
REGULATION

From the Ministry of Food, Agriculture and Livestock:

REGULATION ON THE WORKING PROCEDURES AND PRINCIPLES OF RISK ASSESSMENT**COMMITTEES AND COMMISSIONS****SECTION ONE****Objective, Scope, Legal Basis and Definitions****Objective**

ARTICLE 1 – (1) The objective of the present Regulation is to formulate committees and commissions on the basis of individual specialization to conduct risk assessments, in matters with a direct or indirect influence on food and feed safety, in an independent, impartial and transparent manner in line with scientific principles and also by taking into consideration the protection of animal health and welfare, plant health and environment for the final aim of ensuring maximum protection for human health; to establish a Consultative Committee for exchange of information and opinions on such matters; and to define the working procedures and principles of the aforementioned bodies.

Scope

ARTICLE 2 – (1) The present Regulation covers the establishment of the Consultative Committee and risk assessment committees and commissions along with their duties and authorities and working procedures and principles.

(2) The present Regulation does not cover the provisions of the Regulation on Working Procedures and Principles of Biosafety Boards and Committees published on the Official Gazette dated 13/8/2010 and No. 27671.

Legal Basis

ARTICLE 3 – (1) The present Regulation was prepared on the basis of Articles 26 and 43 of the Law dated 11/6/2010 and No. 5996 on Veterinary Services, Plant Health, Food and Feed.

Definitions

ARTICLE 4 – (1) For the purposes of this Regulation, the following definitions shall apply:

- a) Minister: The Minister of Food, Agriculture and Livestock,
- b) Ministry: The Ministry of Food, Agriculture and Livestock,
- c) Scientific Commission: The commission established to conduct risk assessment in matters with a direct or indirect influence on food and feed safety,
- c) Scientific Committee: The committee established to conduct risk assessment in matters with a direct or indirect influence on food and feed safety that are not included in the area of responsibility of any scientific commission or that are multisectoral matters falling under the scope of more than one scientific commission.

- d) External Expert: Experts not included in the Database of Experts,
- e) General Directorate: The General Directorate of Food and Control,
- f) Consultative Committee: The platform for the exchange of information and opinions on potential risks that have arisen and/or may arise with relation to matters with a direct or indirect influence on food and feed safety,
- g) Risk: The functional relationship between a hazard that may create a negative effect on health and its severity,
- g) Risk analysis: The process comprising three interrelated components, namely risk assessment, risk management and risk communication,
- h) Risk assessment: A scientifically based process consisting of hazard identification, hazard characterisation, exposure assessment and risk characterisation,
- i) Risk communication: The interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions,
- i) Risk management: The process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options,
- j) Hazard: A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect,
- k) Database of Experts: The database including areas of expertise and contact details of experts for the purpose of providing scientific and technical expertise support as required for risk assessment activities performed in matters with a direct or indirect effect on food and feed safety.

SECTION TWO

General provisions, Consultative Committee, Scientific Commissions

Scientific Committee and Database of Experts

General provisions

ARTICLE 5 – The Ministry shall establish a Consultative Committee, a Scientific Committee, Scientific Commissions and a Database of Experts for the performance of the duties specified in the present Regulation in matters with a direct or indirect influence on food and feed safety.

(2) Applications regarding the matters requested to be brought before the Scientific Committee and Scientific Commissions for risk assessment shall be lodged at the General Directorate.

(3) The secretariat of the Consultative Committee, Scientific Committee and Scientific Commissions shall be

undertaken by the General Directorate.

(4) The results of risk assessment activities carried out by the Scientific Committee shall be of an advisory nature.

(5) Members of the Scientific Committee and Scientific Commissions and experts included in the Database of Experts shall act independently in the performance of their duties under this Regulation and shall not receive instructions from any authority, body or person.

(6) Members of the Scientific Committee and Scientific Commissions may not transfer their authorities or responsibilities to another member or a third party.

(7) Members of the Scientific Committee and Scientific Commissions and experts included in the Database of Experts shall yearly submit to the General Directorate the general letter of undertaking, given in Annex-1, declaring their independence and impartiality in the performance of the duties under this Regulation.

(8) Members of the Scientific Committee and Scientific Commissions and experts included in the Database of Experts and external experts shall complete the specific letter of commitment given in Annex-2 declaring their independence and impartiality with relation to the agenda items of each meeting in which they will participate within the scope of their respective fields of expertise and submit the aforementioned letter to the General Directorate before each meeting. A member declaring a relationship of interest in Annex-2 with relation to the matters covered by a meeting agenda may not participate in the respective section of the meeting in question.

(9) If a member fails to participate three consecutive meetings in a calendar year without a valid excuse, their membership to the Scientific Committee and/or Scientific Commission shall be regarded null and void. A member whose duty has been terminated by any reason including the declaration of the membership to be null and void, withdrawal from membership or death shall be replaced by a new member approved by the Minister in a maximum period of one month. The term of duty of the new member shall expiry concurrently with that of other members.

(10) The authority to release a scientific statement to the public opinion with relation to matter or matters subject to risk assessment on behalf of the Ministry and as deemed appropriate by the Ministry shall rest either with the Chairman of the Scientific Committee or a member of the Scientific Committee assigned thereby.

(11) The Ministry may participate in the meetings of the Scientific Committee or the Scientific Commissions as an observer or with the aim of making a statement on an issue relevant to the meeting agenda. However, the Ministry may not be present for or interfere in the decision-making process. No representative other than Ministerial experts may participate in the meetings of the Scientific Committee or the Scientific Commissions as an observer.

(12) In case of crises threatening food and feed safety directly or indirectly, emerging at the instant, creating public indignation and requiring the immediate formation of scientific opinion, if there is no possibility for the members of the Scientific Committee or Scientific Commissions to convene for a meeting, the opinions of the members of the Scientific Committee or Scientific Commissions may be gathered in the electronic format through the

secretariat and a final opinion may be formulated with the agreement of simple majority.

(13) The Ministry may publish the scientific opinions of the Scientific Committee or Scientific Commissions on its Website.

(14) The General Directorate may cooperate with national or international organizations of a similar scope performing risk assessment in matters falling under the scope of the present Regulation.

Establishment, duties and authorities and working procedures and principles of the Consultative Committee

ARTICLE 6 – (1) The membership of the Consultative Committee shall consist of one representative each from the General Directorate departments responsible for animal health and welfare, plant health and food and feed safety; the General Directorate of Agricultural Research and Policies; the Ministry of Environment and Urban Planning; the Ministry of Economy; the Ministry of Customs and Trade; the Ministry of Interior; the Ministry of Forestry and Water Affairs; the Ministry of Health; Turkish Radio and Television Corporation; the Scientific and Technological Research Council of Turkey; the Union of Chambers and Commodity Exchanges of Turkey; the Confederation of Turkish Tradesmen and Craftsmen; the Chamber of Food Engineers; the Chamber of Agricultural Engineers; the Chamber of Chemical Engineers; Turkish Veterinary Medical Association; Turkish Medical Association; non-governmental organizations active in food and feed industries with the highest number of members; the non-governmental organization active in the protection of consumers with the highest number of members; and other agencies and institutions deemed appropriate by the Ministry.

(2) Public agencies and institutions shall participate in the Consultative Committee with representatives at least at the Department Head level from departments responsible for the matters covered by the scope of the present Regulation.

(4) The Consultative Committee shall be chaired by the General Director of Food and Control.

(4) The Consultative Committee shall exchange information and opinions on potential risks that have arisen and/or may arise with relation to matters with a direct or indirect influence on food and feed safety.

(5) The Consultative Committee shall put forth requests and proposals on risk assessment in matters with a direct or indirect influence on food and feed safety. Such requests and proposals shall be submitted to the Scientific Committee and/or the relevant Scientific Commission through the secretariat.

(6) The Consultative Committee shall convene at least twice a year upon the invitation of the Ministry.

Establishment of Scientific Commissions

ARTICLE 7 - (1) The Ministry shall establish Scientific Commissions to conduct risk assessment in matters with a direct or indirect influence on food and feed safety in an independent, impartial and transparent manner based on scientific principles. The number of members and titles of existing Scientific Commissions may be changed by the Minister upon the proposal of the Scientific Committee in line with technical and scientific developments.

(2) The membership of Scientific Commissions shall consist of representatives of research institutions, research institutes and relevant faculties of universities, as well as other experts as required.

(3) Scientific Commissions shall be formulated with a maximum number of 9 members elected from amongst the candidates gathered through an open call and approved by the Minister.

(4) A member already affiliated with a Scientific Commission may not engage themselves in another Scientific Commission.

(5) The term of duty of the Scientific Commission members shall be three years starting from their inauguration. Following the expiry of the term of duty, the term may be extended for two more consecutive periods if so requested by the member in question and deemed appropriate by the Ministry.

(6) A commission member whose term of duty has expired with their current Commission of affiliation may be assigned to another Scientific Commission or the Scientific Committee if so requested by the member in question and deemed appropriate by the Ministry.

(7) Scientific Commissions shall elect their chairmen and deputy chairmen through secret voting during their first meeting. In the absence of the chairman, the deputy chairman shall represent the Commission Chairmanship. If neither the chairman nor the deputy chairman is available for the meeting, the members of the Scientific Commission in question shall elect a provisional chairman solely for the current meeting. The chairman and deputy chairman shall serve their duties for a term of three years and their term of duty is subject to the possibility of re-election.

Duties, authorities and responsibilities of Scientific Commissions

ARTICLE 8—(1) Duties, authorities and responsibilities of Scientific Commissions are as given below:

a) Scientific Commissions shall conduct risk assessment in matters falling under their respective areas of responsibility upon the request of the Ministry or on their own initiative.

b) Scientific Commissions shall prepare work plans by taking into consideration opinions and proposals submitted by the Consultative Committee and the requests communicated by the Ministry.

c) Scientific Commissions shall formulate and submit to the Ministry scientific opinions of an advisory nature with the aim of supporting the activities of the Ministry or providing information to the public opinion with relation to matters with a direct or indirect influence on food and feed safety.

ç) Scientific Commissions may consult the experts included in the Database of Experts and/or external experts as required.

d) When so deemed necessary, Scientific Commissions shall establish working groups with members from the relevant Scientific Commission and/or Database of Experts and/or, as required, external experts and designate their issues and areas of responsibility. The members of the working groups thus established shall elect a chairman from their own group. The working group shall evaluate the available scientific information and data, prepare a report thereon and submit this report to the relevant Scientific Commission.

Working procedures and principles of Scientific Commissions

ARTICLE 9 – (1) Scientific Commissions shall convene for an agenda with at least 2/3 of its total number of members.

(2) Meeting decisions shall be taken with the simple majority of the members present at the meeting. A protocol shall be issued for the decisions taken.

(3) The chairman shall draw up the draft scientific opinion after meeting(s). Opinions of all members of the Scientific Commission shall be gathered through the secretariat. Any opposing views shall be justified in writing and the final scientific opinion shall be formulated with the simple majority of members. The final scientific opinion shall be submitted to the Ministry by all members together with the justification for objections, if any.

(4) A new scientific opinion may be formulated on the basis of all types of data and scientific information emerging or obtained following the issue of the final opinion.

(5) If a member refuses to sign the decisions and/or opinions of the Scientific Commission despite having not submitted an opposing view by participating in meetings or fails to justify an opposing view they have put forth during a meeting, they shall be warned in writing by the Chairman of the Scientific Commission. If such an incident is repeated for a total number of two times in a calendar year, the membership of the previously warned member shall be withdrawn.

(6) Scientific Commissions shall formulate their scientific opinion on the issue in question in the allocated timeframe and in consultation with the Ministry.

(7) The Ministry may request the re-evaluation of an issue on which a scientific opinion has already been formulated. The Scientific Commission may decline such a request in the absence of information and data that require the re-evaluation of the issue in question.

Formation of the Scientific Committee

ARTICLE 10 – (1) The Scientific Committee shall consist of the Chairmen of Scientific Commissions and 6 independent scientists that are not involved in any Scientific Commission and elected from amongst candidates gathered through an open call.

(2) The members of the Scientific Committee shall be subject to the approval of the Minister.

(3) The term of duty of the Scientific Committee members shall be three years starting from their inauguration. Following the expiry of the term of duty, the term may be extended for two more consecutive periods if so requested by the member in question and deemed appropriate by the Ministry.

(4) The Scientific Committee shall elect its chairman through secret voting from amongst the 6 independent scientists that are not involved in any Scientific Commission and its deputy chairman from amongst the whole membership of the Committee. In the absence of the chairman, the deputy chairman shall represent the Committee Chairmanship. If neither the chairman nor the deputy chairman is available for the meeting, the members of the

Scientific Committee shall elect a provisional chairman solely for the current meeting. The chairman and deputy chairman shall serve their duties for a term of three years and their term of duty is subject to the possibility of re-election.

Duties, authorities and responsibilities of the Scientific Committee

ARTICLE 11 - (1) Duties, authorities and responsibilities of the Scientific Committee are as given below:

a) The Scientific Committee shall be responsible for the general coordination among Scientific Commissions with the aim of ensuring consistency specifically in such matters as the determination of the work system and harmonization of work methods during the formulation of scientific opinions.

b) The Scientific Committee shall prepare work plans by taking into consideration opinions and proposals submitted by the Consultative Committee and the requests communicated by the Ministry.

c) The Scientific Committee shall formulate and submit to the Ministry scientific opinions of an advisory nature with the aim of supporting the activities of the Ministry or providing information to the public opinion with relation to matters with a direct or indirect influence on food and feed safety.

c) The Scientific Committee may consult the experts included in the Database of Experts and/or external experts as required.

d) When so deemed necessary for the risk assessment, the Scientific Committee may define the relevant fields of expertise and establish working groups with members from Scientific Commissions, the Database of Experts and/or, as required, external experts. The members of the working groups shall elect a chairman from their own group. The working group shall prepare a report on the basis of the available scientific information regarding its area of work and submits this report to the Scientific Committee.

e) The Scientific Committee shall submit proposals regarding changes in the number and titles of Scientific Commission to the Ministry in line with technical and scientific developments.

Working procedures and principles of the Scientific Committee

ARTICLE 9 – (1) The Scientific Committee shall convene for an agenda with at least 2/3 of its total number of members.

(2) Meeting decisions shall be taken with the simple majority of the members present at the meeting. A protocol shall be issued for the decisions taken.

(3) The chairman shall draw up the draft scientific opinion after meeting(s). Opinions of all members of the Scientific Committee shall be gathered through the secretariat. Any opposing views shall be justified in writing and the final scientific opinion shall be formulated with the simple majority of members. The final scientific opinion shall be submitted to the Ministry by all members together with the justification for objections, if any.

(4) A new scientific opinion may be formulated as required on the basis of all types of data and scientific information emerging or obtained following the issue of the final opinion.

(5) If a member refuses to sign the decisions and/or opinions of the Scientific Committee despite having not submitted an opposing view by participating in meetings or fails to justify an opposing view they have put forth during a meeting, they shall be warned in writing by the Chairman of the Scientific Committee. If such an incident is repeated for a total number of two times in a calendar year, the membership of the previously warned member shall be withdrawn.

(6) The Scientific Committee shall formulate their scientific opinion on the issue in question in the allocated timeframe and in consultation with the Ministry.

(7) The Ministry may request the re-evaluation of an issue on which a scientific opinion has already been formulated. The Scientific Committee may decline such a request in the absence of information and data that require the re-evaluation of the issue in question.

Database of Experts

MADDE 13 – (1) The General Directorate shall establish a Database including areas of expertise and contact details of experts for the purpose of providing scientific and technical expertise support as required for risk assessment activities performed in matters with a direct or indirect effect on food and feed safety.

(2) The Database of Experts shall compose of experts selected through an open call for candidates from research institutions, research institutes and relevant faculties of universities and, when required, other experts with scientific and technical proficiency.

(3) Experts listed in the Database may be invited to the scientific studies of the Scientific Committee, Scientific Commissions and their working groups as required to provide scientific and/or technical expert support on a certain subject."

(4) The listing of Experts in the Database shall be continued as long as they submit the Letter of Undertaking, declaring their independence and impartiality, given in Annex-1 to the Ministry at the beginning of each calendar year.

SECTION THREE

Secretariat, Prohibitions and Confidentiality, Financial Provisions

Duties of the Secretariat

ARTICLE 14 – (1) The duties of the Secretariat are as follows:

a) Undertaking the secretariat affairs of the Advisory Committee, Scientific Committee and Scientific Commissions,

b) Communicating opinions and proposals submitted by the Advisory Committee and requests submitted by the Ministry to the relevant Scientific Committee and/or Scientific Commission depending on their specialization for the preparation of work plans.

c) Collecting the Letters of Undertaking given in Annex-1, Annex-2 and Annex-3 from the members of the Scientific Committee and Scientific Commissions and from experts participating in meetings.

c) Announcing the calls for the meetings of the Advisory Committee, Scientific Committee and Scientific Commissions,

d) Communicating the requests submitted to the Ministry on matters requiring risk assessment to the Scientific Committee and Scientific Commission and providing information on the relevant legislation,

e) Preparing meeting agendas in line with the requests submitted by the Ministry and the opinions and proposals received from the Advisory Committee by taking into consideration the opinions of the Chairmen of the Scientific Committee and Scientific Commissions and submitting the agendas to the members in writing and/or in the electronic format at least one week before scheduled meetings,

f) Preparing the minutes pertaining to the meeting decisions of the Scientific Committee and Scientific Commissions.

g) Preparing the minutes pertaining to the meetings of the Advisory Committee.

ğ) Assisting the Chairmen of the Scientific Committee and Scientific Commissions in the preparation of draft opinion before the formulation of the final scientific opinion,

h) Ensuring the communication and coordination for the provision of the information and documents requested by the Scientific Committee and Scientific Commissions from the relevant public agencies and institutions.

ı) Ensuring communication and coordination among the Advisory Committee, Scientific Committee and Scientific Commissions.

Prohibitions and confidentiality

ARTICLE 15 - (1) The members of the Scientific Committee and Scientific Commissions and all experts participating in the meetings of committees and commissions shall submit the Confidentiality Declaration, given in Annex-3, to the General Directorate.

(2) The members of the Scientific Committee and Scientific Commissions and all experts participating in the meetings of committees and commissions may not disclose the information and documents and commercial, scientific and technical secrets of agencies and institutions they may come to know by reason of their duties and they may neither use nor allow the use by others of such information for or against themselves or third parties even if they have left their post.

(3) The Ministry may not disclose any third-party information for which a request for confidentiality has been made, along with a justification, during the risk assessment procedure. However, information pertaining to facts that do or may constitute a threat to public health is outside the above-mentioned scope.

Travelling allowance and fees

ARTICLE 16--(1) The travelling allowances of experts participating in meetings for the duties to be performed under the present Regulation shall be covered by the Ministry in line with the provisions of the Allowance Law dated 10/2/1955 and No. 6245.

SECTION FOUR

Final Provisions

Effectiveness

ARTICLE 17- (1) The present Regulation shall enter into effect as of its date of publication.

Execution

ARTICLE 18- (1) The present Regulation shall be executed by the Minister of Food, Agriculture and Livestock.