an office, and participate in the work of committees with the same rights as representatives of other organizations.

The Seat of the Alliance is located in Switzerland at Rue de la Vallée, 3 CH-1204 Genève.

Due to the international nature of its activities, English shall be used as the primary language for written and spoken communication within the Alliance.

### **Article 2**

The mission of the Alliance is to contribute to the scientific and medical advancement of Biologicals by facilitating the communication among those who develop, produce and regulate biological products for human and animal health.

The objectives of the Alliance are:

- To provide a unique forum where consensus can be reached on topics of importance to medical scientists and other healthcare professionals by serving as a platform for discussion and the development of consensus positions on contemporary issues related to Biologicals;
- To create an ongoing interface among leaders in clinical and basic research, biological product development, public health, manufacturing, and regulation by organizing scientific conferences, and publishing the reports of such meetings;
- To promote the use of international reference materials and the formulation of international guidance documents for Biologicals used in human and veterinary medicine through its conferences and publications;
- To promote uniform methods for establishing the international quality of biological products;
- To promote the knowledge and use of international reference materials established by the World Health Organization (the "WHO") and the World Organization for Animal Health (the "OIE");
- To encourage research in connection with the discovery, characterization, standardization, quality control, production, and clinical use of biological products.

In addition, the Alliance is prepared to offer assistance to national and international organizations active in this field.

## **II. MEMBERSHIP**

### **Article 3**

Members shall be persons and organizations interested in research, characterization, standardization, quality control, production, or clinical assessment and the marketing authorization of biological products. Each member must formally subscribe to the mission and objectives of the Alliance, as described in Article 2.

The Alliance shall be composed of the following classes of members:

A. *Member organizations* including national and international scientific societies active in the field of Biologicals: governmental organizations, industrial organizations, foundations, associations, trusts and other entities similarly interested in supporting the objectives of the Alliance. They pay no dues.

B. *Individual Members* comprising the following subclasses:

- *Ordinary Members*: individuals active in the field of Biologicals, who may be members of a for-profit organization acting in their personal capacity, and (1) who pay dues ; or (2) are members of the Board or Committees, in which case they pay no dues.

- *Honorary members*: The Honorary category is meant as a recognition of persons for their contributions to the field of Biologicals who are not members of IABS in any other category. They pay no dues

- *Emeritus members*: Individuals who meet the following conditions: (1) have informed IABS that they are retired, (2) are no longer active in IABS; and (3) are recognized by the Board as having contributed to the Alliance. They pay no dues.-

- *Complimentary Members*: individuals who attend an IABS conference and received complimentary membership for a period of up to one year subject to article 3. They pay no dues. Upon expiration of their complimentary membership, they may join as ordinary members.

#### **Article 4**

The membership dues are decided at the General Assembly for a two-year period.

Voluntary contributions exceeding the annual dues shall be considered as donations.

#### **Article 5**

Applications for membership, indicating the desired category of membership and, for individual members, the desired subclass of membership, shall be addressed to the Secretariat of the Alliance, which shall refer such applications to the Board for its decision as to the admission of the applicant. The Board shall also decide on the category and subclass of membership.

#### **Article 6**

Membership shall be terminated by:

A. Resignation.

B. For those members who have to pay dues according to this Constitution, failure to pay such dues to the Alliance for two years.

C. For complimentary members, the expiration of their complimentary membership, unless they are admitted in another category of membership upon such expiration.

D. Expulsion for such reasons as the Board shall determine to be in the interest of the Alliance. If a member is expelled by the Board, the member may appeal to the General Assembly. A two-thirds (2/3) majority of members shall be required to overrule the Board. Voting shall take place by secret ballot.

### **III. ORGANIZATION**

#### **Article 7**

The Alliance shall include the following bodies:

A. The General Assembly

B. The Board

C. The Executive Committee

D. Other committees that the Board determines as appropriate and which are listed in Appendix 1 of this Constitution

E. The Alliance may establish affiliates, which are listed in Appendix 2 of this Constitution, and may join other nonprofit organizations with similar interests.

### **IV. THE GENERAL ASSEMBLY**

#### **Article 8**

The supreme authority of the Alliance is vested in the General Assembly which shall be constituted from the membership. The General Assembly covers and controls all of the other organs of the Alliance and assumes all tasks not assigned by the Constitution to the other organs. The General Assembly reserves the right to revoke the organs of the Alliance and to supervise the activities of the organs. In particular, the General Assembly shall not delegate to the Board or to another organ the responsibility to approve or reject the accounting reports, and to dismiss the auditors.

Except as provided in Article 3A of the present Constitution, each Individual Member of the Alliance shall be entitled to one vote.

Unless the present Constitution provides otherwise, each Member Organization shall be entitled to one vote, and may select one voting representative to attend the General Assemblies.

#### **Article 9**

The General Assembly shall convene every two years on the occasion of a scientific conference sponsored by the Alliance.

The Secretary shall notify the membership by post and/or email, with documentation of receipt, at least one month in advance of the date, hour, and place where the General Assembly will be held. The proposed agenda shall accompany such notification.

Each member may, within a period of one month, ask for an amendment or amendments to the agenda. The final agenda, including any amendments to the proposed agenda, shall be sent to the membership one month before the General Assembly. The General Assembly shall not take any decisions on items not included on the agenda.

#### **Article 10**

The General Assembly is validly constituted if a quorum of at least five percent (5%) of the members of the Alliance is present or represented by proxy in accordance with article 13 of the present Constitution.

If a quorum is not present, a second Assembly shall be announced within a period of one month with the same agenda. This Assembly must be held not earlier than one month and not later than two months after the announcement has been sent to the membership.

This second Assembly is validly constituted whatever the number of members present or represented by proxy.

#### **Article 11**

The General Assembly shall be presided over by the President, or in his absence, by one of the two Vice Presidents.

#### **Article 12**

The following items shall be presented to the General Assembly for approval:

- the Minutes of the last General Assembly
- the Report of the President
- the Report of the Secretary
- the Report of the Vice President for Human Biologicals
- the Report of the Vice President for Veterinary Biologicals
- the Report of the Treasurer
- the Report of the Auditors
- the Budget.

The General Assembly shall:

- elect the Board members
- approve the annual membership dues
- discuss and decide upon the other items on the agenda

## **Article 13**

Unless the present Constitution provides otherwise and providing there is a quorum, all decisions at the General Assembly shall be reached by an affirmative vote of the majority of the members present and represented by proxy and shall take place by a show of hands. Two members of the Board or five members of the General Assembly may, however, demand a secret ballot.

Voting by proxy shall be permitted. A member voting by proxy shall give her/his representative, who shall be a member of the Alliance, at the General Assembly an authorization to vote on her/his behalf. The Secretary shall be notified in writing of such authorization prior to the General Assembly.

A vote by proxy is equivalent to a vote by a member present at the General Assembly.

## **V. THE BOARD OF DIRECTORS (BOARD)**

### **Article 14**

The Alliance shall be administered by a Board of Directors whose members fulfill their function *pro bono*. Except as provided in article 16 below, the Board shall have fifteen members, each elected for a period of six (6) years. Unless the present Constitution provides otherwise, a Board member may serve for no more than two consecutive terms of six years each.

To the extent possible and taking into account the relative representation of the various scientific fields among the membership of the Alliance, the Board shall include at least two members from the following scientific fields: Human Vaccines, Human Biotherapeutics, Cell & Gene Therapy and Veterinary Biologicals. No Member Organization is entitled to be represented by more than one person on the Board and Individual Members must strictly represent only their own personal views.

Unless the present Constitution provides otherwise, any Individual Member or Representative of a Member Organization in good standing may be nominated as a candidate for election to the Board by five Alliance members or two members of the Board.

The election of the members of the Board shall be carried out by postal or electronic vote among all Member Organizations and Individual members of the Alliance. A vote is valid if a quorum of at least five percent (5%) of such members submits a ballot. If less than five percent (5%) of such members submit a ballot, a second vote shall be announced. The vote must not be earlier than one month and not later than two months after the announcement has been sent to the membership. A paper or electronic ballot shall be sent to such members by the Secretary or the President.

In the event of a vacancy occurring on the Board during a Board member's term of office, the vacancy may be filled by a nominee of the Board for the remaining portion of the defaulting Board member's six-year term. The Secretary may receive nominations proposals for a replacement member from one or more Board members three weeks in advance of a Board meeting. These nominations proposals shall be sent to Board members with the regular Board meeting agenda, to be voted upon at the next Board meeting.

Approval of the nominee shall be documented by the Secretary and communicated to the Board and the membership. The time served by the Board member filling the vacancy shall not count towards the maximum consecutive number of terms of office as specified above.

Resignation from the Board must be in writing and received by the Secretary. A Board member may be removed for excess absences from the Board if she/he has two unexcused absences from Board meetings in a year. A Board member may be removed for other reasons by a three fourths vote of the remaining Board members.

The Board is responsible for ensuring that the Alliance's goals are respected and that all of its activities are undertaken in a satisfactory manner. The Board also is responsible for ensuring that the present Constitution is properly applied and that the Alliance's assets, including its income, are adequately employed.

The Board shall review the annual accounts of the Alliance and submit these every two years to the General Assembly for ratification.

The Board decides upon the admission and expulsion of members in accordance with the present Constitution. The Board has the discretion to refuse new members and/or to limit the number of Individual Members and/or of Member Organizations if it deems the interests of the Alliance and/or the balance of its membership require doing so.

### **Article 15**

The Board shall meet face-to-face or by teleconference or videoconference at least twice a year, and at such other times as the activities of the Alliance require.

The Board shall be convened by the President with at least 14 days advance notice, except if urgent matters warrant a shorter notice. The form, time and place of the meeting shall be determined by the President and notified by the Secretary. The Board may also be convened with the same advance notice by the Secretary upon the request of either three members of the Board or of thirty members of the Alliance. In all cases, the initiator(s) of such special meeting shall specify its purpose(s) and such purpose(s) shall be set forth in the notice of the meeting.

A member voting by proxy shall give his/her representative, who shall be a member of the Board, an authorization to vote on his/her behalf. The Secretary shall be notified in writing of such authorization prior to the Board meeting.

A decision by a majority of the Board shall be valid if a quorum of at least ten Board members takes part in person or are represented by proxy. The President shall have the deciding vote if the number of votes cast is equal.

Upon being proposed by the President or by at least three members of the Board and provided that all members of the Board agree to this procedure, a decision may be taken by correspondence, including fax or electronic mail.

Once the agreement of all the Board members has been ascertained, the decision to be taken is communicated to all the members for their vote. With regard to quorum, majority and casting vote, the decision by correspondence is governed by the same rules as a vote made during a meeting.

#### **Article 16**

The Board shall elect the following Officers from among its members, each for a term of two years:

- The President
- The Vice President for Human Biologicals
- The Vice President for Veterinary Biologicals
- The Executive Director
- The Secretary
- The Treasurer

The President is expected to serve as the Immediate Past President at the conclusion of his/her term as President. The Immediate Past President shall serve in this capacity and be an ex officio member of the Board for a term of two years, which may be in addition to his regular six-year term(s) as member of the Board. In that instance, he or she shall be a sixteenth (16th) member of the Board.

One of the two Vice Presidents ordinarily will be elected to the Presidency.

The President and Vice Presidents may serve in the same office for no more than three consecutive terms of two years each. The other Officers are not limited in the number of terms they can serve.

#### **Article 17**

The Board shall delegate the daily planning and implementation of the Alliance's various activities to the following bodies, which shall act in accordance with the functions attributed to them by the present Constitution: a) the Executive Committee, and b) the other standing committees established according to their competencies as listed in Appendix 1 hereto.

#### **Article 18**

In order to ensure the ongoing administrative functions of the Alliance, to disseminate information and to coordinate the Alliance's activities, the Board shall maintain a Secretariat. The Secretary and one other officer, selected by the Board, shall manage the Secretariat with the support of the Executive Committee, which shall be authorized to make decisions with regard to the engagement of permanent staff for the secretariat as well as concerning the day-to-day supervision and running of the secretariat, within the limits of the approved budget.

### **VI. OFFICERS**

#### **Article 19**

The Board may approve reasonable compensation to some of the officers and members of the Alliance for their function and activity, in addition to reasonable expenses, as specified in internal guidance documents.

The President shall preside over the meetings of the General Assembly, the Board and the Executive Committee. He/she shall represent the Alliance in negotiations with external bodies, but may delegate those responsibilities to other appropriate members of the Alliance when it is in the interest of the Alliance to do so. The President directs the activities of the Alliance and takes all appropriate steps to implement, the decisions of the General Assembly and of the Board. In doing so, he shall be assisted by the Executive Committee. If the President resigns during his/her term of office, he/she shall be considered also to have resigned from the Immediate Past President position.

The Immediate Past President shall assist the President, Executive Committee and Board as required.

The two Vice Presidents shall assist the President in the execution of his/her duties, and one of the two Vice Presidents shall preside at meetings of the Alliance, including the Board and Executive Committee meetings, in the President's absence.

The Secretary shall report to the General Assembly regarding the administration of the Alliance. He/she also shall be responsible for recording the Minutes of meetings of the General Assembly, the Board and the Executive Committee..

The Treasurer shall be responsible for the financial administration of the Alliance including the implementation of the financial decisions of the Executive Committee, the preparation of the budget, and the statement of audited accounts for presentation at the General Assembly. The treasurer shall assist in the preparation of the budget, help develop fundraising plans, and make financial information available to Board members and the public. The Treasurer shall present a report at each Board meeting.

If a vacancy arises among the Officers during such Officer's term of office, the Board shall elect one of its members to serve in that Officer's position until the end of the defaulting Officer's term of office. Time served to fill a vacancy does not count towards the maximum number of consecutive terms. In case of a vacancy in the Immediate Past President position, the vacancy shall not be filled.

## **VII. THE EXECUTIVE COMMITTEE**

### **Article 20**

The Executive Committee is constituted by the President, the Immediate Past President, the Secretary, the two Vice Presidents, the Treasurer, and the Executive Director. The Executive Committee shall be presided over by the President or in his absence by one of the two Vice Presidents.

The Executive Committee shall have all of the powers and authority of the Board of Directors for the day-to-day operations of the Alliance in the intervals between meetings of the Board of Directors, subject to any limitations that may stem from decisions of the Board. This includes the authority to make decisions with regard to the engagement of permanent staff for the Secretariat as well as concerning the day-to-day supervision and running of the secretariat, within the limits of the approved budget.

The Executive Committee shall approve the programme of activities and coordinate the activities of the different committees that are established by the Board and listed in Appendix 1 hereto.

The Executive Committee may meet by teleconference or in person and make decisions at its meetings or by email. All decisions shall be documented by the Secretary in the minutes. All decisions made by the Executive Committee must be unanimous and made by an affirmative vote of all of its members. The Executive Committee shall meet whenever requested by the President with reasonable advance notice.

A summary of the Executive Committee's activities will be contained in the general report made to the General Assembly by the Secretary.

## **VIII. OTHER COMMITTEES**

### **Article 21**

The Board may create committees as needed. The current committees and their functions are listed in Appendix 1 hereto, which the Board is entitled to update whenever relevant.

Each committee established by the Board shall be under the responsibility of a chairman appointed by the Board. At the start of each calendar year, the chairman shall submit to the Executive Committee for approval an activity report for the past year as well as an action plan and a budget for the new year. Each committee shall have as many members as necessary. The Board has the right to dismiss a committee chairman or an entire committee, if, in the view of the Board, the chairman or the committee fails to meet its responsibilities, or for other reasons that are in the interest of the Alliance.

## **IX. AUDITORS**

## **Article 22**

Two auditors shall be appointed by the Executive Committee and report to the General Assembly. Only the General Assembly may dismiss the auditors.

## **X. COMMITMENT BY SIGNATURE**

### **Article 23**

The signature of two of the following: the President, the Secretary or the Treasurer, shall constitute a valid and binding commitment of the Alliance towards third parties.

## **XI. SOURCES OF INCOME**

### **Article 24**

The Alliance's income shall be derived from:

- A. Members' dues and donations
- B. Grants which it may receive
- C. Gifts or legacies which it may receive
- D. Scientific conferences and publications
- E. Other sources

## **XII. CHANGES TO THE CONSTITUTION AND DISSOLUTION OF THE ASSOCIATION**

### **Article 25**

Proposals for changes to the Constitution shall be submitted to the General Assembly by the Board. At least three members of the Alliance shall be required to petition the Board to submit such proposals to the General Assembly. The text of such proposed changes shall be sent to the Secretary at least two months before the General Assembly.

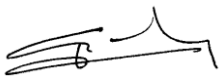
Changes to the Constitution must be approved by a two-thirds majority of the quorum of members voting at the General Assembly.

### **Article 26**

The Alliance may propose its dissolution by notice in the Agenda of the General Assembly. Such decision shall be taken by the General Assembly voting by secret ballot. The result of the vote shall be communicated to all members of the Alliance in writing.

After all liabilities have been met, the balance of monies remaining shall be credited to one or more scientific organizations concerned with medical biology. The choice of such a body or bodies shall be made by the General Assembly, to which the Board shall submit its proposals in this connection.

**This Constitution was approved on September 28<sup>th</sup>, 2014  
by the General Assembly at its 30<sup>th</sup> Meeting, Strasbourg, France**



**Daniel Gaudry**  
Secretary



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**APPENDIX 1 OF THE CONSTITUTION OF THE  
INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION**

**STANDING COMMITTEES**

**Section 1: Organization of Committees**

Unless provided otherwise in the Constitution of the IABS:

- The Chairmen and Vice-chairmen of all committees shall be appointed by the Board
- The Chairman of each Committee, other than the Strategic Advisory Committee, shall decide on the number of members of such committee and appoint the members with the approval of the Executive Committee;

**Section 2: The Scientific Conference Committees**

The scientific activities of the Alliance shall be the responsibility of the Scientific Conference Committees, representing special interests within the fields of Human Biologicals and Veterinary Biologicals.

Any Individual Member or representative of a Member Organization of the Alliance in good standing may be appointed as chairman of a Scientific Conference Committee.

The Chairman of the relevant committee shall be responsible for the organization of scientific conferences and will be assisted by the Scientific Secretariat. This responsibility includes the selection of the local meeting coordinator (if needed), the selection of a scientific committee, the budget and the overall preparation of the meeting, including the publication of proceedings. The decision of the venue of the meeting shall be taken by the Executive Committee after presentation of the preliminary scientific program and budget.

The Vice Presidents shall report to the General Assembly regarding the scientific activities undertaken by the Scientific Conference Committees.

**Section 3: The Alliance Development Committee**

The Alliance Development Committee (ADC) is responsible for building working relationships with nonprofit, government and commercial organizations that have an interest in Biologicals. Subcommittees of the ADC shall include: 1) Governmental, and 2) Non-governmental organizations. The chairman of the ADC shall be responsible for coordinating the activities of the subcommittees and for providing overall strategic direction to the activities of the committee.

The Strategic Advisory Committee shall be composed of 18 members representing special interests within the fields of Human Biologicals and Veterinary Biologicals. The Alliance Development Committee shall propose members of the Strategic Advisory Committee to the Board for its consideration, and the Board shall appoint the members of the Committee.

Any Individual Member or representative of a Member Organization of the Alliance in good standing may be appointed as chairman of the Strategic Advisory Committee.

**Section 5. The Publications Committee**

The Publication activity of the Alliance shall be the responsibility of the Publications Committee.

Any Individual Member or representative of a member organization of the Alliance in good standing may be appointed as Chairman of the Publications Committee.

At the beginning of each calendar year, the Chairman shall submit to the Executive Committee for approval a list of the Publications, which are planned for the following year together with a budget. The Chairman will then be responsible for achieving each Publication upon schedule and within the budget as well as for marketing the Publications in conjunction with the Alliance's publishers. The Chairman shall report to the General Assembly regarding the publications activities undertaken.

**APPENDIX 2 OF THE CONSTITUTION OF THE  
INTERNATIONAL ALLIANCE FOR BIOLOGICAL STANDARDIZATION**

**AFFILIATES**

1. **IABS-EU (International Alliance for Biological Standardization – Europe)**  
World Trade Center (WTC)  
10-12 Boulevard Vivier Merle  
69393 Lyon Cedex 03