

chapter. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the entry of the order constitutes a waiver under FFDCA section 408(i) or 409(g)(1) of the right to judicial review of the order and of any regulation promulgated by the order.

§ 178.70 Administrative record.

(a) For purposes of judicial review, the record of an administrative proceeding that culminates in an order under § 178.37 consists of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under § 177.125 of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(3) Any order issued under § 177.130 of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(4) Any order issued under § 180.7(g) of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(5) Any order issued under § 180.29(f) of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(6) Any comments submitted by members of the public in response to the Notice of Filing or Notice of Proposed Rulemaking, any data or information submitted as part of the comments, the Administrator's response to

comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(7) All other documents or information submitted to the docket for the rulemaking in question.

(8) The order issued under § 178.37.

(b) The record will be closed as of the date of the Administrator's decision unless another date for closing of the record is specified in the order issued under § 178.37.

PART 179—FORMAL EVIDENTIARY PUBLIC HEARING

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AUTHORITY: 21 U.S.C. 346a, 348, 371(a); Reorg. Plan No. 3 of 1970.

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Subpart A—General Provisions**§ 179.3 Definitions.**

Administrator means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator has delegated the authority to perform functions under this part.

Agency means the United States Environmental Protection Agency.

Assistant Administrator means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of OPPTS to whom the Assistant Administrator has delegated the authority to perform functions under this part.

FFDCA means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136–136y.

Judicial Officer means a person who has been designated by the Administrator under § 179.117 to serve as a judicial officer.

Office of the Administrator means the Agency's Administrator and Deputy Administrator and their immediate staff, including the judicial officer.

OPPTS means the Agency's Office of Prevention, Pesticides and Toxic Substances.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

§ 179.5 Other authority.

Questions regarding procedural matters arising under this part or part 178 of this chapter that are not addressed by this part or part 178 of this chapter shall be resolved by the Administrator or presiding officer, as appropriate.

Subpart B—Initiation of Hearing**§ 179.20 Notice of hearing.**

(a) If the Administrator determines under § 178.32 of this chapter that a hearing is justified on any issue, the Administrator will file with the hearing clerk and publish in the FEDERAL REGISTER a Notice of Hearing. The Notice of Hearing will set forth:

(1) The docket number for the hearing.

(2) Each order, regulation, or petition denial that is the subject of the hearing, and a statement specifying any part of any such regulation or order that has been stayed in the Administrator's discretion.

(3) The identity of each person whose request for a hearing has been granted, and of any other person whose petition under § 177.81 or § 180.7 of this chapter occasioned the order that the hearing concerns.

(4) A statement of the issues of fact on which a hearing has been found to be justified.

(5) A statement of the objections whose resolution depends on the resolution of those issues of fact.

(6) A statement that the presiding officer will be designated by the Chief Administrative Law Judge.

(7) The time within which notices of participation should be filed under § 179.42.

(8) The date, time, and place of the preliminary conference, or a statement that the date, time, and place will be announced in a later notice, and the place of the hearing.

(9) The time within which parties must submit written information and views under § 179.83.

(10) Designations with respect to separation of functions published under § 179.24(b)(2).

(b) The statement of the issues of fact on which a hearing has been justified determines the scope of the hearing and the matters on which evidence

may be introduced. The issues may be revised by the presiding officer. A party may obtain interlocutory review by the Administrator of a decision by the presiding officer to revise the issues to include an issue on which the Administrator has not granted a request for a hearing or to eliminate an issue on which a request for a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the Notice of Hearing.

§ 179.24 Ex parte discussions; separation of functions.

(a) Any person may meet or correspond with any officer or employee of the Agency concerning a matter under parts 177, 178, or 180 of this chapter prior to publication of a Notice of Hearing under § 179.20.

(b) Upon publication of a Notice of Hearing, the following separation of function rules apply:

(1) OPPTS, as a party to the hearing, is responsible for presentation of its position at the hearing and in any pleading or oral argument before the Administrator. The Pesticides and Toxic Substances Division of the Office of General Counsel shall advise and represent OPPTS with respect to the hearing and in any pleading or oral argument before the Administrator. An employee or other representatives of OPPTS may not participate in or advise the Administrator or any of his representatives on any decision under this part, other than as witness or counsel in public proceedings, except as provided by paragraph (b)(2) of this section. There is to be no other communication between representatives of OPPTS and the presiding officer or any representative of the Office of the Administrator concerning the merits of the hearing until after issuance of the decision of the Administrator.

(2) The Administrator may designate persons who otherwise would be regarded as representatives of OPPTS, to serve as representatives of the Office of the Administrator on matters pertaining to the hearing, and may also designate persons who otherwise would be regarded as representatives of the Office of the Administrator to serve as representatives of OPPTS. Such des-

ignations will be included in the Notice of Hearing published under § 179.20.

(3) The Office of the Administrator is responsible for the final decision of the matter, with the advice and participation of anyone in the Agency other than representatives of OPPTS.

(c) Between the date of publication of the Notice of Hearing and the date of the Administrator's final decision on the matter, communication concerning the matter involved in the hearing will be restricted as follows:

(1) No person outside the Agency may have an ex parte communication with the presiding officer or any representative of the Office of the Administrator concerning the merits of the hearing. Neither the presiding officer nor any representative of the Office of the Administrator may have any ex parte communication with a person outside the Agency concerning the merits of the hearing.

(2) A written communication contrary to this section must be immediately served on all other participants and filed with the hearing clerk by the presiding officer at the hearing, or by the Administrator, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other parties and filed with the hearing clerk. A person, including a representative of a party in the hearing, who is involved in an oral communication contrary to this section, must, to the extent necessary to determine the substance of the communication, be made available for cross-examination during the hearing with respect to the substance of that communication. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted.

(d) The prohibitions specified in paragraph (c) of this section also apply to a person who, in advance of the publication of a Notice of Hearing, knows that the notice has been signed. The prohibitions become applicable to such a person as of the time the knowledge is acquired.

(e) The making of a communication contrary to this section may, consistent with the interests of justice and

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the policies underlying the FFDCa, result in a decision adverse to the person knowingly making or causing the making of the communication.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart C—Participation and Appearance; Conduct

§ 179.42 Notice of participation.

(a) OPPTS shall be a party to a hearing under this part. Any other person may participate as a party in such a hearing to the extent specified by this section.

(b) A person desiring to participate in a hearing must file with the hearing clerk within 30 days after publication of the Notice of Hearing under § 179.20, a Notice of Participation in the following form:

NOTICE OF PARTICIPATION

Docket No. _____
Under 40 CFR part 179, please enter the participation of: _____

(Name) _____

(Street address) _____

(City and State) _____

(Telephone number) _____

Service on the above will be accepted by:

(Name) _____

(Street address) _____

(City and State) _____

(Telephone number) _____

Signed: _____

Date: _____

(c) An amendment to a Notice of Participation must be filed with the hearing clerk and served on all parties.

(d) No person may participate in a hearing who has not filed a written Notice of Participation or whose participation has been stricken under paragraph (f) of this section.

(e) The presiding officer may permit the late filing of a Notice of Participation upon a showing of good cause. Arrangements and agreements previously made in the proceeding shall apply to any party admitted late.

(f) The presiding officer may strike the participation of a person for failure to comply with any requirement of this subpart. Any person whose participation is stricken may obtain interlocu-

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tory review thereof by the Administrator.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

§ 179.45 Appearance.

(a) A party to a hearing may appear in person or by counsel or other representative in the hearing.

(b) The presiding officer may strike a person's right to appear in the hearing for violation of the rules of conduct in § 179.50.

§ 179.50 Conduct at oral hearings or conferences.

The parties and their representatives must conduct themselves with dignity and observe the same standards of practice and ethics that would be required of parties in a judicial proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing constitute grounds for immediate exclusion from the proceeding by the presiding officer.

Subpart D—Presiding Officer

§ 179.60 Designation and qualifications of presiding officer.

The presiding officer in a hearing will be an administrative law judge qualified under 5 U.S.C. 3105 and designated by the Agency's chief administrative law judge.

§ 179.70 Authority of presiding officer.

The presiding officer shall conduct the hearing in a fair and impartial manner subject to the precepts of the Administrative Procedure Act. The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to:

(a) Specify and change the date, time, and place for conferences, and issue and modify a schedule for the hearing.

(b) Establish an orderly manner for developing evidentiary facts at preliminary conferences under § 179.87, for making rulings on oral testimony and

cross-examination under § 179.93, and for making other similar evidentiary rulings in accord with these regulations.

(c) Prepare statements of the areas of factual disagreement among the participants.

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing.

(e) Administer oaths and affirmations.

(f) Control the course of the hearing and the conduct of the participants.

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions.

(h) Rule on, admit, exclude, or limit evidence.

(i) Set the time for filing pleadings.

(j) Rule on motions and other procedural matters.

(k) Rule on motions for summary decision under § 179.90.

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex.

(m) Strike the participation of any person under § 179.42(f), or exclude any person from the hearing under § 179.50, or take other reasonable disciplinary action.

(n) Take any other action for the fair, expeditious, and orderly conduct of the hearing that is not in conflict with law or these rules.

§ 179.75 Disqualification of deciding officials.

(a) A deciding official in a hearing under this part (including, e.g., the Administrator, judicial officer, or presiding officer) shall not decide any matter in connection with which he or she has a financial interest in any of the parties, or a relationship that would make it otherwise inappropriate for him or her to act.

(b) A party may request that a deciding official disqualify himself/herself and withdraw from the proceeding. The party may obtain interlocutory review by the Administrator of a denial of such a request made to any deciding official other than the Administrator.

(c) A deciding official who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 179.78 Unavailability of presiding officer.

If the presiding officer is unable to act for any reason, his or her powers with respect to the hearing will be assigned by the Chief Administrative Law Judge to another presiding officer. The substitution will not affect the hearing, i.e., the testimony of the witnesses will not be taken anew except as the new presiding officer may order upon the request of a party where the credibility of a witness is of particular importance.

Subpart E—Hearing Procedures

§ 179.80 Filing and service.

(a) All documents required or authorized to be filed by a party to a hearing under this part regarding any matter to be decided by the presiding officer, the judicial officer, or the Administrator shall be filed in triplicate with the hearing clerk, in the manner specified by § 178.25(b) of this chapter. Each filing shall prominently note the docket number. To determine compliance with deadlines in a hearing, a document is considered filed on the date it is actually received by the hearing clerk. When this part allows a response by a party to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) Each notice, order, decision, or other document issued under this part by the presiding officer, the judicial officer, or the Administrator shall be filed with the hearing clerk. The hearing clerk shall immediately serve all parties with a copy of such order, decision, or other document.

(c) At the same time that a party files any document with the hearing clerk, the party shall serve a copy thereof on each other party, unless the presiding officer specifies otherwise. Each filing shall be accompanied by a certificate of service, or a statement that service is not required. Service on a party is accomplished by mailing a submission to the address shown in the Notice of Participation or by personal delivery.

(d) The presiding officer may grant an extension of time for the filing of

any pleading, document, or motion (1) Upon timely motion by a party, for good cause shown, and after consideration of prejudice to other parties, or (2) upon the presiding officer's own motion.

(e) A motion by a party for an extension may only be made after serving a copy of the motion on all other parties, unless the movant can show good cause why doing so is impracticable. The motion shall be filed in advance of the date on which the pleading, document, or motion is due to be filed, unless the failure of the party to make a timely motion for an extension was the result of excusable neglect.

§ 179.81 Availability of documents.

(a) All orders, decisions, pleadings, transcripts, exhibits, and other docket entries shall become part of the official docket and shall be retained by the hearing clerk. Except as otherwise provided by paragraph (b) of this section or part 2 of this chapter, all documents that are a part of the official docket shall be made available to the public for reasonable inspection during Agency business hours. Copies of such documents may be obtained by members of the public as provided in part 2 of this chapter.

(b) Whenever any information or data are required to be produced or examined in a hearing and any party makes a business confidentiality claim regarding such information under part 2 of this chapter, the availability of such information to the other parties or to the public shall be determined by EPA in accordance with part 2 of this chapter, including specifically the procedures and principles set forth in § 2.301(g)(3) and (g)(4) of this chapter. The presiding officer shall make the determinations with respect to the matters referred to in § 2.301(g)(3) and (g)(4) to the extent provided, and shall take such steps as are necessary for the protection of information entitled to confidential treatment or otherwise exempt from public disclosure, including issuance of protective orders to parties or taking testimony in a closed hearing.

§ 179.83 Disclosure of data and information.

(a) Within 60 days of the publication of the Notice of Hearing under § 179.20, or, if no party will be prejudiced, within another period set by the presiding officer, the Assistant Administrator shall file with the hearing clerk, in accordance with § 179.80, the following documents numbered and organized in the manner prescribed by the presiding officer:

(1) The portions of the administrative record of the proceeding developed under part 178 of this chapter, and under parts 177 or 180 of this chapter, that are relevant to the issues in the hearing.

(2) All documents in the files of OPPTS containing factual information or expert opinion, whether favorable or unfavorable to the position of OPPTS, which relate to the issues involved in the hearing. For purposes of this paragraph, "files" means the principal files in OPPTS in which documents relating to each of the issues in the hearing are ordinarily kept. Documents that are internal memoranda reflecting the deliberative process, or are attorney work product, or were prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information upon which OPPTS plans to rely upon in the hearing.

(4) A narrative position statement on the factual issues in the Notice of Hearing and the nature of the supporting evidence that OPPTS intends to introduce.

(5) A signed statement that, to the best knowledge and belief of the Assistant Administrator, the submission complies with this section.

(b) Within 70 days of the publication of the Notice of Hearing or, if no party will be prejudiced, within another period of time set by the presiding officer, each party other than OPPTS shall submit to the hearing clerk in accordance with § 179.80 the following documents, numbered and organized in the manner prescribed by the presiding officer:

(1) Any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete.

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(2) All documents (other than those filed under paragraph (a) of this section) in the party's files containing factual information or expert opinion, whether favorable or unfavorable to the party's position, that relates to the issues involved in the hearing. For purposes of this paragraph, "files" means the party's principal files in which documents relating to each of the issues in the hearing are ordinarily kept. Documents that are attorney work product, or were prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information the party plans to rely upon in the hearing.

(4) A narrative position statement on the factual issues in the Notice of Hearing and the nature of the supporting evidence the party intends to introduce.

(5) A signed statement that, to the best knowledge and belief of the party, the submission complies with this section.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known by or available to the party when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen.

(d) If a party fails to comply substantially and in good faith with this section, the presiding officer may infer that such failure was for the purpose of withholding information that is unfavorable to the party's position, and may make such further adverse inferences and findings with respect to such failure as are warranted.

(e) Parties may reference each other's submissions. To reduce duplicative submissions, parties are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

§ 179.85 Purpose of preliminary conference.

The presiding officer will conduct one or more preliminary conferences for the following purposes:

(a) To determine the areas of factual disagreement to be considered at the hearing.

(b) To establish any necessary procedural rules to control the course of the hearing and the schedule for the hearing.

(c) To group parties with substantially similar interests, for purposes of presenting evidence, making objections, cross-examination, and presenting oral argument.

(d) To obtain stipulations and admissions of facts.

(e) To take other action that may expedite the hearing.

§ 179.86 Time and place of preliminary conference.

A preliminary conference will commence at the date, time, and place announced in the Notice of Hearing, or as otherwise specified by the Administrator or presiding officer in a subsequent notice. The preliminary conference may not commence until after expiration of the time for filing notices of participation under § 179.42. The presiding officer may specify that two or more such conferences shall be held.

§ 179.87 Procedures for preliminary conference.

Parties in a hearing must appear at the preliminary conference(s) prepared to present a position on the matters specified in § 179.85. A preliminary conference may be held by telephone, or other electronic means, if appropriate.

(a) To expedite the hearing, parties are encouraged to prepare in advance for the conference. Parties should cooperate with each other and should request information and begin preparation of testimony at the earliest possible time. Failure of a party to appear at the preliminary conference or to raise matters that could reasonably be anticipated and resolved at that time

will not delay the progress of the hearing, and constitutes a waiver of the rights of the party regarding such matters as objections to the agreements reached, actions taken, or rulings issued. Such failure to appear may also be grounds for striking the party's participation under § 179.42(f).

(b) Each party shall bring to the preliminary conference the following specific information, which will be filed with the hearing clerk under § 179.80:

(1) Any additional information to supplement the submission which may have been filed under § 179.83, and/or which may be filed if approved under § 179.83(c).

(2) A list setting forth each person who has been identified as a witness whose oral or written testimony will be offered by the party at the hearing, with a full curriculum vitae for each and a summary of the expected testimony (including a list of the principal exhibits on which the witness will rely) or a statement as to when such a summary will be furnished. A party may amend its witness and document list to add, delete, or substitute witnesses or documents.

(c) The presiding officer may hold preliminary conferences off the record in an effort to reach agreement on disputed factual or procedural questions.

(d) The presiding officer shall issue and file under § 179.80 a written order reciting the actions taken at each preliminary conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 179.89 Motions.

A motion, unless made in the course of a preliminary conference or a transcribed oral hearing before the presiding officer, must be filed in the manner prescribed by § 179.80 and include a draft order. A response may be filed within 10 days of service of a motion. The moving party has no right to reply, except as permitted by the presiding officer. The presiding officer shall rule upon the motion.

§ 179.90 Summary decisions.

(a) After the hearing commences, a party may file a written motion, with

or without supporting affidavits or brief, for a summary decision on any issue in the hearing. Any other party may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause shown, serve opposing affidavits or brief or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs if not submitted by the parties.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine disagreement as to any material fact bearing on the issue and that a party is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a party opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must demonstrate specifically that there is a genuine issue of material fact for the hearing.

(d) Should it appear from the affidavits of a party opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If a summary decision is not rendered upon all issues or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A party may obtain interlocutory review by the Administrator of a summary decision of the presiding officer.

§ 179.91 Burden of going forward; burden of persuasion.

(a) The party whose request for an evidentiary hearing was granted has the burden of going forward in the hearing with evidence as to the issues relevant to that request for a hearing.

(b) The party or parties who contend that a regulation satisfies the criteria of section 408 or 409 of the FFDCA has the burden of persuasion in the hearing on that issue, whether the proceeding concerns the establishment, modification, or revocation of a tolerance or food additive regulation.

§ 179.93 Testimony.

(a) The presiding officer will conduct such proceedings as are necessary for the taking of oral direct testimony and for the conduct of oral examination of witnesses by the parties. The presiding officer shall limit oral examination to prevent irrelevant, immaterial or unduly repetitious examination.

(b) Direct testimony shall be submitted in writing, except that the presiding officer may order direct testimony to be presented orally in those unusual cases where the memory or demeanor of the witness is of importance. Written direct testimony shall be in the form of a verified statement of fact or opinion prepared by the witness, in narrative form or in question-and-answer form. Written direct testimony may incorporate exhibits. Such a verified statement or exhibit may not be admitted into evidence sooner than 14 days (or such other reasonable period as the presiding officer may order) after the witness has delivered to the presiding officer and each party a copy of the statement or exhibit. The admissibility of the evidence contained in such a statement is subject to the same rules as if such testimony had been given orally.

(c) Oral cross-examination of witnesses will be permitted. Each exhibit that a party intends to rely upon in cross-examining a witness shall be furnished to the other parties not later than 3 days (or such other reasonable period as the presiding officer may order) before such exhibit is used in the cross-examination.

(d) Witnesses shall give testimony under oath or affirmation.

§ 179.94 Transcripts.

(a) The hearing clerk shall make arrangements to have all oral testimony stenographically reported or recorded and transcribed, with evidence that is admitted in the form of written testimony or exhibits attached or incorporated as appropriate.

(b) Unless the presiding officer orders otherwise, parties shall have 15 days from the date that the transcript of particular oral testimony first becomes available to propose corrections in the transcript of that testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

(c) As soon as practicable after the taking of the last evidence, the presiding officer shall certify:

(1) That the original transcript is a true transcript of the oral testimony offered or received at the hearing, except in such particulars as the presiding officer specifies.

(2) That the written testimony and exhibits accompanying the transcript are all the written testimony and exhibits introduced at the hearing, with such exceptions as the presiding officer specifies.

(3) The transcript with attached or incorporated material, as so certified by the presiding officer, shall be submitted to and filed by the hearing clerk under § 179.80.

(d) Copies of the transcript shall be available to the public in accordance with § 179.81; parties may make special arrangements through the hearing clerk to obtain copies on an ongoing, expedited basis.

§ 179.95 Admission or exclusion of evidence; objections; offers of proof.

(a) Written material identified as direct testimony or as an evidentiary exhibit and offered by a party in a hearing, and oral testimony, whether on direct or on cross-examination, is admissible as evidence unless the presiding officer excludes it (on objection of a party or on the presiding officer's own initiative) because it is irrelevant, immaterial, or unduly repetitive, or because its exclusion is necessary to enforce a specific requirement of this

part relating to the admissibility of evidence.

(b) If a party objects to the admission or rejection of any evidence or to the limitation of the scope of any examination or cross-examination, the party shall state briefly the grounds for such objection. The transcript shall include any argument or debate thereon, unless the presiding officer, with the consent of all the parties, orders that such argument not be transcribed. The ruling and the reasons given therefor by the presiding officer on any objection shall be a part of the transcript. An automatic exception to that ruling will follow.

(c) Whenever evidence is deemed inadmissible, the party offering such evidence may make an offer of proof, which shall be included in the transcript. The offer of proof for excluded oral testimony shall consist of a brief statement describing the nature of the evidence excluded. If the evidence consists of a document or exhibit, it shall be inserted in the record in total. If the Administrator in reviewing the record under § 179.112 decides that the presiding officer's ruling in excluding the evidence was erroneous and prejudicial, the hearing may be reopened to permit the taking of such evidence, or, where appropriate, the Administrator may evaluate the evidence and proceed to a final decision.

(d) Official notice may be taken of Agency proceedings, any matter that might be judicially noticed by the courts of the United States, or any other fact within the knowledge and experience of the Agency as an expert agency. Any party shall be given adequate opportunity to show that such facts are erroneously noticed by presenting evidence to the contrary.

§ 179.97 Conferences during hearing.

The presiding officer may schedule and hold conferences as needed to monitor the progress of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, or other matters concerning the development of the evidence.

§ 179.98 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer

will announce a schedule for the filing of briefs. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

Subpart F—Decisions and Appeals

§ 179.101 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 179.20(b), 179.42(f), 179.75(b), and 179.90(f), rulings of the presiding officer may not be appealed to the Administrator before the Administrator's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Administrator if the presiding officer certifies on the record or by document submitted under § 179.80 that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any party or substantial harm to the public interest. When an order or ruling is not certified by the presiding officer, it shall be reviewed by the Administrator only upon appeal from the initial decision except when the Administrator determines upon the request of a party and in exceptional circumstances, that delaying review would be deleterious to vital public or private interests. Except in extraordinary circumstances, proceedings will not be stayed pending an interlocutory appeal. Where a stay is granted, a stay of more than 30 days must be approved by the Administrator.

(c) Ordinarily, the interlocutory appeal will be decided on the basis of the submission made to the presiding officer, but the Administrator may allow further briefs and oral arguments. Any oral argument will be transcribed and the transcript will be prepared and certified in the same manner as provided in § 179.94.

§ 179.105 Initial decision.

(a) After the filing of briefs and any oral argument, the presiding officer

shall prepare and file an initial decision on the issues of fact in the hearing and the objections relating to those issues.

(b) The initial decision must be based on a fair evaluation of the entire record, and must contain:

(1)(i) A conclusion that no change is warranted in the order or regulation to which objection was taken; or

(ii) A conclusion that changes in the order or regulation are warranted, the language of the order or regulation as changed, and an effective date for the order or regulation as changed, which date must not be earlier than the 90th day after it is published unless the order contains findings as to the existence of emergency conditions that necessitate an earlier effective date.

(2) Findings of fact supported by reliable, probative and substantial evidence that has been found admissible by the presiding officer, and adequate citations to the record supporting those findings.

(3) Conclusions on legal and policy issues, if such conclusions are necessary to resolve the objections.

(4) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any party.

(c) Except as otherwise provided by order of the Administrator filed in accordance with § 179.80, after the initial decision is filed, the presiding officer has no further jurisdiction over the matter and any motions or requests filed with the hearing clerk will be decided by the Administrator.

(d) The initial decision becomes the final decision of the Administrator by operation of law unless a party files exceptions with the hearing clerk under § 179.107 or the Administrator files a notice of review under § 179.110.

§ 179.107 Appeal from or review of initial decision.

(a) A party may appeal an initial decision to the Administrator by filing exceptions with the hearing clerk, and serving them on the other parties, within the period specified in the initial decision. The period may not exceed 30 days, unless extended by the Administrator under paragraph (d) of this section.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law or policy in the initial decision and, if errors in the findings of fact are alleged, must provide supporting citations to evidence of record. Oral argument before the Administrator may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within the timeperiod specified in the initial decision. The timeperiod may not exceed 30 days after the end of the period (including any extensions) for filing exceptions, unless extended by the Administrator under paragraph (d) of this section.

(d) The Administrator may extend the time for filing exceptions or replies to exceptions for good cause shown.

(e) If the Administrator decides to hear oral argument, the parties will be informed of the date, time, and place; the amount of time allotted to each party, and the issues to be addressed.

§ 179.110 Determination by Administrator to review initial decision.

Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Administrator may file with the hearing clerk, and serve on the parties, a notice of the Administrator's determination to review the initial decision. The Administrator may invite the parties to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

§ 179.112 Decision by Administrator on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Administrator shall have the same powers as did the presiding officer in making the initial decision. On the Administrator's own initiative or on motion, the Administrator may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal to, or on review by the Administrator is the same as the scope of the issues before the presiding officer, unless the Administrator specifies otherwise.

(c) After the filing of briefs and any oral argument, the Administrator will issue a final decision on the issues of fact in the hearing and the objections related to those issues. A final decision must contain the elements required for an initial decision by § 179.105(b).

(d) The Administrator may adopt the initial decision as the final decision.

(e) The Administrator's decision, or a summary of the decision and a notice of its availability, will be published in the FEDERAL REGISTER.

§ 179.115 Motion to reconsider a final order.

A party may file a motion requesting the Administrator to reconsider a final decision under this part. Any such motion must be filed within 10 days after service of the final decision, and must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such a motion shall not stay the effective date of the final decision unless specifically so ordered by the Administrator.

§ 179.117 Designation and powers of judicial officer.

(a) One or more judicial officers may be designated by the Administrator. A judicial officer shall be an attorney who is a permanent or temporary employee of the Agency or of another Federal agency. A judicial officer may perform other duties. A judicial officer who performs any duty under this part may not be employed by OPPTS, by the Pesticides and Toxic Substances Division of the Office of General Counsel, or by any other person who is a representative of OPPTS in the hearing. A person may not be designated as a judicial officer in a hearing if he or she performed any prosecutorial or investigative functions in connection with that hearing or any other factually related hearing.

(b) The Administrator may delegate to the judicial officer all or part of the Administrator's authority to act in a given proceeding under this part. Such a delegation does not prevent the judicial officer from referring any motion or case to the Administrator when appropriate.

[55 FR 50293, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

Subpart G—Judicial Review

§ 179.125 Judicial review.

(a) The Administrator's final decision is final agency action reviewable in the courts as provided by FFDCA section 408(i) or 409(g)(1), as of the date of entry of the order, which shall be determined in accordance with §§ 23.10 and 23.11 of this chapter. The failure of a person to file a petition for judicial review within the period ending on the 60th day after the date of the entry of the order constitutes a waiver under FFDCA sections 408(i) or 409(g)(1) of the right to judicial review of the order and of any regulation promulgated by the order.

(b) The record for judicial review of a final decision under this part consists of the record described in § 179.130.

§ 179.130 Administrative record.

(a) For purposes of judicial review, the record of a hearing that culminates in a final decision of the Administrator under § 179.105(d) or § 179.112(c) ruling on an objection shall consist of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under § 177.125 of this chapter to which the objection related, and:

(i) The regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(3) Any order issued under § 177.130 of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(4) Any order issued under § 180.7(g) of this chapter to which the objection related, and:

(i) The regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

(v) The notice of filing of the petition.

(5) Any order issued under §180.29(f) of this chapter to which the objection related, the regulation that was the subject of that order, and each related Notice of Proposed Rulemaking.

(6) The comments submitted by members of the public in response to the Notice of Filing or Notice of Proposed Rulemaking, and the information submitted as part of the comments, the Administrator's response to comments and the documents or information relied on by the Administrator in issuing the regulation or order.

(7) All other documents or information submitted to the docket for the rulemaking in question under parts 177 or part 180 of this chapter.

(8) The Notice of Hearing published under §179.20.

(9) All notices of participation filed under §179.42.

(10) Any FEDERAL REGISTER notice issued under this part that pertains to the proceeding.

(11) All submissions filed under §179.80.

(12) Any document of which official notice was taken under §179.95.

(b) The record of the administrative proceeding is closed:

(1) With respect to the taking of evidence, when specified by the presiding officer.

(2) With respect to pleadings, at the time specified in §179.98(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN FOOD

EDITORIAL NOTE: An alphabetical listing of pesticide chemicals appears at the end of this table of contents.

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