

# 美國食品衛生法規

## FEDERAL FOOD DRUG AND COSMETIC ACT

翻譯 金 碩 根

校閱 서울대학교 保健大学院  
教授 鄭 文 植

### CHAPTER IV - FOOD

#### 第四章 食 品

- (A) the name, chemical identity, and composition of the pesticide chemical;
- (B) the amount, frequency, and time of application of the pesticide chemical;
- (C) full reports of investigations made with respect to the safety of the pesticide chemical;
- (D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;
- (E) practicable methods for removing residue which exceeds any proposed tolerance;
- (F) proposed tolerances for the pesticide chemical if tolerances are proposed; and
- (G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

- (A) 農藥의 名稱, 化學의 名稱 및 成分
- (B) 農藥의 使用量, 頻度 및 使用時間
- (C) 農藥의 安全性에 關하여 取해진 調査의 完全한 報告
- (D) 分析法을 包含한 農藥殘存量의 試驗 結果  
    驗의 結果
- (E) 提案된 許容量을 超過하는 殘存農藥을 除去하는 實用的 方法
- (F) 萬一 許容量을 提案할 때는 그 農藥에 對해서 提案할 許容量
- (G) 請願을 支持할 正當한 根據와 長官의 要請이 있으면 그 農藥의 샘플(標木)을 長官에게 提出하여야 하며 이와같은 請願 申請公示는 그 申請이 된 다음부터 30日 以內에 長官이 公示한다. 이 公示는 그 農藥에 對한 提案된 許容量 또는 許容量의 適用 除外에 對해서 殘存하는 農藥의 試驗을 하기 爲한 分析方法을 包含한다.

(2) Within ninety days after a

(2) 請願이된 農藥에 關한 (1) 項의 規

certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1), with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as herein-after provided, the committee shall,

定에 의한 農務省長官에 의한 有用性の 證明이 된 다음부터 90日以内に 保健教育厚生省長官은 請願 其他方法으로 提出된 데이터에 對해서 正當한 檢討를 한 다음에

(A) 有用하다고 證明된 使用目的에 關한 請願의 農藥에 對한 許容量을 設定한다. 또 는

(B) 그 使用目的에 있어서는 “ 許容量의 適用을 除外하다” 라는 規則을 命令으로서 公告한다.

但 이 90日 期間内に 請願을 提出한 사람이 請願을 諮問委員會에 付託할 것을 要請하거나 長官이 이와같은 委託이나 付託을 必要한다고 생각될 때는 本項(3)이 代身 適用된다.

(3) 請願을 한 農藥에 關해서 (1)項 規定에 의한 農務省長官에 의한 有用性 證明이 되고서부터 90日以内に 請願을 提出한 사람이 諮問委員會에 請願을 付託할 것을 要請하였을 경우나 保健教育厚生省長官이 이 期間内に 付託하는 것이 必要하다고 생각했을 경우에는 保健教育厚生長官은 即刻 本條(g)項의 規定에 依하여 請願書와 判 데이터를 諮問委員會에 提出하여야 한다. 이와같은 付託을 한 다음에 實行할 수 있을 때는 即刻 또는 60日以上 遲滯되지 않는 期間内に 다음에서 記述되는 延長이 없는 限 委員會는 長官에 의해서 提出된 데이터와 其他의 데이터를 獨自的으로 研究한 다음에 長官에 對해서 請願中에 提案된 事項에 關한 報告

after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

- (A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or
- (B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection

와 勸告를 모든 基礎가 될 데이터와 勸告의 基礎가 된 理由說明과 같이 證明하여야한다. 여기에서 말하는 60日의 期間은 万若 諮問 委員會가 必要하다고 생각할 때에는 그 위에 30日間の 延長을 할 수 있다. 이 證明이 提示되고부터 30日以内의 期間에 長官은 이와같은 報告, 勸告, 의 基礎가 될 데이터와 說明을 包含한 모든 데이터에 對하여 正當한 檢討를 한 다음 命令에 依해서

(A) 有用하다고 證明된 目的의 使用法에 關한 請願이 行하여진 農藥에 對한 許容量을 定할것. 또는

(B) 그와같은 目的에 對한 許容量의 必要性에서 그 農藥을 除外하는 일의 規則을 公示하여야 한다.

(4) 本項 (2)와 (3)의 規定에 依하여 發行된 規則은 公告에 보다 効力을 發生한다.

(5) 公告된 다음 30日以内期間에 있어서 本項 (2), (3)과 (e)項에 따라서 發行된 規則에 依해서 不利한 影響을 받는 사람은 언제든지 長官에 對해서 그 規則의 異議있는 特

(e) may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefore, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006 (c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: Provided, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation.

Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall

別項目을 指定하고 그 反對理由를 記述하고 公聽會를 開催할것을 要求할 수가 있다.

請願者以外的 사람에 의해서 取해진 異議申立書의 複寫는 規則이 請願에 따라서 發表된 것이라면 請願者에 提示된다.

請願者는 그 異議申立에 對해서 文書로서 應答하기 爲해 2 週間の 期間을 받게 된다. 長官은 正當한 公示後에 이와같은 異議申立에 의해서 提起된 問題에 對한 證據와 資料를 받아들임을 目的으로 하고 公聽會를 開催하여야 한다.

行政手續法(合衆國法律 第5號 第1006條 (c)의 第7條 (c)項에 따라서 關聯있는 것이며 또한 重要하다면 모든 報告書, 勸告, 基礎가 되는 데이터와 諮問委員會가 長官에 對해서 證明을 한 理由等은 公聽會記錄의 一部로하여야 한다.

國立科學아카데미는 長官과 請願者 및 公聽會를 管理하는 官吏의 要請에 依해서 이와같은 委員會報告와 報告에 關해서 公聽會에 出席하고 証言할 諮問委員會의 數를 指定하여야하며 其他 諮問委員會 會員이 公聽會에 出席하고 証言하는일을 妨害하는 것은 아니다. 公聽會가 끝난 다음에 實行可能케 된 때에는 長官은 即刻 異議申立에 對해서 行動을 取하고 命令으로서 規則을 公告하여야 한다. 이와같은 規則은 모든 報告, 勸告, 데이터와 諮問委員會가 長官에 對해서 證明한 理由를 包含해서 公聽會에 提出된 實質的 證據에만 따라야 하며 그 規則의 基礎로 된 事實의 詳細한 所見을 提示하여야 한다. 이와같은 命令은 그의 公告後 90日을 經過치않으면 發効치 않는다. 但 長官이 그보다

set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance.

Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred

먼저 發効시킴을 必要로 하는 緊急 狀態가 있다고 看做될 때는 此限에 不在임. 이 때에는 長官은 그의 命令속에 이와같은 緊急 狀態에 關한 長官의 所見을 明確히 하여야 한다.

(e) 長官은 언제든지, 스스로 또는 關心 있는 사람의 請願에 依해서 農藥許容量을 定하는 規則과 許容量을 設定할 必要에서 除外하는 規則을 提案할 수가 있다. 이와같은 提案이 公示된 다음, 30日經過한 다음에 長官은 命令에 依해서 提案에 따른 規則을 公布할 수가 있다. 이는 이 30日間에 「聯邦殺虫劑, 殺菌劑 및 殺鼠劑法」에 依據해서 經濟上의 毒物登錄을 한 사람 또는 登錄申請을 提出한 사람이 長官提案이 諮問委員會에 委託될 것을 要求하지 않는 限, 公告로서 有効하게 된다. 이와같은 要請이 이루어진 경우 長官은 即刻 提案과 本條(g)項에 따라

to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section.

As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations.

The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section.

指定되는 他 關聯있는 데이터를 諮問委員會에 提出하여야 한다. 委員會는 이와같은 委託이 있는 다음에 實行可能하게되면 即時但, 다음에 定하는 延長이 없는 限 60日 以內에 委員會는 長官이 提出한 데이터와 其他 데이터를 獨自的으로 研究한 다음에 長官에게 提案에 關한 報告와 勸告를 모든 基礎가 되는 데이터와 勸告의 理由 및 그 基礎의 說明과 같이 稟申하여야 한다. 이 60日이란 期間은 諮問委員會가 必要하다고 認定될때는 30日間을 더 延長할 수가 있다. 이와같은 稟申後 30日以內에 長官은 報告, 勸告, 基礎가 되는 데이터와 陳述을 包含한 모든 데이터에 對해 正當한 檢討를 한 然後 命令으로 提案에 실린 農藥에 對해서 許容量을 定하는 規則이든가 許容量을 設定할 必要에서 除外시키는 規則을 公布할 수가 있다. 이는 公告로서 有效하다. 本項에 의해서 公布된 規則은 (d)項의 (5) 規定에 依해서 公告하여야 한다.

(f) 本條에 의한 請願의 뒷바라지가 되는 長官과 諮問委員會에 提出되는 모든 데이터는 本條 (d)項 (2)와 (3)에 의한 規則이 公布될때까지는 長官과 諮問委員會에서 秘密이 지켜진다. 이 公布까지 데이터는 長官과 諮問委員會에 의해서 本條에 따른 公的義

Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary, the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon.

Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral

務를 遂行하기 爲하여 許可된 者 以外에 누구에게도 洩泄시켜서는 안된다.

(g) 諮問委員會에 對한 請願과 提案委託이 本條에 의거 要求될 때와 長官이 이와같은 委託이 必要하다고 認定될 때는 언제든지 長官은 迅速하게 請願과 提案을 檢討하고 報告와 勸告를 함에 있어 適切한 專門家を 任命하여야 한다.

各 諮問委員會는 請願에 關한 問題의 有資格專門家와 國立科學아카데미에서 選出된 適切하게 各 職種의 背景을 갖고 있거나 農工大學에서 한사람 또는 두사람의 代表를 包含시켜야 한다. 委員會의 規模는 長官이 決定한다.

諮問委員會委員은 그 業務에 對해서 委員會의 業務에 實際적으로 消費되는 時間에 關해서 長官이 規則으로 定하는 適當한 日當을 받으며 居住하는 場所를 떠나서 業務를 하기위해선 必要한 旅費와 生活費에 對한 補償을 받는다. 委員은 合衆國의 職員任用 및 補償에 關한 法律의 條項은 適用되지 않는다. 長官은 委員會에 充分한 事務上 其他 援助를 提供할것이며 規則에 따라 委員會가 取하는 手續을 規定하여야 한다.

(h) 請願을 提出한 사람이나 提案이 本條規定에 의하여 諮問委員會에 付託될것을 要

of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i) (1) In a case of actual controversy as to the validity of any order under subsection (d) (5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substan-

求한 사람은 保健教育厚生省의 代表와 같이 請願이나 提案에 關한 (g)項에서 規定한 어느 諮問委員會에 對해서도 相談할 수 있는 權利를 갖는다.

(i) (1), (d)項(5), (e)項 및 (l)項 規定에 立脚한 命令의 有効性에 關한 實際 論争에 있어서는 이 命令에 의한 不利한 影響을 받게 되는 사람은 누구든지 이와같은 命令이 내린後 60日以内に 그 命令의 全部 또는 一部를 取消하도록 本人이 居住하는 地区나 主營業場所에서와 巡廻裁判 때문에 合衆國上級 裁判所나 코롬비아特別區巡廻裁判을 위한 合衆國上級 裁判所に 對하여 請願을 하고 司法上의 再審을 要求할 수가 있다.

(2) (d)項(5)와 (e)項規定에 立脚한 命令에 關한 請願의 경우에는 裁判所書記는 迅速히 그 請願의 寫本을 長官이나 長官이 指定하는 官吏에게 傳達하여야 한다. 그리고 合衆國法律第28号 第2112條 規定에 따라서 長官은 그 命令의 基礎가 되었던 諸記錄을 提出하여야 한다. 이와같은 請願申込에 의하여 裁判所는 그 命令을 肯定하거나 全部 또는 一部를 取消시키든가의 高級裁判 權을 갖는다. 事實의 疑問에 關한 長官의 決定은 諮問委員會의 모든 報告와 勸告를 包含한 記錄을 全般的으로 考慮했을 때에 本質的인 證據에 의해서 支持된다고 하면 承認된다.



Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary, the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon.

Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral

務를 遂行하기 爲하여 許可된 者 以外에 누구에게도 洩泄시켜서는 안된다.

(g) 諮問委員會에 對한 請願과 提案委託이 本條에 의거 要求될 때와 長官이 이와같은 委託이 必要하다고 認定될 때는 언제든지 長官은 迅速하게 請願과 提案을 檢討하고 報告와 勸告를 함에 있어 適切한 專門家를 任命하여야 한다.

各 諮問委員會는 請願에 關한 問題의 有資格專門家와 國立科學아카데미에서 選出된 適切하게 各 職種の 背景을 갖고 있거나 農工大學에서 한사람 또는 두사람의 代表를 包含시켜야 한다. 委員會의 規模는 長官이 決定한다.

諮問委員會委員은 그 業務에 對해서 委員會의 業務에 實際적으로 消費되는 時間에 關해서 長官이 規則으로 定하는 適當한 日當을 받으며 居住하는 場所를 떠나서 業務를 하기위해선 必要한 旅費와 生活費에 對한 補償을 받는다. 委員은 合衆國의 職員任用 및 補償에 關한 法律의 條項은 適用되지 않는다. 長官은 委員會에 充分한 事務上 其他 援助를 提供할것이며 規則에 따라 委員會가 取하는 手續을 規定하여야 한다.

(h) 請願을 提出한 사람이나 提案이 本條規定에 의하여 諮問委員會에 付託될것을 要

of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i) (1) In a case of actual controversy as to the validity of any order under subsection (d) (5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code.

Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substan-

求한 사람은 保健教育厚生省의 代表와 같이 請願이나 提案에 関한 (g)項에서 規定한 어느 諮問委員會에 對해서도 相談할 수 있는 權利를 갖는다.

(i) (1), (d)項(5), (e)項 및 (l)項 規定에 立脚한 命令의 有効性에 関한 實際 論争에 있어서는 이 命令에 의한 不利한 影響을 받게 되는 사람은 누구든지 이와같은 命令이 내린後 60日以内に 그 命令의 全部 또는 一部를 取消하도록 本人이 居住하는 地区나 主營業場所에서와 巡廻裁判 때문에 合衆國上級 裁判所나 코롬비아特別區巡廻裁判을 위한 合衆國上級 裁判所に 對하여 請願을 하고 司法上의 再審을 要求할 수가 있다.

(2) (d)項(5)와 (e)項規定에 立脚한 命令에 関한 請願의 경우에는 裁判所書記는 迅速히 그 請願의 寫本을 長官이나 長官이 指定하는 官吏에게 傳達하여야 한다. 그리고 合衆國法律第28号 第2112條 規定에 따라서 長官은 그 命令의 基礎가 되었던 諸記錄을 提出하여야 한다. 이와같은 請願申込에 의하여 裁判所는 그 命令을 肯定하거나 全部 또는 一部를 取消시키든가의 高級裁判 權을 갖는다. 事實의 疑問에 関한 長官의 決定은 諮問委員會의 모든 報告와 勸告를 包含한 記錄을 全般的으로 考慮했을 때에 本質的인 證據에 의해서 支持된다고 하면 承認된다.

tial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (1), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below.

The Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, may

(3) (e) 項規定에 따른 命令에 關한 請願의 경우, 裁判所書記는 即刻 請願의 寫本을 農務長官이나 農務長官이 指定한 官吏에게 傳達하여야 하며 이에 對하여 農務長官은 合衆國法律第28号第2112條規定에 立脚해서 命令의 基礎로 되었던 諸記錄을 裁判所에 提出하여야 한다. 이와같은 請願에 의해서 裁判所는 命令을 肯定하거나 命令의 全部 또는 一部를 取消할 高級裁判權을 갖는다. 疑問이 있는 事實에 關한 長官의 決定은 記錄 全般을 檢討한 後에 本質的인 證據에 依支 되는 것이라면 承認된다.

(4) 万若 더욱 追加해서 證據를 引用하도록 裁判所에 申請이 되었을 경우에는 이와같은 證據가 重要하며 手續中에 引用치 않았던 것이 잘못이었다는 妥當한 理由가 있으면 裁判所는 이와같은 追加的인 證據를 保健教育厚生長官이나 農務長官앞으로 提出하도록 命令하고 裁判所가 適當하다고 생각되는 時期와 狀態와 方法으로 聽問에 引用할 수가 있다. 保健教育厚生長官이나 農務長官은 이와같은 경우, 事實에 對해서 그 決定을 修正하고 他의 證據를 받아드려 命令을 하고 裁判所에 修正된 決定과 命令을 提

modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applic-

(5) 本條 規定에 의거 命令을 肯定하거나 全部 또는 一部를 取消한 裁判所의 判決은 合衆國法律第28号第1254條에 規定하는 裁判調書移送命令書나 證明書에 對한 合衆國最高裁判所의 再審에 따라서 最終의 決定으로 된다. 本條規定에 立脚한 手續開始는 特別히 裁判所에서 反對命令을 내리지 않는 限 命令을 停止시키고 運營해서는 안된다.

裁判所는 判決記錄을 作成하고 本條에 의거 提出된 모든 訴訟原因으로 되었던 事項의 處理를 促進시켜야 한다.

(j) 長官은 「聯邦殺虫劑, 殺菌劑 및 殺鼠劑法」이 規定한데 따라서 農藥實驗을 하기 위한 許可를 받은 사람의 申請에 의해서 또는 스스로의 생각으로 公衆의 健康을 지킴에 必要하다고 判斷하였을 때에는 언제든지 農藥을 그가 使用法을 限定시켜서 暫定的인 許容量을 設定하거나 暫定的으로 許容量을 除外시킬 수가 있다. 이와같이 許容量을 設定함에 있어서는 長官은 이와같은 作業에 包含되는 適切하고 安全하며 經濟的인 食品供給을 發展시키는 일의 必要성과 「聯邦殺虫劑, 殺菌劑, 殺鼠劑法」의 當該規定에 의해서 行하여 질때에 이와같은 作業에 包含되는 公衆保健에 對하여 限定된 危害에 對해 當然히 해야할 注意를 기울리해서는 안

able regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406 (a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701(e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d) (1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be

된다.

(k) 第701條(e)項에 의하여 1953年, 1月 1日以前에 열린 公聽會에 立脚해서 第406條(a)項 權限으로 公布된바 있는 날 農産物 表面이나 속에 使用되는 農藥에 영향을 주는 規則은 本條規定에 依한 規則으로 看做되며 (m)項에 規定한 修正이나 廢止의 對象이 된다.

(l) 農務長官은 「聯邦殺虫劑, 殺菌劑, 殺草劑法」에 依한 經濟上 毒物의 登錄을 한 사람이나 登錄을 申請한 사람의 要請에 따라서 또는 그 要請이 이와같은 經濟上의 毒物을 構成하거나 그 原料를 構成하는 農藥에 關해서 (d)項(1)에 立脚해서 提出된 請願寫本이 添付되어 있으면 30日사이나 이 30日이 끝나기 前에 長官이 必要하다고 認定하여 延長할 것을 公示한 60日사이에 提出된 데이타에 의해서

(1) 保健教育厚生省長官에 對해 이와 같은 農藥은 許容量과 免除가 考慮되고 있는 目的을 위해서 有益하다고 하는 것을 證明하여야 한다. 또는

(2) 證明을 要求하는 사람에게 그 農藥은 許容量이나 免除가 考慮되고 있는 目的때문에 有用하다고는 믿어지지 않는다든가 許容量이나 免除가 考慮되고 있는 目的中 몇 가지만이 有用하다고 생각된다고 하는 것을 証

useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary, of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and hearing. If no such action is taken, the Secretary may by order make the certification as proposed.

In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested.

In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days.

The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner rea-

명한다고 하는 提案을 通知하여야 한다. 農務長官이 (2)의 行動을 取할 경우에 證明을 要求하는 사람은 提案된 證明을 받고서부터 一週日以内에는 다음 어떤것도 要請할 수가 있다.

(A) 提案된 證明을 基礎로해서 保健教育 厚生長官에 對하여 證明할 것을 農務長官에 要請하는 일.

(B) 提案된 證明이나 反對하는 部分에 關해서 聽問을 要請하는 일.

(C) 證明과 聽問의 兩者를 要求하며 이와 같은 行動이 取해지지 않을때는 長官은 提案된것과 같은 證明을 命令으로서 行한다.

(A)와 (C)에서 말하는 行動이 取해질때는 長官은 命令으로 要請된 部分에 對해서 提案된바의 證明을 해주어야 한다.

聽問이 要請되었을 때는 農務長官은 迅速하게 그 機會를 주어야 한다. 이 聽問結果로서의 農務長官의 證明은 命令으로서 行하여져야하며 聽問에서의 記錄의 實質的인 證據에 立脚해서 事實에 對한 詳細한 所見을 提示하여야 한다. 어떠한 경우를 莫論하고 本項規定에 立脚한 證明의 請願과 農務長官이 證明을 行하기까지의 期間은 160日을 超過해서는 안된다. 農務長官은 請願者에 의해서 提案된 許容量이나 免除이거나 證明을 바라는 目的을 위한 提案된 方法에 의해서 農藥이 使用되었을 때는 殘存量을 正確하게 反映시킬 結果가 되겠는가하는 點에 對해서 提出된 데이터에 의해 本項에서 規定하는 有用性證明과 같이 意見을 保健教育 厚生長官 앞으로 提出하여야 한다. 農務長官은 正當한 通告와 公聽의 機會를 준다음에 本項의

sonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

(m) The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provide in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) The provisions of section 303 (c) of the Federal Food, Drug, and Cosmetic Act with respect to the furnishing of guaranties shall be applicable to raw agriculture commodities covered by this section.

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this

條件을 實施하기위한 規則을 公布할 權限을 갖는다.

(m) 保健教育厚生長官은 本條의 規定에 의한 規則을 改正하거나 廢止할 수 있는 手續節次의 規則을 制定해야 하며 그리고 이와같은 手續은 本條에 의거 規定된 諮問委員會의 任命과 請願을 諮問委員會에 委託하는 手續을 包含 許容量을 設定할 規則의 公布를 위한 手續과 一致시켜야 한다.

(n) 保證에 関한 食品, 藥品, 化粧品法第 303條(c)項의 規定은 本條에 規定하는 農産物에 適用한다.

(o) 保健教育厚生長官은 規則(FDC 規則 第120部)에 依據 本條에 의한 長官의 機能을 遂行하고자 長官判斷에 의해서 充分한 일을 하도록 設備하고 業務를 維持하기 위한 金額이 不足되지 않도록 充分한 料金の 支拂을 要求하여야 한다.

section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) the acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i) (2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

This Act shall take effect upon the date of its enactment [July 22, 1954] except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug and Cosmetic Act, the amendment to section 402(a) of such Act made by section of this Act shall not be effective—

- (1) for the period of one year following the date of the enactment of this Act; or
- (2) for such additional period fol-

이 規則 밑에서는 本條에 저촉되는 다음 事項을 包含해서 長官이 行하는 業務나 他 機能은 料金 支拂을 前提條件으로 할 수가 있다.

(1) (d)項規定에 의하여 提出된 請願을 接受하는 일.

(2) 本條規定에 依한 許容量을 設定하며 許容量設定을 免除하는 規則公布와 이와같은 規則을 改正하거나 廢止하는 일.

(3) 本條規定에 依하여 諮問委員會에 請願이나 提案을 委託하는 일.

(4) (d)項 (5)規定에 依한 反對는 申請을 接受하는 일.

(5) (i)項 (2)規定에 依하여 議事錄과 記錄의 謄本을 裁判所에 提出하거나 證明하는 일.

이와같은 規則은 더욱 長官이 正當하며 本項의 目的에 違背되지 않다고 判斷될 때 는 料金의 全部 또는 一部를 免除하거나 返 還할 수가 있도록 規定할 수가 있다.

이 法律은 發効와 같은 날에 (1954. 7. 22) 實施되지만 食品, 藥品, 化粧品法의 第 408 條規定에 依하여 許容量이나 免除가 設定되 어있지 않는 農藥에 關해서 第402條(a)項의 改正은 다음의 境遇에는 效果를 發生치 못 한다.

- (1) 이 法律發効의 日字로부터 1年間.
- (2) 保健教育厚生長官의 狀況에 따라서 必要하다고 認定될 때에는 그 위에 1年間.



lowing such period of one year, but not extending beyond two years after the date of the enactment of this Act, as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.

但 發効後 2年을 超過 해서는 안된다.

## Food Additives

### 食 品 添 加 物

#### Unsafe Food Additives

Sec. 409 [348] (a) A food additive shall, with respect to any particular use, or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402(a), unless—

- (1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or
- (2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of

#### 不 安 全 食 品 添 加 物

##### 第409條[348]

(a) 食品添加物은 다음 各號에 該當하는 것을 除外하고는 特別한 使用法이나 食品添加物으로서의 使用法에 關해서 第402條 (a)項 (2)의 (C)의 適用目的때문에 不 安 全 하다고 看做된다.

(1) 그것과 그 使用法이나 意圖된 用法이 本條(i)項에 의해서 免除條件에 該當할 것.

(2) 그 添加物이 安全하게 使用되는 條件을 記述한바가 本條에 의거 發行한 規則이 있을것과 그것과 그 使用法이나 意圖된 使用法이 規則과 一致할것.

食品添加物에 關한 이와같은 規則이 有効한 동안은 規則에 따라 이와같은 添加物이 附着하거나 含有되어 있다는 理由로서 食品은 第402條 (a)項 (1)이 意味하는 範圍內에

clause (1) of section 402(a).

서 不良食品이라고 生覺해서는 안된다.

### Petition To Establish Safety

### 安全性을 設定하기 위한 請願

(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(b) (1) 누구든지 食品添加物の 意圖하는 使用法에 關해서 長官에게 그와같은 食品添加物이 安全하게 使用할 수 있는 條件을 記述한 規則의 公布를 提案한 請願을 提出할 수가 있다.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(2) 이같은 請願은 說明이나 支持하는 데이터-에 附加해서 다음과 같은 것을 包含하여야 한다.

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(A) 그 食品添加物에 關한 名稱과 모든 適切한 情報 및 該當있으면 그 化學的 名稱과 成分.

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(B) 그 添加物の 提案된 使用法의 狀態에 關한 陳述. 이는 그 添加物の 用途에 關한 모든 使用法 勸告 및 示唆을 包含하며 나아가서 그 行하고자하는 표시서의 見本을 添付할것.

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(C) 그 添加物이 効能을 나타내리라고 意圖한바 物理的 및 技術的인 効果를 記述한 모든 關聯있는 데이터와 効果를 나타내기 위한 必要한 分量.

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(D) 食品속에서 그 添加物の 量을 決定하기위한 實用的方法과 그 添加物을 使用함으로써 食品속에 生成하는 物質의 分析法.

(E) full reports of investigations made with respect to the safety for

(E) 그 添加物の 安全性에 關해서 取해진 完全한 調查報告, 이는 그 調查를 하였

use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner), a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

#### Action On The Petition

(c) (1) The Secretary shall—  
(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be

든 方法과 管理에 關한 모든 報告를 包含할 것

(3) 長官要求에 따라 請願者는 其 添加物 生産에 쓰여진 方法, 設備類와 管理方法에 對한 完全한 說明을 提供하여야 한다.

(萬一 請願者가 製造業者가 아닌 경우는 請願者는 製造業者로 하여금 提供토록 하여야 한다).

(4) 長官要求에 따라 請願者는 食品添加物의 見本(샘플)이나 그 構成物로서 쓰여지고 있는 物質의 見本과 그 添加物을 使用하고자 하는 食品의 見本을 提供하여야 한다.

(5) 請願者에 의하여 提案된 規則公告는 長官에 의해서 그 請願提出後 30日 以內에 發行되어야 한다.

#### 請願에 對한 行爲

(C) (1) 長官은

(A) 命令으로서 (請願者 提案에 의하거나 請願者 提案에 따르지 않고) 食品添加物 한가지 또는 그 以上의 使用法에 關해서 그 것이 安全하게 使用할 수 있는 條件(그 添加物이 使用되는 特別한 食品이나 食品類에 關한 特別한 用法과 食品에 殘存을 許容되는 最大量, 그 添加物을 食品에 使用 하는 方法과 그 用途의 安全性을 確實히 하기 위해서 長官이 必要하다고 認定하는 使用法과 其他 표시법과 包裝基準을 包含(단 이들에만 限定치 않음)을 記述한 規則을 設定하여

added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food

야 한다). 그리고 이 命令과 이와같은 行爲를 하게되는 理由를 請願者에게 通告하여야 한다.

(B) 命令에 의해서 請願을 拒否하고 그 行爲를 取한 理由를 請願者에게 通告하여야 한다.

(2) 本項(1)의 (A)와 (B)에서 規定하는 命令은 請願을 提出한 日字로부터 90日以内に 發行되어야 한다. 但 長官은(이 90日以前에 있어서) 請願者에 對한 書面 通告로서 長官이 그 請願을 研究하고 調査함에 必要하다고 믿어지는 期間까지(請願提出後 180日을 經過하지 말것) 延長시킬 수가 있다.

(3) 이 같은 規則은 長官에게 提出된 데이터가 다음 (A)와 (B)에 該當할 경우에는 發行해서는 아니된다.

(A) 그 使用法에 있어서 그 添加物 使用이 安全하다고 하는 것을 確立시킬 수가 없는 것. 但 添加物이 사람과 動物에게 攝取되었을 때의 癌의 原因이 됨이 判明되었을 때와 食品添加物의 安全性評價를 하고자 適當한 試驗을 한다음에 사람이나 動物의 癌의 原因이 됨이 判明되었을 때는 安全하다고 看做해서는 아니된다. 但 이 條項은 長官이 다음 두가지 경우에 該當한다고 認定하였을 때에는 食品生産을 增大시키기 爲한 家畜飼料의 原料로서의 物質로 使用하여서는 아니된다.

production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling an reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(i) 標示에 特別히 提示된 飼料로서 使用法과 習慣에 따른 使用法下에서는 이와같은 添加物이 飼料로서의 用途가 되거나 反對의 影響을 動物에게 주지 않는것.

(ii) 動物의 도살後에 食用部分에 (長官이 規則으로 認定한 試驗法(f)項과 (g)項에 該當되지 않음)에 殘存해 있지 않을것.

(B) 그 添加物이 提示된 使用法이 消費者에게 이 法律에 違反되는 詐欺行爲를 促進하거나 그 法律이 意味하는 範圍內에서 不良食品 또는 不正標示 食品이라는 結果를 갖어오는 것일것.

(4) 萬一 長官은 얻어진 데이터-에 對한 公正한 評價로서 判斷함에 있어 提示된 使用法으로 食品添加物이 安全하기 때문에 許容量限度가 必要하다면 長官은

(A) 그 添加物이 目的으로 하는 物理的 또는 技術的 效果를 올리기 爲해서 必要하다고 믿어지는 量보다 많은 量으로 許容量을 定해서는 아니된다.

(B) 얻어진 데이터로 公正한 評價를 한 다음 데이터가 그 添加物의 使用目的으로 하는 物理的 및 其他 技術的 效果를 올린다고 하는 것을 確立하고 있지 않음을 發見했을 때는 그 使用을 認定하는 規則을 定해서는

안된다.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

- (A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;
- (B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and
- (C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

#### Regulation Issued

##### On Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal

(5) 本條의 目的에 因하여 添加物의 使用法이 安全한가 不安全한가를 決定함에 있어서는 長官은 其他 關聯있는 要素中에서 다음과 같은 要素를 考慮에 넣어야 한다.

(A) 그 添加物이 消費된 可能性과 그 使用法에 따라서 食品속이나 그 위에 生成되는 物質

(B) 사람이나 動物이 飲食에 있어 添加物이 畜積되는 영향과 飲食物에 있어 化學的 및 藥物學的으로 關聯있는 物質을 考慮에 넣을 것.

(C) 食品添加物의 安全性 評價하는 科學的 訓練과 經驗 있고 有資格 專問家의 意見에 따라서 動物實驗에 의한 使用法에 비추어서 一般的으로 安全하다고 認定되는 安全性 要素.

#### 長官이 自發的으로 發行하는 規則 規則

(d) 長官은 언제든지 그의 自發的인 意思로서 食品添加物의 特定한 使用에 關해서 그 添加物이 安全하게 使用되는 狀態와 그 理由를 記述한 規則發行을 提할 수가 있다. 이 提案 30日 후에 長官은 命令으로 그 提案에 의거 規則을 定할 수가 있다.

**Publication And Effective  
Date Of Orders**

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f)

**Objection And Public Hearings**

(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in de-

**命令公布와 發行日字**

(e) 本条(c)項과 (d)項에 의거 發行된 命令(그 命令으로 定하여진 規則을 包含)은 發表하여야 한다. 그리고 公布로서 發効된다. 그렇지만 그 命令發行후에 (f)項規定에 의하여 聽問이 要求될 때는 長官은 發効를 停止시킬 수가 있다.

**異議中立과 公聽會**

(f)(1) 本条(c)項과 (d)項에 의한 命令公布后 30日以内に 이와같은 命令으로 不利한 影響을 받은 사람은 누구든지 그 命令條項中的 反對部分에 限定하여 그 理由를 記述하고 長官에게 異議申立을 提出하고 그 異議申立에 對해서 公聽會를 열도록 要求할 수가 있다.

長官은 正當한 通告를 한 然後에 될수있는 限 迅速하게 關聯있는 証拠와를 받을 目的으로 公聽會를 열어야 한다.

公聽會가 完了하고 實行하도록된 때에는 限時 長官은 命令으로 이와같은 異議申立에 對해서 行動하고 그 命令을 公告하여야 한다.

(2) 이와같은 命令은 公聽會에서의 모든 記錄이 公正한 評價에 立脚하여야 한다. 그 命令의 基本이된 所見과 結論에 對해서 詳

tail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

#### Judicial Review

(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of

細한 說明을 包含하여야 한다.

(3) 長官은 命令속에 發効日字를 明確히 하여야만 한다. 그 公告后 90日까지는 發効시켜서는 안되나 長官이 그 보다도 以前에 發効시킬만한 必要로하는 緊急事態가 있다고 認定될 때는 此限에 不在임. 이 境遇에는 長官은 命令속에 그와같은 狀態에 關한 意見을 明確히 하여야한다.

#### 裁判上の 審査

(g)(1) 本條에 의한 規則의 改正과 廢止에 關한 命令을 包含 (f) 項에 따라서 公布된 命令의 有効性에 關한 實際論争에 있어서 그와같은 命令으로 不利한 影響을 받게 되는 사람은 누구든지 이와같은 命令이 發表되어서부터 60日以内に 그 住居所在地 거나 主營業場所가 位置한 合衆國上告裁判所나 코롬비아 特別區上告裁判所に 命令의 全部 또는 一部를 取消할것을 目的으로 하는 請願을 提出할 수가 있다.

(2) 裁判所書記는 이 請願의 寫本을 長官이나 그 目的때문에 長官이 指定한 官吏에 送達하여야하며 長官은 合衆國法律第28號第2112條 規定에 따라 命令의 基礎로 되었든



the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

審理記錄을 裁判所에 提하여야 한다. 이와같은 請願에 따라서 法廷은 長官命令의 全部 또는 一部를 肯定하거나 廢止시키는 權限을 갖는다. 記錄提出에 앞서 長官은 命令을 修正하거나 廢止시킬 수가 있다.

疑問에 關한 長官所見은 모든 記錄이 公正한 評價에 立脚한 것이라면 是認되어야 한다. 法廷은 事件表를 提出하고 本條에 關해서 提議된 모든 訴訟의 事由處理를 促進시켜야만 한다.

(3) 裁判所는 審査에 있어서 長官命令이 本條(f)項(2)에 의하여 長官에 賦課된 要件은 充足하고 있지 않으면 長官命令을 支持하여서는 아니된다.

(4) 万一 追加証拠를 引用할 許可申請이 되었을 때는 이 証拠가 重要하며 訴訟手續에 그 証拠를 引用하지 아니한 것에 처한 正當한 背景이 있으면 裁判所는 適當하다고 認定되는 方法과 時期와 狀態에서 聽取한 다음 長官에게 提出할것을 命할 수가 있다. 長官은 事實에 關한 所見을 修正하고 追加된 証拠의 따라서 命令을 내고 이와같은 修正과 命令을 法廷에 提出할 수가 있다.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

#### Amendment Or Repeal Of Regulations

(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

#### Exemption For Investigational Use

(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(5) 本条規定에 의한 命令의 全部 또는 一部를 肯定하거나 取消한 裁判所命令은 合衆国法律第28号 第1254条에 規定하는 裁判調書移送命令書와 證明에 對한 合衆国最高裁判所に 의한 再審을 條件으로 해서 마지막이다. 本条에 의한 訴訟手續開始는 特別히 裁判所命令이 없는 限, 命令을 停止하고 行하여서는 아니된다.

#### 規則改正 또는 廢止

(h) 長官은 規則으로서 本条의 前述條項에 立脚해서 規則을 改正하거나 廢止하는 手續을 定하여야 하며 이와같은 手續은 本条에 의한 規則公布手續과 一致시켜야 한다.

#### 研究目的의 用途에 對한 免除

(i) 本条 (b)項에서 (h)項까지의 規定에도 不拘하고 長官은 食品添加物이나 그것을 附着했거나 그것을 含有한 添加物을 有資格專門家가 研究目的으로만 使用할때로서 長官이 그것을 本条의 條項을 適用시킬것을 免除하는것이 公衆衛生上의 目的에 違反되지 않는다고 믿어질때는 適用을 免除시킬 수가 있다.

## Effective Dates

(a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment [September 6, 1958].

(b) Except as provided in subsection (c) of this section, section 3 of this Act [amending sections 402(a) and 406, and inserting section 409] shall take effect on the one hundred and eightieth day after the date of enactment of this Act.

(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

(1) either (A) one year after the effective date established in sub-

section (b) of this section, or (B) at the end of such additional period (but not later than two years from such effective date established in subsection (b) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective, whichever date first occurs.

[Transitional Provisions Amendment of 1961.

Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act to March 5,

## 發行日字

(a) 本条 (b)項과 (c)項에 規定한 경우를 除外하고 이 法律은 制定日字의 發効한다. [1958年 9月 6日]

(b) 本条 (c)項에 定하는 경우를 除外하고 本法律 3条[第402条(a)項과 第406条改正 및 第409条의 插入]은 이 法律發効后 180日 후에 有効하게 된다.

(c) 食品添加物의 特別한 業務上 使用에 關해서도 그것이 1958年 1月 1日以前期間에 行하여졌다면 다음의 경우에는 이 法律의 3条는 効力を 發生한다.

(1)(A) 本条 (b)項에서 定해진 發効日부터 1年 후에 있어서

(B) 保健教育厚生長官이 延長하는 것이 公衆衛生에 對해서 危險을 가져오는 것이 아 니라는 것과 延長이 必要하다고하는 所見에 따라서 定하여진 追加期間(但 (b)項에서 定한 發効期間부터 2年을 超過할 수는 없다. 또는

(2) 聯邦食品藥品化粧品法의 第409条規定에 따른 使用法에 關한 命令이 有効로된 日字에 있어서

[1961年의 過渡的改正條項]

長官이 本項 (1)의 (B)에 의해 이 法律 3条의 有効期限을 1961年 3月 5日까지 延長했을 때와 食品添加物의 特殊한 使用法에 關해서 그 日字에 延長保留請願이 長官에게

1961, or has on that date a request for such extension pending before him, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date, not beyond June 30, 1964, under the authority of that clause (but subject to clause

(2) ) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and

(ii) that in the Secretary's judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409.

The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension.]

提出되었을 때는 언제든지 前節의 1961年 3月 5日이란 期限에도 不拘하고 長官은 (1)節 (B)에 要求된 所見에 附加해서

(i) 그 用法에 對해서 第409條를 適用시킬 수가 있음을 決定할 眞實한 行動이나 同條에 必要하다는 科學的 데이터를 開發하는 것이 1960年 3月 6日以前에 關心을 갖인 사람에 의해서 始作되고 그 후에도 慎重하게 繼續되어 왔으면

(ii) 長官의 이와같은 延長은 第409條 規定에 따라서 必要한 科學的 調查의 完成이란 目的에 一致한다고 判斷된 다면 이와같은 添加物使用에 關해서 (또는 그 以上 限定된 特定使用에 關해서)(2)節의 權限에 立脚해서 1964年 6月 30日까지 延長시킬 수가 있다.

長官은 그 以上 延長할 必要가 없다고 判斷했을 때나 주위狀況의 變化에 따라 延長할 基礎가 벌써 없어졌다고 判斷될 때 든가 進行狀況報告를 提出한다는 條件과 이 延長에 關하여 붙여진 其他 條件을 履行하는 일을 怠慢하였을 때에는 언제든지 延長承認을 끝말일 수가 있다.

# CHAPTER VII - GENERAL ADMINISTRATIVE PROVISIONS

## 第七章 一般行政規定

### Regulations and Hearings

### 規則 및 聽問

Sec. 701 [371]. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

第701条[371]

(a) 이 法律을 効果的으로 施行하기 爲한 規則을 公布하는 權限은 本条에서 特別히 定하는바를 除外하고는 保健教育厚生長官에 賦与되어 있다.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(b) 財務長官과 保健教育厚生長官은 第801条規定을 効果的으로 施行하기 爲하여(同条에 特別히 定한 경우를 除外) 合同으로 規則을 制定하여야 하며 이같은 規則은 正當한 公告 후에 있어서 保健教育厚生長官이 定하는 方法과 發行期日에 있어서 이를 公布하여야 한다.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(c) 이 法律에 依해서 認定되거나 要求되는 聽問은 保健教育厚生長官이나 長官이 이 目的 때문에 指定한 官吏와 傭員에 의해서 管理되어야 한다.

(d) The definitions and standards of identity promulgated in accordance with the provisions of the Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(d) 이 法律의 規定에 따라 公布와 定義와 基準은 合衆國의 同 法律과 거기에 따른 規則에 包含되는 定義와 基準에도 不拘하고 이 法律施行目的을 爲해서 有效하다.

(e) (1) Any action for the issuance, amendment, or repeal of any

(e)(1) 第401条, 第403条(i)項, 第404条(a)項, 第406条, 第501条(b)項, 第502条(d)

regulation under section 401, 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public.

Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a

項과 (h)項에 立脚한 規則의 制定, 改正 또는 廢止는 (A) 長官이 스스로의 發意에 의한 提案에 따르거나 (B) 利害關係 있는 사람이 妥當한 理由를 提示하여 長官에게 請願하는것에 따른 提案으로서 始作된다. 長官은 이와같은 提案을 公告하고 모든 關心을 갖고 있는 사람이 口頭 또는 文書로서 그에 答할 생각을 提出할 機會를 주어야 한다. 그 다음 實施할 수 있도록 即刻 長官은 이 提案에 對해서 命令으로 行動하고 그 命令을 널리 公表해야 된다.

(2)에 定한 경우를 除外하고 命令은 그에 따라 定해진 期日에 發効한다. 但 그 期日은 反對意見이 提出되는 最終日보다. 앞서 있어서는 아니된다.

(2) 앞서 定한 命令이 公表된다음 30日以內에 그 命令이 施行되면은 不利한 影響을 받을 사람은 그 命令에 反對하는 條項은 特定해서 그 理由를 말하고 長官에게 反對하는 超旨를 申立하여 公聽會를 要求할 수가 있다.

反對를 表明할 期間이 지나고 實行할 수 있도록 되거든 即時 長官은 反對意見表明을 爲하여 期間을 둔 特別條項과 反對意見이 表明되지 않았든 것이 事實임을 밝히고 聯邦登錄에 通知를 揭載해야 한다.

notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) (1) in a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the

(3) 公聴會開催1/2 要求받은 다음에 實行할 수 있도록 되었으면 即時 長官은 正当한 通知를 한다음에 이와같은 反對의 資料나 關聯있는 証拠를 받아드릴 目的으로 公聴會를 開催하여야 한다.

公聴會에서는 關心을 갖고있는 사람은 自己自身이나 代理人으로 하여금 意見을 陳述할 수가 있다.

公聴會가 끝나고 實行할 수 있도록 되면 即時 長官은 命令으로 이 反對意見에 對해서 行動하고 그 命令을 公告하여야 한다. 이와같은 命令은 公聴會에서의 記錄의 本質的 証拠만에 立脚하여야 하며 命令의 一部 로써 事實의 詳細한 所見을 陳述하여야 한다.

長官은 命令속에 發効하는 日字를 明確하여야 하며 이는 長官이 早期發効를 必要로하는 緊急事態가 存在한다고 認定한 경우를 除外하고 命令公告 約 90日後로 하여야한다. 萬一 緊急事態때문에 早期發効를 行할 때는 長官은 그 狀態에 關한 所見을 그 命令속에 밝혀야만 된다.

(f)(1) (e)項規定에 의한 命令의 妥當性에 關한 論爭에서는 이와같은 命令이 發効함으로써 不利한 影響을 받을 사람은 누구든지 命令이 내린 다음 90日을 經過치 안은 以前期間의 本이 居住하는 場所 또는 主

Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition

營業場所에서 命令의 裁判上審査를 要求하기 위해서 合衆國訴願의 巡廻裁判所에 언제든지 訴願을 提出할 수가 있다.

裁判所書記는 訴願의 寫本을 保健教育厚生長官이든가 長官이 指定하는 官吏에게 送達하여야 한다. 長官은 이에 對해서 合衆國法律第28号第2112條規定에 따라 長官이 그 命令의 基礎가 되었던 手續의 記錄을 裁判所에 提出하여야 한다.

(2) 万一 訴願者가 追加証拠를 引用할것을 裁判所에 申請하고 그 証拠가 重要하며 訴訟手續에 있어서 그 証拠를 引用하지 않았던것에 妥當한 理由가 있었다는 두점에서 裁判所가 滿足한다면 裁判所는 이와같은 追加証拠 및 原告의 反論에 있어서의 証拠를 長官에게 提出하고 裁判所가 適當하다고 여겨지는 方法과 時期와 狀態에서 公聽會에 引用하도록 命令할 수가 있다. 長官은 追加된 証拠의 理由에 따라 事實에 關한 所見을 修正하거나 새로운 所見을 追加할 수가 있다. 그리고 長官은 이와같은 追加된 証拠에 對돌아가서 最部命令을 修正하거나 取消하기 爲해서 修正되거나 새로운 所見과 万一 있거든 勸告를 提出할 수가 있다.

(3) 本項(1)에 定하는 請願提出로서 裁判



referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently.

If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254]

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of

所는 命令을 肯定하거나 命令의 全部 또는 一部를 永久 또는 一時的으로 廢止 시키는 權限을 갖는다. 万若 長官命令이 規則을 發表하거나 改正하는 일이나 廢止시키는 일을 拒絶한다면은 이 命令이 法律에 立脚해 있지 않으면 裁判所는 그 判断에 따라서 長官에 對해 法律에 의하여 이와같은 規則에 關해서 行動하도록 하여야 한다. 事實에 關한 長官의 所見은 万若 實質의 証據에 의해서 支持된다면 最終的인 것으로 한다. (現在는 合衆國法律第28号第1254條에 의해서 카버되고 있다.)

(4) 長官命令을 肯定하거나 全部 또는 一部를 廢止한다고 하는 裁判所判断은 裁判上의 規則第239條와第240條에서 定한 裁判調書移送命令書나 證明書에 對한 合衆國最高 裁判所에 의한 審査를 條件으로해서 끝장이 난다.

(5) 本項때문에 開始된 行爲는 保健教育 厚生長官事務所를 占하고 있는 官吏의 交代와 事務所에서 어떠한 缺員과 같은 事態로 일어나서도 繼續되어야 한다.

(6) 本項에서 定하여진 救濟策은 法律에서 定해진 單 어떤 救濟策에 代替되는 것이 아니고 追加 되는 것이다.

(g) 長官은 (e)項에 規定한 記錄과 手續의 謄本이 證明된 寫本을 如何한 關係方面에도 그 請求와 費用負擔에 의 提供하여야 하며 그 謄本이 證明된 寫本은 命令에 關한

the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

[Regulation] §1.1 General regulation. (a) The provisions of regulations promulgated under the act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

手続이 以前에 成立되고 또한 (f) 項에서 定한 마지막것으로 되었을 경우에도 이에 구애됨이 없이 如何한 司法上の 事件과 販賣禁止의 告訴와 輸入의 除外와 이 法律의 規定에 의거 提起되었든 手続에서도 받아들여져야 된다.

[規則] §1.1 一般規則, (a) 行動을 行하는 일에 關해서 法律에 立脚하여 公布된 規則의 條項은 그 行爲를 하는 原因이 된 事項에도 適用된다.

(b) 第201條에 包含된 語句의 定義와 解釋은 法律에 立脚 公布된 規則속에 使用하는 때에도 같이 適用된다.