3. 分野別特記事項

3-1 各専門家報告

- ① 実験動物飼育・繁殖及び動物実験
 - I 機材供与計画

動物飼育施設関係の機材については先方に専任者がないため、 BFAD総務部長 (Chief, Administ. Div.) の Castillo 氏と協議した。センターの建築完成後の事業 の展開見込と合せて逐年機材を整備するというわれわれの原案は了承され、その案に沿って 要請書が作成されることになった。

ただし,進行中の建築との関係で機材のサイズの調整が必要であり, これからも細心の配 慮が必要であろう。

II 機材ならびに部品・消耗品等の現地調達可能性

動物飼育機材はほとんどが日本国内で調達することになろう。 部品および消耗品について もほぼ同じである。薬品およびガラス器具類についてはある程度現地調達も可能であり、場 合によってはその方がよいものもあろう。この方面については理化学分析部門で詳細な検討 がなされている。

動物実験関係では、測定器具としては、ポリグラフのみが問題であるが、日本の主要なメーカーのうち日本光電のみが現地に代理店をもっており、一定の手順(コミッション)により現地サービスを受けられる模様である。特殊機器に関する専門知識の程度は懸念されるところではあるが、最近のこれら測定機器は故障部分をユニットごと交換することができるようになっており、故障部分の判断ができれば対応できるようになっているようである。

熱帯医学研の話では、空調機、複写機の故障修理には難渋したとのことで、この方面の調達は現地主体で行うか、ある程度の技術指導を受けさせるべきであろう。

Ⅲ 技術協力実施に関する諸問題

- 1. 機材,材料の調達をはじめ、技術協力の具体的諸問題について、11月6日、熱帯医学研究所にて金子博士およびコォーディネーターの一の瀬氏と懇談し、具体的問題について種々助言を受けた。その内容についてはチーム各員の報告にも反映されると思うが、主要な点は次の通りであった。
 - (1) 機器調達はメンテナンスの関係で、できるだけ現地代理店を通じて行うことが望ましい。ただし、納期は長く、価格も高い傾向がある。部品についても同様である。現地 agent を通じて購入すると輸出入関税・手数料などが加算され、Peso 払いで約 1.5 倍 につくという。今年 2 月の政変で日本の企業がかなり引きあげたが、その影響はまだ残っている由である。
- (2) フィリピンの国家予算はRITMでは建物維持費(光熱費)と人件費のみである。外

国の援助を受けている機関には備品購入費はつかない、とのことで、当面JICA技術協力のみが頼りとなる。RITMではほかにWHO、米、加、豪各政府などから研究費を獲得している。

- (3) RITMの動物飼育施設のスタッフは獣医 2名と技術者 3名であり, うち技術者 1名は, JICAの業務費で雇用している(¥300/月)。現在マウス(日本から携行。通関は円滑だった由)。モルモット・ウサギ(いずれもベットショップまたは農家から購入。毒性試験には適当でないと考えられる), ヤギ(屋外)を飼育しているが, 繁殖には成功していないという。マウス・ラットの飼育室を開放式自然換気で設計したが, これは結局失敗で, ルームエアコンを増設して対応した。自然換気の飼育にはそれなりの設計, 工夫が必要であり, 空調方式との切替えを単に窓を開ける程度の操作で行うことは不可能である。飼料の製造は, 経費の関係で良質の原料が購入できないなど困難がある。
- (4) 派遣専門家の活動と生活について十分な処遇が望まれると述べられた。長期派遣専門家は現地で研究ができるようでないと技術の伝達ができない。専門書はきわめて乏しく, 医師が個人で所有しているものが主である。短期専門家は, 専門にもよろうが, 一般に最低1カ月は必要である。1年は不要である。通勤・移動のための車輌の確保は絶対に必要である。

2. 動物飼育-実験の技術協力について

今回動物飼育施設を担当する予定のOscar G. Gutierres Jr. 氏と面接する ことができ、この施設の将来に見通しが開けてきた。しかし、彼は獣医学部で実験動物学を学んだとはいえ、動物飼育施設の運転・安全性試験の実施には全く経験がなく、これから研修を開始する段階である。従って当面この動物飼育施設の諸業務は日本側主導ですすめなければならないと考えられる。動物飼育施設を利用した研究業務計画が必要であろう。

(なお、今回の滞在中、筆者は現地食品製造業者から動物を用いる安全性試験依頼の打 診を受けた。これは現地においてある程度動物試験の需要があることを示すものと考えら れる)

3. 技術協力の基本姿勢について

マニラWHOの梅内拓生博士と会い、懇談した。博士は東北大学医学部出の筆者の後輩で、かつ内科学教室の同門であり、旧知の間柄である。彼は内科学のかたわら細菌学を専攻し、4年来マニラWHOに勤務している。彼の現地での業績は、中国をフィールドとして、肝炎ワクチン集団接種し、肝癌の発生を予防しようとするブロジェクトを実施したことである。

彼のこれまでのJICAプロジェクトの成果を総体的に不十分と評価し、その失敗の主因は、技術協力派遣専門家の不徹底な態度にあると主張した。技術協力は本来当地の事業にお手伝いするのであるから、現地の主体性を尊重すべきであるというような基本姿勢は、

当地の人間を理解しない甘い判断であり、いわば怠惰に等しい。専門家は強力な指導性を 発揮して事をすすめなければ成功は覚つかない、と彼は評した。

筆者は必ずしもその意見に組するものではなく、技術協力には自ずから活動の範囲に限 度があり、現地をいたずらに混乱させるべきではあるまい、と考えるものである。しかし、 行動の統制は別として、動物飼育・実験に関する限り、効果的な指導性を発揮すべきこと は正当であろうと思う。

② 当部門に対する無償資金による機材供与は、汎用機材に限定されていたため、「微生物部門」 1本として取り扱われてきたが、この部門が、「食品微生物」および「薬品微生物」から成り 立っており、業務の内容が画然と区別されていることを考慮し、技術協力による機材の供与お よび技術の移転に関しては、個別に立案することが適当と考えられる。

1986 年度の機材供与計画は、今回の調査期間中に両セクションの代表者と話し合うことによって決定されたが、特定が困難な小型機材に関しては、"Fisher カタログ記載の型番と同等品"という表現をとった。

なお 1987 年度の機材供与計画に関しては、無償資金による機材と、BFADが現在所有している機材の移転による効果をみきわめたのち実行計画を策定することがのぞましいと考えられる。

研修員の受入れおよび専門家の派遣計画に関しては現時点では変更の必要性が認められない ため、調査期間中先方と話し合うことはなかった。

- ③ 食品理化学分析
 - 1. 協議·調査内容
 - 11.5 (水) 9時からの全体会議に引続きルセロの部屋で打合せを行う。
 - (i) 機材リストの作製法,目的を説明し,機材毎に検討を加え必要機材,不必要機材の選別を行った。
 - (ii) 機材の配置について詳細な検討を行った。
 - (III) 1988~1990年の必要機材リスト作製を指示。 6 日午後,確認の為の再検討を行うことを約束して BFADを辞去。

研修生, 6~7ヶ月(1ヶ月は語学研修) Mrs Aeba が選ばれた(4月頃来日の予定), 農薬分析経験者

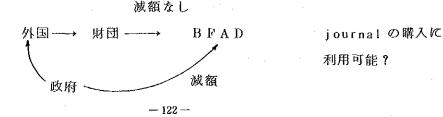
11.6 (木) 9時にRITMを訪問,金子リーダー及び一ノ瀬氏にRITMでの経験を 聞き所内見学後12時頃RITMを辞去

〔会議内容〕

(1) 機材及び知識の独占化に注意すること。

- (2) 管理面での上意下達が円滑に行われない傾向がある。
- (3) 建物周辺の木々を残し日陰を作ることが望ましい。
- (4) レクリエーションの為のコート (バレー, バスケット) を作ることが望ましい。
- (5) ガスボンベの inch ⇄ meter に注意(フィリピンはインチ)
- (6) 危険物倉庫は外部に作る
- (7) 消耗品在庫のリストを作らせること。 (BFAD職員が予算を要求するときに便利)
- (8) 自動車 (職員及びエキスパートの送迎) は必須
- (9) 機器の研修をしっかり行うこと(機器の寿命に関係する)
- (1) エキスパートの住居はマカティがよい
- (i) 電圧の変化が大きい 220Volt ~ 250Vol.従って stabilizer は必須 (コンピュータ内臓の機器は誤動作することがある)
- (12) 蒸留水湯アカがすぐにたまる。
- (13) Manual の盗難がある。
- (4) 機器の運搬;陸あげしてから手元にとどく迄に2ヶ月位かかる。(通 関料をブローカーに支払うと1~2週間で済む由,2000ベソ)
- 69 基礎的な専門書は原地調達可能。ペンをユニセフのクーポンにかえて おくと、発行元からの購入が容易。
- 00 棒温度計は中国製が手に入るが、目盛が細かくない。
- (17) 一般的な試薬(酸,アルカリ)は米国製が現地調達可能。フィッシャー,シグマのカタログは入手可能 ピベットーギプソン
- 08 カタログのリストはJETROにあるかもしれない。
- (9) RITMにフィリピン政府から認められている予算の内訳けは、人件費、光・熱・水料費だけである。研究費はつかない。外国からの資金は国家機関を通すと手元に入る迄に"目滅り"する由。但し、フィリピンでは国の機関でも特殊法人の財団をつくることが認められているので資金の受け皿としての機能をもった財団をつくりそれをうまく利用するとよい由。下図

11.6 (木) 外国からの資金の流れ図



(4) エクスパートの長期滞在はよくない由、ある程度力がついたらトラン スファーをうまくやる方が良い。

2時 30 分より、BFADにおいて食品部門の責任者ルセロと話し合う。 ディープフリーザー(検定用に一台納入)を入れて欲しい由、依頼をうけ る。バロス(検定)と話し合うよう指示してBFADを辞去(翌日の返事 では、サンチェス局長に一任した由)。

11.7 (金) 9時より、BFADに於て前夜の打合せ事項について協議後、食品関連部門の見学を行う。1990年の研修生の受入れを依頼された(work plan では未定としておいた)

〔注意事項〕

(1) 実験に使用する多量の蒸留水について

湯わかし型の装置を使用、毎月一回湯アカ落しを行う由。

製造能力約16 ℓ/hr. (専任の製造者1人)。

イオン交換樹脂の寿命は短かいと考えられる。

新しい装置を使って製造する場合には、装置の使用法についての指導 の強化が必要。

- (2) 引火性のエーテル(Ca. 20ℓ)が実験室内に保管してある,溶媒倉庫の設置が必要。
- (3) TLC用の製造装置はCosmetic Section と共用している。
- (4) 食品関連の情報源はCodex Arimentarius 1年1度発刊?)のみ。2時にFTI (Food Development Center)訪問。

参加者 斎藤,武田

付添入として、カルミナ・パーセ (Carmina Parce)

FTIのレイエス (Devinig S. Reyes)の案内で所内見学後, 所長(Dr. Alicia O. Lustre), 及び副所長と歓談。

〔見学内容〕

- (1) 大型機器は殆どない。 (2) 農薬の分析は近い将来始める由。
- (3) 食品関連の情報源は米国のBFAD。
- (4) かび毒の検査体制はほぼ完成(但しアフラトキシンのみ)。
- (5) 溶媒倉庫完備 (6) 溶媒の廃棄施設はない。
- (7) 異物検査は充実している。
- (8) BFADとの役割分担は明確(現在迄は)。

BFAD…Regulatory Analysis …試料は一般市場から。研究はいっさい行っていない。予算は政府から。

- FTI……Government Marketsの食品及び依頼検体が分析対象。 半官半民。資金はBFADより豊富らしい。研究業務を行っている由。Government Marketsの食品の分析を行っている。
- (9) 将来はBFADと合同セミナー等を通じて情報交換,研究協力を行いたい由?(性の質問に対する答えなので smooth に行われるかどうかは不明),情報量はFTIの方が多いと判断される。

4 時半よりアラバンの建築現場見学。滝川氏の案内で分析棟内部のみを見 学。後,危険物倉庫について話し合う。(雨のため)

2. 提 言 等

(I) ャル気を起させるために

BFAD Project の成功の鍵の一つは、BFADの職員の一人一人がいかに「ヤル気」を持つかにかかっている。

彼らが、自分達の業務の重要性を十分に理解し、将来に向って、フィリピン共和国に於ける食品衛生行政は何をやるべきかについて独自の考えを持つように指導し、機材の供与 も無駄なく行うべきである。

- [1] 安全に、健全に業務を行うために
 - ① 危険物保存倉庫,廃棄物処理施設の完備。
 - ② レクレーション施設(バレーコート,テニスコート及びバスケットコートelc を造り, FTI,RITM職員との対抗試合を試みるとよい。その際JICA杯を提供しておく と良い)の建造。
- [11] 食品衛生行政の指導的国家機関となるために

職員がフィリピン共和国の食品衛生の行方と意義とを明確に把握し、世界の各機関(日本厚生省、WHO、米国FDA、EPAetc)との接触を通し、食品衛生に関する外国の情勢を理解させ、フィリピン共和国に生かすよう指導すべき。

又、BFADの供与機材、例えばGC-MASSなどはFTIにもない機器なので、将来、必要な場合には測定の便を与える等の機材の有効利用を行い、更に情報の交換、合同ゼミ(FTI、大学等と)等を積極的に実施し、BFADの国の機関としての指導性を確立してゆくよう指導してやるべきである。

〔結 論〕

- (I),(II) 及び(II) はBFAD Project 成功のための必要条件ではあるが、十分条件ではない。この必要条件を満足させるためには、少なくとも下記2条件の実行が必須である。
- (i) Journal (新しい文献)を定期購読できるよりJICAが資金面の援助をする。

(ii) (II) の①及び②を完備する。

④ 医薬品理化学分析

1. 供与機材に関するBFADからの要望について

医薬品理化学分析分野に関しては、日本側提案に対して若干の修正要望と共に、参考図書(20冊)の供与要望があった。参考図書は技術移転の実をあげるために必要不可欠であるので、先方の要望に十分そった対応が必要と考えられる。

2. 機材の現地調達について

日本製又は外国製機器の現地代理店について、機材の現地調達事情を調査した。調査先 (括弧内は取扱機器メーカー名)は次の6社であった。

ANALYST SUPPLY HOUSE INC. (METROHM)

EDWARD KELLER (PHILS) INC. (METTLER)

BELGOR INVESTMENTS INC. (島津)

DAKILA TRADING CO. (BUCHI)

PHILAB INDUSTRIES INC. (日本分光, ヤマト)

MICRO BIOLOGICAL LAB, (日立)

- 1)機器の現地価格:いずれの代理店も輸入機器の現地価格表の用意はなかったので、現地価格の現状把握は困難であったが、いくつかの品目につき、品名をあげて現地価格を照会した結果から推察すると、輸入機器の現地価格は、日本国内価格よりもかなり割高になる模様であった。また各代理店共在庫は少なく、注文に応じ製造元から取寄せる場合が多い印象であった。
- 2) 日本国内調達機器のメンテナンスについて:いずれの代理店も日本国内で調達し、現地 に送付した機器の、据付調整、取扱指導、保証期間中の修理については、日本側代理店又 は製造元からの指示があったものについては無償で応ずるが、それ以外のものについては 有償で対応するとのことであった。また修理に関しては、修理用部品の在庫は豊富ではな く、その都度製造元から取り寄せる場合が多い模様であった。
- 3) 機器運転に用いるガス類の調達について:供与機材中にはガスクロマトグラフ等ガスを 用いる機器があり、これらの運転に用いるガスの供給は輸送上の問題もあるため、現地調 達によることが望ましい。そこで島津製作所の代理店であるBELGOR社に現地の機器用 ガス類の調達事情を照会した。その回答によると、CONSOLIDATED INDUSTRIAL GASES、INC・製の窒素、酸素、水素、アセチレン、ヘリウム、アルゴン、酸化窒素に ついては、納期2日で納入可能とのことであった。なお、品位はHIGH PURITY OR INSTRUMENT GRADEとのことであるが、窒素がECDガスクロマトグラフィに使 用可能か否かについては調査が必要と考えられる。また、現地のポンベのネジはインチ規

格であり、日本製機器のネジはメートル規格であるが、異規格ネジ結合用ジョイントは BELGOR社で調達可能との回答であった。

4) 消耗機材について:BFADで現在使用している消耗器材のほとんど全てが輸入品であ り、ガラス器具はPYREX及びKIMAX、試薬類はFISCHER、BAKER及びMERCK 社製であった。消耗器材の現地価格、納期等は未調査である。

3. 機材調達に関する提言

供与測定機器類には現地における据付調整,取扱指導,供用開始後の修理等専門技術者の 関与を要するものが多く,それらを円滑に実施するには現地調達が望ましい。しかし、今回 の調査から現地価格は日本国内価格に比し、かなり割高になる模様であり、また少なくとも 1986 年度分については日本人専門家の現地赴任の目途も立っていないことから、日本国内 調達が主体となると考えられる。したがって国内調達に当たっては、現地代理店が無償で据 付調整等のサービスに応ずるよう手配することを必須条件とする必要がある。また、現地代 理店の補修用部品の在庫が少ない模様であるので、予想される補修用部品をあらかじめ供与 するよう心掛けることが望ましい。なお、取扱説明書は、十分な内容の日本語及び英語のも のを添付させることが必要である。

4. 危険物の保管について

供与機材中には、引火性低沸点溶媒等の危険物も含まれているので、それらの安全な保管 について、慎重な対応が必要と考えられる。

資 料

実施協議調査団収集資料	
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(61.7.25 現在)

Republic of the Philippines

Ministry of Health

BUREAU OF FOOD AND DRUGS

FUNCTIONAL CHART

OFFICE OF THE DIRECTOR

Provides consulative and advisory services and acts as the administrative and executive arm of the Minister of Health on matters pertinent to food, drug, cosmetic, traditional medicine, device and household products containing hazardous substances. Develope and recommends rules, regulations and standards in accordance with Republic Act No. 3720 and other pertinent laws and coordinates with Regional Health Offices in the technical supervision of the same. It shall plan, direct, coordinate and evaluate the over-all Bureau operation and shall perform other functions as may be provided by law or assigned by the Minister.

PRODUCT EVALUATION DIVISION

Formulates and recommends policies, standards, guidelines and operational procedures on scientific evaluation, registration and monitoring of advertisement of food, drugs including traditional medicine, cosmetic, device and household products containing hazardous substance and the system of monitoring adverse drug reactions. Plans directs and conducts evaluation and registration of products as well as the monitoring of its advertisement in various mass media as well as drug adverse reactions. Conducts research and evaluates the program on product evaluation/ control and monitoring system of adverse drug reactions. Performs other functions as may be assigned by the Director.

REGULATION DIVISION

Formulates and recommends policies, standards, guidelines and operational procedures on: inspection and licensing of establishments dealing on food, drug, including traditional medicine, cosmectic, device and household products contraining hazardous substance; investigation; surveillance; product sample collection; and data collection on adverse drug reactions and on emergency activities in time of poison outbreaks, national recalls, etc. Plans, directs and conducts inspection and licensing of establishments, collection of product samples and data on adverse drug reactions. Performs other functions as may be assigned by the Director.

LABORATORY DIVISION

Formulates and recommends policies, standards, guidelines and operational procedures on laboratory testing of food, drug including traditional medicine, cosmetic device and household products containing hazardous substances. Plans, directs and conducts laboratory testing of products for identity, purity, quality and fill of container and prepare certificates of compliance or non-compliance with standards. Conducts systematic scientific laboratory research and studies. Performs other related functions as may be assinged by the Director.

ADMINISTRATIVE DIVISION

Develops and recommends the short/long range plan and budget estimates of the Bureau. Provides the Bureau with general administrative support services related to personnel recruitment tainning and development; record and property management; cash collection and disbursement; accounting; communication and transportation and general maintenance services. Performs other functions as may be assigned by the Director.

(Section) (61, 7, 25 現在)

Republic of the Philippines
Ministry of Health
BUREAU OF FOOD AND DRUGS
FUNCTIONAL CHART

OFFICE OF THE DIRECTOR/ASST. DIRECTOR

Provides consultative and advisory services and acts as the administrative and executive arm of the Minister of Health on matters pertinent to food, drug, cosmetic, traditional medicine, device and household products containing hazardous substances. Develops and recommends rules, regulations and standards in accordance with Republic Act No. 3720 and other pertinent laws and coordinates with Regional Health Offices in the technical supervision of the same. It shall plan, direct, coordinate and evaluate the over-all Bureau operation and shall perform other functions as may be provided by law or assigned by the Minister.

PRODUCT EVALUATION DIVISION
Plan, direct, coordinate and control activities of all sections under it.

PRODUCT EVALUATION

Formulates and recommends policies, standards, guidelines and operational procedures on scientific evaluation of products under BFAD jurisdiction and conducts evaluation of the same.

PRODUCT REGISTRATION

Formulates and recommends policies, standards, guidelines and operational guidelines in the registration of products under BFAD jurisdiction and conducts registration of the same.

PRODUCT ADVERTISEMENT

Prescribes and recommend general standards and guidelines on the veracity of nutritional and medical claims in the advertise-ment of food, drug and cosmetic and monitor its advertisement in mass media.

ADVERSE DRUG REACTION
Maintains and operates the
system on monitoring of adverse
drug reactions.

REGULATION DIVISION

Plan, direct, coordinate and control activities of all sections under it.

INSPECTION

Formulate and recommend general standards and procedures on inspection of establishments under BFAD jurisdiction and conducts inspection of the same.

LICENSING

Process and issue licenses to operate on establishments under BFAD jurisdiction and maintains registry of the same on a nationwide scope.

IMPORT AND EXPORT

Conducts inspection in different port of entries and bonded warehouses of imported and exported products under BFAD jurisdiction.

LABORATORY DIVISION

Plan, direct, coordinate and control the actitivies of all sections under it.

PHYSICO-CHEMICAL

Conducts physical and checmical testing of products for identity, purity, quality and fill of container and prepare certificates of compliance or non-compliance with standards.

MICROBIOLOGY

Conducts microbiological testing of products under BFAD jurisdiction and prepare certificates of compliance or non-compliance with standards.

TOXICOLOGY

Conducts toxicological testing of products under BFAD jurisdition.

EXPERIMENTAL ANIMALS

Care and breeding of experimental animals.

(head; veterinarian) (ALABANG新施設への移転後)

ADMINISTRATIVE DIVISION

Plan, direct, coordinate and control activities of all sections under it.

PLANNING AND BUDGET

Develops and recommends the short/long range plan and budget estimates of the Bureau.

PERSONNEL

Performs personnel recuitment, training and development.

ACCOUNTING

Provides accounting services for the financial operation of the Bureau.

CASH COLLECTION AND DISBURSEMENT

Collect fees and charges imposed by virtue of RA 3720 and PD 881 and disburses funds for expenses incurred by the Bureau.

PROPERTY AND GENERAL SERVICES

Supply and property management, transportation and other general maintenance services.

CENTRAL RECORDS

Maintains a general recordskeeping system of the Bureau.

資料II BFAD人員配置図

(61.7.25 現在)

(一部数字の不一致有)

OFFICE OF THE DIRECTOR

1 - Director

1 - Pharmacologist

1 - Pharmacy Adviser

1 - Senior Statistician

1 - Senior Clerk

1 - Stenographer

1 - Messenger

1 - Secretary

g

(Pharmacist)

(Doctor of Medicine)

(Pharmacist)

PRODUCT EVALUATION DIVISION

1 - Food and Drug Evaluation Chief

1 - Supvg. Pharmaceutical Researcher

2 - Senior Pharm. Researcher

3 - Research Chemist II

3 - Pharmaceutical Researcher

2 - Food & Drug License Examiner

2 - Senior Clerk

1 - Bacteriologist

2 - Clerk II

1 - Chem. Lab. Tech.

1 - Bact. Lab. Tech.

1 - Bact. Lab. Helper

(Pharmacist)

(Pharmacist)

(both Pharmacists)

(all Chemists)

(all Pharmacists)

(both Midwife)

(Med. Tech.)

20

REGULATION DIVISION

1 .	- Food and Drug Regulation Chipf	(Pharmacist)
4.	- Supvg. Food and Drug Inspector	(all Pharmacists)
2 -	- Supvg. Food and Drug License Examiner	(both Pharmacists)
1 -	- Senior Pharmaceutical Researcher	(Pharmacist)
1.2	- Senior Food and Drug Inspector	(all Pharmacists)
18 -	- Food and Drug Inspector	(all Pharmacists)
4 -	- Senior Food & Drug License Examiner	
6 -	- Senior Food Inspector	(Med. Tech. Food Tech.)
4.	- Food and Drug License Examiner	
1 -	- Records Officer I	
7 -	- Food Inspector	
6 -	- Clerk II	
2 -	- Chem. Lab. Tech.	
68		
2 · 	- Chem. Lab. Tech.	

LABORATORY DIVISION

(Pharmacist)
(all Pharmacists)
(all Chemists)
(all Pharmacists)
(all Chemists)
(1-Pharmacist; 2- Med. Tech.; 1- Tech.)
(all Pharmacists)
(all Chemists)
(Pharmacist)
(both Chemists)
(all Pharmacists)
(Biochemist)
(all Chemist)
(B,S.E.)

- 5 Chem. Lab. Tech.
- 2 Bact. Lab. Tech.
- 4 Bact, Lab, Helpor
- 1 Utility Man

71

ADMINISTRATIVE DIVISION

1 - Administrative Officer II (Bus. & Pub. Adm.) 1 - Chief Accountant (Bus. Adm.) 1 - Budget Officer I (Bus. Adm.) 1 - Cashier III (Commerce) 1 - Personnel Officer (Bus. Adm.) 1 - Accountant I (Commerce) (Bus. Adm.) 1 - Administrative Asst. II 1 - Records Officer II (B.S.E. Educ.) 1 - Cashier I (Commerce) 1 - Information Editor (B. Masscom) 1 - Budget Examiner

1 - Bacteriologist (Med. Tech.)

1 - Bookkeeper I (B.S. Adm.)

1 - Reference Librarian (B.S.E.)

2 - Senior Clerk

1 - Accounting Clerk III

1 - Acotg. Clerk II

1 - Shop Electrician

3 - Clerk II

2 - Driver

3 - Security Guard

3 - Chem. Lab. Tech.

3 - Bact. Lab. Tech.

1 - Cash Clerk

1 - Supply Officer

3 - Utility Man

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38

Grand Total of Personnel = 205

※ 総職員数 206(205)

それに対し総ポスト数 274

即ち, 68(69)のポストが現在空席である。

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LABORATORY DIVISION

O FOFICE E

(61.7.25 現在)

Virginia Barros (代行)

Parce	Guzman
-;	Ś
Carmina	Soledad
{	7

Madura 3. Frances S.

4. Antonio T. Tuazon

(Consuelo A. Buenvenida) PHYSICO-CHEMICAL

(Alicia G. Salazar) MICROBIOLOGY

(Ofelia M. Alba)

TOXICOLOGY

Elisea B. Elveña Dory B. Duran Drug:

Rosa Marceline Cruz

Jocelyn Alcasabas

Luzminda Fabila

Nazarita Lanuza

Elenita Ong

Rosario Daria

Marilou Martinez

1. Lydia G. Silvestre Teresita D. Romero Drug:

2. Remedios Pascual 1. Elisa Caballero Toxicology:

3. Felicisima Rosal

4. Virginia Gracia 5. Romeo Pagayucan

Animal Care and

Unit:

Breeding

Teresita Vaño Uy

Buenaflor Balasta Edna V. Macandili Leonila A. Agbay

Presentacion Hicban Leonora Advincula

Zenaida T. Baumann Jesus Salamanca

Delfin Sarmiento Blanca Alfonso

Amelita Manalansan

Canunita Edmilao

Melinca Eusebio

Victorino Alejar

Naida de Ramos

Editha Opulencia

1. Alicia Lorenzo

Cosmetic:

Zorina Fausto 14. Loida Isip Pyrogen, Histamine Assay Unit:

1. Isabel N. Dy Food:

Remedios Venturina Elisa Autea

Emma D. Cabello

Hermelina Sevilla

Socorro de Guzman

Leonida Castillo (PED & LAB.) Catherine P. Cruz (PED & LAB.) Ma. Fely Senfelices Rosanna Peralta

Gloria P. Tomboc

Josefa Lucero

Food:

Danilo Cruz

Nancy Mercado (PED & LAB.) Purificacion de Guzman

Ma. Fides Eustaquio Corazon Dagsan

Norman Henson

Lourdes Cruz

Teresita Franco

Rosario Martin

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[z.] S [1]

2. Amelita Manalansa 1. Alice Lorenzo

3. Melinca Eusebio

Zenaida Bumanlag Gracia Julieta

Violeta Buen

- 136

Veneranda Catriz

Virginia Ortiz

Rodolfo Palma

Brief Information

on

Bureau of Food and Drugs

I - Organization

The Bureau of Food and Drugs (BFAD) is a new staff and line office of the Ministry of Health created by virtue of the provisions of Executive Order No. 851 dated December 2, 1962. It assumed the objectives, duties and functions of the abolished Food and Drug Administration.

As a staff bureau, BFAD provides consultative and advisory services and acts as the executive arm of the Minister of Health on matters pertinent to food, drugs, device, cosmetic and household products containing hazardous substances. It developes and recommends rules, regulations and standards in accordance with the present BFAD laws.

Technical supervision of the Food and Drug Services of the 12 RHO in the implementation of the rules and regulations on food, drugs, cosmetic, devices and household products containing hazardous substances is provided by this Office.

Line functions in Metro Manila Area (National Capital Region) are undertaken by conducting inspection and licensing of establishments and collection of product samples. Of the total 29,000 food, drugs, cosmetic and household hazardous substance establishments in the Philippines, 10,000 establishments are located in Metro Manila Area. Testing of all products under BFAD jurisdiction is done by the Laboratory Division for purposes of checking the safety and good quality of products for consumers protection. In 1985, a total of 54,000 laboratory examinations and analyses were performed by the Laboratory Division. See Annexes A, B and C, BFAD Organizational and Functional Chart.

II - Mandate, Objectives and Functions

1. Mandate

- a) Republic Act No. 3720 An Act to ensure the safety and purity of Foods, Drugs and Cosmetics being made available to the public by creating the Food and Drug Administration which shall administer and enforce the laws pertaining thereto.
- Date of Effectivity: June 22, 1963
 b) Republic Act No. 5921 An Act regulating the practice of pharmacy and setting standards of pharmaceutical education in the Philippines and for other purposes.
 - Date of Effectivity: June 23, 1969
- c) Republic Act No. 6425 Dangerous Drugs Act of 1972
 Date of Effectivity: March 30, 1972

d) Republic Act No. 953 - An Act to provide for the registration of, with the collector of internal revenue and the imposition of fixed and special taxes upon all persons who produce, import, manufacture, compound, deal in, dispense, sell, distribute, or give away opium, marijuana, opium poppies or coca leaves, or any synthetic drug which may hereafter be declared habit forming by the President of the Philippines, their salts, derivatives or preparations, and for other purposes.

Date of Effectivity: June 20, 1953

e) Presidential Decree No. 881 - Empowering the Secretary of Health to regulate the Labelling, Sale and Distribution of Hazardous Substances.

Date of Effectivity: Jan. 30, 1976

f) Presidential Decree No. 280 - Authorizing the FDA to order the Closure or Suspend or Revoke the License of any Drug Establishment which may be found Administratively to have violated the Laws and Regulations governing the Sale or Dispensation of Prohibited or Regulated Drugs, Medicines and Similar Substances.

Date of Effectivity: August 27, 1973

g) Letter of Instruction No. 1223 - Authorizing the Minister of Health, through the Food and Drug Administration, to effectively administer R.A. 3720, otherwise known as the Food, Drug and Cosmetic Act, in the interest of Consumer Protection.

Date of Effectivity: April 13, 1982

h) Executive Order No. 776 - Regulation of importation of semisynthetic antibiotics such as all forms and salts of ampicillin and amoxycillin.

Date of Effectivity: Feb. 24, 1982

i) Executive Order No. 851 - Reorganizing the Minister of Health, integrating the components of health care delivery into its field operations, and for other purposes.

Date of Effectivity: Dec. 2, 1982

j) Central Bank Memorandum -

To Authorized Agents Banks No. 56 - Applications to Import
"Sodium Cyanide" (EP 511-09.62) under
all modes of payment may be given due
cause provided these are properly
covered by written approval from the
Food and Drug Administration.

Date of Effectivity: July 21, 1977

k) Central Bank Memorandum -

To Authorized Agents Banks No. 2 - All application for importation of "Chlorofluorocarbon" shall be given due course after prior clearance from Bureau of Food and Drugs for reason of public health and safety.

Date of Effectivity: Jan. 14, 1983

2. Objectives

To ensure safe and good quality supply of food, drugs including traditional medicine, device, cosmetic and household products containing hazardous substances by regulating their production, sale and distribution to protect the health of the people as mandated by the provisions of the Food, Drug and Cosmetic Act (RA 3720), Household Hazardous Substance Decree (PD 881) and other pertinent laws and regulations.

3. Functions

The Bureau assumed the functions of the abolished Food and Drug Administration (Section 4 of E.G. 851)

The Bureau as a regulatory agency whose activities shall be consistent with the goals and objectives of the Ministry of Health shall undertake the following functions:

- a. Provide consultative and advisory services to the Minister of Health on matters pertaining to food, drug including traditional medicine, device, cosmetic and household products containing hazardous substances;
- b. Develop and recommend policies, regulations and standards in accordance with Republic Let No. 3720 (Food, Drug and Cosmetic Let) R. 5921 and other pertinent laws and regulations for approval of the Minister of Health;
- c. Coordinate with the Regional Health Offices in the technical supervision of the enforcement of the same laws and its implementing rules and regulations.

- d. Administer and execute the implementation of the policies, rules, regulations and standards approved by the Minister in accordance with the Food, Drug and Cosmetic Act (RA 3720) Decree on Hazardous Substances (PD 881) RA 5921 and other pertinent laws;
- e. Conduct inspectional, investigational, sample collection, surveillance programs, seizure and condemnation of product that is adulterated;
- f. Conduct the evaluation and registration of prudtes as well as the development of a system in monitoring adverse drug reactions;
- g. Issue licenses for the operation of establishments dealing with products within its jurisdiction:
- h. Undertake testing of products to determine compliance with standards of identity, purity, quality and fill of containers;
- i. Fix the rates of and levy, assess and collect fees for the licensing of establishments, testing and/or registration of products;
- j. Recommend institution of criminal action and administrative sanction for violation of the laws and its implementing rules and regulations;
- §. Prescribe general standards and guidelines with respect to the veracity of nutritional and medicinal claims in the advertisement of food, drugs and cosmetics in the various media, to monitor such advertisement and to call upon any erring manufacturer, distributor or advertiser to desists from such inaccurate nutritional or medicinal claims in their advertising:
- Conduct and/or support research and related activities to obtain necessary information;
- m. Devilop and implement a broad program to promote voluntary compliance and cooperation between the consuming public, the regulated industries, multidimensional professional groups through educational and informational activities;
- n. Divelop guidelines on emergency preparedeness in time of poison outbreaks, national recalls, etc., in coordination with field personnel;

- o. Conduct continuing manpower development programs in coordination with the Health Education and Manpower Development Service of the Ministry; and
- p. Perform such other functions as may be provided by law or assigned by the Minister.

III - Program and Projects:

1. Program (- laws)

Food, Drug, Cosmetic and Household Hazardeus Substances Control.

- 2. Projects/Services (Strategy)
 - 2.1. Inspection and Licensing of Establishments and Collection of Product Samples through the Regulation Division.

<u>Objectives</u>

To plan, program, direct and provide technical guidance in the inspection, sample collection and registration of establishments engaged in the manufacture, distribution and sale of good, drugs, cosmetics, devices and household products containing hazardous substances.

2.2. Laboratory Examination/Analysis of roducts through the Laboratory Division.

Objectives

To plan, program and provide technical guidance in the laboratory testing of food, drugs, cosmetics, devices and household products containing hazardeus substances.

2.3. Policy formulation, product evaluation and information, programs planning and standard development including general administrative and support services through the Office of the Director, Product Evaluation Division and Administrative Division.

<u>Objectives</u>

To undertake policy formulation, product evaluation and information program planning and standard development including general administrative and support services.

IV - Types of Licenses, Certificates, Permits/Clearance Authorization

Issued to the Public:

3.1. Licenses/Certificates

- 1. License to Operate Food Establishment
- License to Operate Drugstore
 License to Operate Cosmetic Laboratory
- 4. License to Operate Pharmaceutical Laboratory
- 5. License to Cperate Drug Department
- 6. License to Operate Hospital Pharmacy
- License to Operate Botica sa Barangay
- 8. License to Operate Household Hazardous Substance Establishment
- Renewal of License to Operate:
 - a. Household Remedy Storeb. Chinese Drug Store
- 10. Certificate of Compliance with $^{\rm T}$ echnical Requirements 11. Certificate of $^{\rm P}$ roduct Registration
- 12. Certificate of Registration of "edical Director
- 13. Certificate/Report of Laboratory Analysis
- 14. Certification of Registered Products of a Drug Company
- 15. Certification of Registered Establishments

3.3. Permits/Clearances and Authorizations

- 1. Clearance of Business/Trade Names
- 2. Clearance of Product Brand Names
- Export Commodity Clearance for Food Products
- Import Clearance for Food Color Additices
- Authority to Import Potassium Cyanide, Chlorofluorocarbon and Borax
- 6. Authority to Release Imported Samples (Finished Products) from Custom Custody
- 7. Authority to Reluase Imported Products Under BFAD jurisdiction from Point of Entry
- 8. Permit to Export Pharmaceuticals
- 9. Permit to Import intibiotics
- 10. Permit to Send Samples for Leboratory Analysis Abroad 11. Permit to Mail/Handearry to other countries drugs and food for personal use

For the period January to December 1985, the Bureau of Food and Drugs helped in the protection of the health of the Filipino people by ensuring that: processed foods are safe and wholesome; drugs, devices and cosmetics are safe and effective for their intended usage; and; that household products containing hazardous substances are properly labelled.

Its major accomplishments for the year were as follows:

- 1. Developed and recommended the approval of the following rules and regulations:
 - a) Administrative Order No. 106-A s. 1985: Ammendments to A.O. no. 60 s. 1968 on Regulations Governing the Operation of Drug Establishments.
 - b) Administrative Order No. 116-B s. 1985: Implementation of Section 4 and 8 of Executive Order No. 851, Creating the Bureau of Food and Drugs which shall assume the functions of the abolished Food and Drug Administration.
 - c) Administrative Order Mo. 123-A s. 1985: Standard for Banana Sauce.
 - d) Administrative Order No. 129 s. 1985: Banning and Withdrawal of FLOSINT TABLETS (Indoprofen) from the market.
 - e) Memorandum Circular No. 1 s. 1985: Sale and Distribution of Glacial Acetic acid as Vinegar or for vinegar manufacture.
- 2. Hosted the 1985 ASEAN Experts Neeting on Drug Evaluation and Control (Registration) in Cooperation with the Technical Cooperation Among ASEAN Countries on Pharmaceuticals held on 5-7 November 1985 in Manila; participated in by Malaysia, Singapore, Thailand and Indonesia.
- 3. Prepared and established a Secondary Reference Substances in coordination with five Lean countries and the NHO.
- 4. Prepared and recommended two additional antibiotic reference substances for validation and final adoption.
- 5. Conducted major studies on important topics such as Cinchona Bark, Kargasok Tea and Fluoride Stability in Toothpastes.
- 6. Destroyed expired, spoiled, returned and bad order finished pharmaceuticals, raw materials and packaging materials approximately worth P2.9 million.
- 7. Surveyed fake drugs in Metro Manila and outside Metro Manila which led to the discovery of a number of adulterated, misbranded and unregistered drugs.
- 8. Confiscation of adulterated and misbranded parenteral, and oral preparation as a result of an intensive survey of suspicious/fake drugs.
- 9. Officially recognized by the WHO as a training ground for fellows from Indonesia and the Trust Territory, South Pacific for food inspection.

				.1925.
Program/Project	Unit	Physical Target	Physical Accomplishment	Project Cost
Program				·
Food, Drug, Cosmetic and Household Hazardous Control				
Project	· .			
l. Inspection and Licensing of Establishments and Collection of Preduct Samples	Inspection and Licensing Division			P2,119,000
a. Inspection	·			
 No. of Estabs. No. of Estabs. 		10,012 6,6,4	10,220 9,864	
<pre>inspected 3. No. of import/ export/product inspection</pre>		as received	10,349	
b. Licensing of Estabs.		10,220	8,219	
c. Collection of product samples		as received/ required	2,886	
2. Laboratory Examination Analysis of Products	Leboratory Division	as received	53,704	P2,079,000
6. Product Evaluation and Registration	Prod. Eva- lustion &			
a. Old Drugs	Reg. Div.	5,005	9,635	Included in
b. New Drugs		as regeived	1,879	No. 4 below
c. Cosmetic		as received	334	
d. Household Hazardous Substance		as received	84	
e. Food		as received	1,894	
4. General Administration and Support Services	Office of the Direc- tor and Idminis- trative Division	non-measura-	non-measura-	P1,788,880
		ble	ble	P5,986,880

(動物の輸入等とその取扱いに関する諸規則)

Republic of the Philippines
Department of Agriculture and Natural Resources
BUREAU OF AMIMAL INDUSTRY
Manila

August 3, 1966

ANIMAL INDUSTRY
ADMINISTRATIVE ORDER
NO. 7-2

SUBJECT: Rules and regulations governing the importation, bringing, or introduction of animals into the Philippines from foreign countries, and prescribing the treatment to which they shall be subject before shipment and after their arrival in the Philippines.

Pursuant to the provisions of Section 1762, sub-sections (a), (b) and (c) of Section 1765 and Section 1770 of the Revised Administrative Code, as amended by Act No. 3639, the following rules and regulations governing the importation, bringing, or introduction of domestic animals into the Philippine Islands from foreign countries and prescribing the treatment to which they shall be subjected before shipment and after their arrival in the Philippines, are hereby promulgated for the information and guidance of all concerned:

GENERAL PROVISIONS

- 1. Definition For the purpose of this Order, the terms herein used are defined as follows:
 - (a) "Domestic animals" shall apply to and include horses, mules, cattle, carabaos, hogs, sheep, poats dogs, cats, rabbits, deer, fowls, circus, and pet animals, and those intended to be used for show or oxperimental purposes. (Section 1, Act No. 3630, as amended by Act No. 3830).
 - (b) "Dangerous communicable diseases", as herein used, include glanders or farcy, surra, nagana, douring, encophalomyelities, anthrox, rinderpest, tuberculosis, hemorrhagic septicemia, blackley, contagious abortion, contagious pleuropheumonia, hydrorhobia, actinomycosis, leptospirosis, piroplasmosis, anaplasmosis, hop cholera, swine plague, vesicular exanthema, swine erysipelas, European fowl pest, fowl pox, fowl typhoid, fowl cholera, pullorum, leukosis complex, blackhead of turkey or any other acute communicable disease which may cause a mortality of over five per centum in the period of one (1) month.
 - (c) "Persons" shall be construed as either singular or plural, as the case demands, and shall apply to and include corporations, firms, associations, companies, societies and tother legal entities.
 - (d) "And" may be read "or" and "or" may be read "and", if the sense requeres it.

- 2. It shall be unlawful for any person to import, bring or introduce live cattle, including carabaos, buffaloes, and horses, into the Philippines from any foreign country. However, the Director of Animal Industry may, with the approval of the Secretary of Agriculture and Natural Resources, authorize the importation of live cattle, including carabaos, buffaloes and horses into the Philippines for breeding and draft purposes and bovine cattle for the manufacture of serum, and of those which are authorized by law to be imported, subject to the provisions of this Order.
- 3. General requirements before making importation Any person contemplating the importation or bringing in or introduction into the Philippines from any foreign country of any domestic animal shall file a request in writing with the Director of Animal Industry, stating the number and kind of animal he desires to import, the point of origin, port of embarkation, probable date of shipment, and the object or purpose for which the animals are to be used. IN CASE OF POULTRY, THE IMPORTER SHALL INDICATE THE KIND, BREED, STRAIN AND CLASSIFI-CATION AS TO GRANDPARENT STOCK, PARENT STOCK OR COMPERCIAL STOCK, AS THE CASE MAY BE, THE NUMBER AND RATIO OF MAINS TO FEMALES, AND THE NAME OF THE POULTRY FARM OR ESTABLISHENT ISSUING THE FRANCHISE, IF THE IMPORTER IS A FRANCHISE HOLFER. ALL FRANCHISES MUST BE RECISTERED WITH THE BUREAU OF ANTVAL INDUSTRY. Upon approval of the application, the Pirector shall designate the point of debarkation and advise as to the probable quarantine restrictions that will be necessary in case at or about the time of shipment a dangerous and communicable animal disease exists in the country of origin, and make possible quarantino station accomodations so as to prevent unnecessary inconvenience and loss. Animals coming from foreign countries without permits shall not be allowed to be landed.

All animals imported into the Philippines shall be subject to such quarantine and test as amay be prescribed by the Director of Animal Industry and those that may be found to be infected with dangerous communicable animal diseases shall immediately be condemned, killed and properly burnt or buried in the present of a representative of the Bureau of Animal Industry at the expense of the importer.

TASMANIA OR NEW ZEALAND

h. Importation of dairy or breeding cattle from Australia. No dairy or breeding cattle from Australia shall be admitted into the Philippines unless accompanied by a certificate of health and origin to be issued by the Chief Federal Quarantine Officer of the state in Australia. Said certificate shall contain information furnished by the owner on the following points; Breed, color, age, sex, brand, place of birth, and the places or locations to which the animal was taken before the date of departure. The owner shall declare under oath that the information furnished by him is true and that the animal never had contapious pleuro-pneumonia and contapious abortion (brucellosis) nor has been in contact with any animal so affected.

The Dollowing certification is required:

(a) A declaration by the owner stating that to the best of his knowledge and belief the cattle are healthy and free from disease, that they

have not been in contact with any disease animal during the proceding six months and that they have not originated from or been kept in any of the following areas:—

- ···(1) Queensland
 - (2) That portion of the Northern Territory lying outside of the Central Australia Contagious Pleuro-pnuemonia Protect Area
 - (3) That portion of Western Australia lying north of the 260 south parallel of latitude.
 - (h) Any other states or portion thereof where Contagious Pleuro-pneumonia is known to exist!
- (b) A certificate by a povernment veterinary surgeon:
 - (1) That the cattle had been subjected to the intradermal tuberculin test with negative results on two occasions at a thirty day interval, the last test being within five days before shipment.
 - (2) That the cattle are from a Brucellosisfree herd in which vaccination is not practised or that they were vaccinated between the age of Wand R months with strain 19 vaccine.
 - (3) That the cattle had been subjected to the argulativation test for Brucellosis on two occasions at a thrity day interval, the last test being within 5 days before shipment unless waived by the Director of Animal Industry to be limited only to one test and that the results of the test were:
 - (sa) merative in the case of animals from a Brucellosis-free herd, or
 - (bb) showed a post vaccination titre only in the case of animals which have been vaccinated.
 - (h) That the cattle originated from herds where neither Trichomoniasis nor Vibriosis nor Leptospirosis nor "Q" Fever are known to exist or that the cattle have been tested for these diseases with negative results.
 - (5) That the cattle originated from a property where Johne's Disease has never been known to exist.
 - (6) That he has exmained the cattle and their places of origin or confirement and found no evidence of Contagious Pleuro-pneumonia or other contagious disease, also that he has no reason to doubt the owner's decla-

ration. (Note: The Philippine Buying Commission should inquire from State Veterinary Authorities regarding properties known to be infected with Trichomoniasis, Vibriosis, Leptospirosis, "Q" Fever and Jone's Disease. Where possible cattle will be tested for Johne's Disease) (

(7) That the cattle had been subjected to the complement fixation test for Contagious Bovine Pleuro-pneumonia on two occasions at a 20 to 30 days interval between tests, both tests being not more than forty days before shipment. That the results of these tests in all cases, were negative.

The said certificate of heatlh and origin shall be in the manner required by the form prescribed in section (7) hereof.

- 5. Importation of dairy or breeding cattle from Tasmania or New Zealand. - No dairy and breeding cattle from Tasmania and New Zealand shall be allowed entry in any port of the Philippines unless accompanied by a certificate from the local Federal Quarantine Officer of the Australian port where transhipped, to the effect that the animals were kept under covernment supervision during transhipment and were not exposed to infection with contagious pleuro-pneumonia and contagious abortion. Such dairy and breeding cattle from Tasmania and New Zealand shall be allowed to land in the Philippines only when transported from Australia under the conditions above specified and those required for a similar stock ordginating from Australia. Such cattle from Tasmania and New Zealand shall also be accompanied by a certificate from the Department of Agriculture of Australia to the effect that Tasmania and New Zealand are wholly free from contagious pleuro-pneumonia; that the animals have been tested with tuberculin and two consecutive contagious abortion agglutination test with the negative results; performed at thirty days interval, the last test to be made within five days before shipment; that the cows or bulls should come from brucellosis and tuberculosis-free herds as certified by the Chief, Quearantine Officer of the state of origin or when the 4 to 8 months of age and less than 36 months old; that the shin has been thoroughly disinfected if it transported infected cattle on its preceding voyage; and that a complete record of the temperatures of the animals tested, date of test, etc., is attached to the certificate.
- 6. Prohibition to land dairy or breeding cattle from Australian ports carried in a vessel not disinfected. Except those for slaughter at any National Slaughterhouse, cattle accompanied by a certificate may be refused landing in the Philippines, upon proof that such animals have been transported from Australian ports in a vessel that carried cattle not certified during the same trip or on previous trips, without such vessels duly authorized representative of the Commonwealth of Australia or of the Republic of the Philippines.
- 7. Contents of certificates accompanying dairy or breeding cattle from Australia, Tasmania and New Zealand. All certificates accompanying cattle from Australia, Tasmania and New Zea-

land shall be addressed to the Director of Animal Industry, Manila, in care of the Master of the vessel transporting them, and shall be prepared and certified substantially in the following manner.

, 	(He	ading)		
Donamintian at in	d mala.			
Description of an Breed	inais:	Age		* -
Color		· Sex		
Brands: Right		Left		
Born at				
	district).		(State)	
Second location _ Third location	. 		·	
Fourth location				
Present location				
T	<u> </u>			
that the above in	formation is cumonia or co	correct and ntarious abo	al, hereby declare that the animal no ortion or has been	C
I further de been kept in any			is not originated o	or
(a) Que	cnsland			
out		entral Austr	n Territory lying ralia Contagious irea.	
(c) Tha	t portion of the 26° south	Western Aust parallel of	tralia lying north Flatitude.	
			thereof where con known to exist.	- '
		•		
-	•			
			(Owner)	 ·
SWBSCRIBED A	MD SMORT to b	efore me at	, 10	
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		(Porson a	evthorized to admi	niste
			for animals in the	
	t the above i	nformation i	is true and correc	t.
			ibed has always be t or districts in	en

Veterinary Hygiene.

which the condition as regards animal diseases have been constantly and exactly known by the Department of Apriculture or the Director of

- (c) That the animal has not at any time during the six months next preceding the issuance of the certificates suffered from nor been in contact with any animal infected with any dangerous and communicable diseases (tuberculosis nossibly excepted) and has never been in any district in which pleuro-pneumonia existed at the time.
- (d) That the animal was tuberculin tested by

 , a qualified veterinarian
 approved by the Chief, Quarantine Officer of
 Animal Services and a satisfactory negative reaction was obtained.
- (e) That the record of the tuberculin test attached hereto and indorsed by me is complete and refers to the animal described above.
- (f) That the animal is being shipped on the steam—
 ship ______ on ______
- (g) That the fodder supplied for use on the voyage has not been exposed to an infection or contagious pleuro-pheimonia.
- (h) That I have ascertained from an official source that the vessel in question did not transport on its latest preceding voyage infected cattle or cattle not accompanied by a certificate similar to this, or if such cattle were transported I certify that the vessel has since been properly disinfected.
- (i) That before shipment the animal was twice subjected at one month interval to applutination test for contagious abortion on the following date _______ and satisfactory negative reactions were obtained. The last test was performed five days before shipment.
- were vaccinated with _______ Brucella abortus vaccine strain 19, when h to 8 months old and presently less than 36 months of are. The certificates of vaccinetion of each animal showing the brands or tattoes of vaccination are attached with the health certificates.
- (k) That the cattle originated from herd where neither trichomoniasis nor vibriosis nor leptospirosis hor "Q" fever nor Johne's disease are known to exist or that the cattle had been tested for these diseases with negative results.
- (1) That the cattle had been subjected to the complement fixation test for contagious bovine pleuropneumonia on two occasions at a 20 to 30 days interval between tests, both tests being not more than forty days before shipment and that the results of these test in all cases were negative.

CATTLE FOR SLAUGHTER

- 8. No cattle from Australia for slaughter purposes shall be landed into the Philippines unless accompanied by health certificate. Said health certificate shall include the following requirements:
 - (a) A declaration by the owner stating that to the best of his knowledge and belief the cattle are healthy and free from disease and have not been in contact with any animal affected with contagious pleuro-pneumonia during the last preceding 6 months.
 - (b) A certificate by a Government Veterinary Surgeon that
 - (1) He has examined the cattle on the property of origin of the cattle for export, and
 - (2) He has checked the port mortem records at the Abattoir at which cattle from the property of origin have been slaughtered, and
 - (3) After these examinations and checks he has no reason to doubt the truth of the owner's declaration, and
 - (h) The animals have not been drawn from a property on which Contagious Pleuro-pneumonia is known to exist or from a property within 25 miles of a property where active Contagious pleuro-pneumonia is known to exist (the distance to be measured from the outer boundary of each property).
 - (5) That the cattle had been vaccinated against Contagious Pleurs pneumonia not less than 7 days nor more than thirty days before shipment.
 - (6) He has examined the cattle for export and found them apparently healthy and free from disease.
 - 9. Place of landing of cattle imported for slaughter -

Cattle imported for slaughter purposes shall be discharged and landed at any port or point which may be designated by the Director of Animal Industry:

The proper entry of the vessel must, however, be first arranged with the Commissioner of Customs in Manila before any cargo can be discharged.

10. Duties of the importer of cattle intended for slaughter The importer shall unload, transport in leak-proof trucks, or vans, feed, and butcher the cattle, and shall be responsible for transporting the meat to Manila or other points. The conditions under which the meat is kept during transportation must be satisfactory to the Director of Animal Industry; but the owner shall not be relieved from the responsibility of landing the meat in Manila or elsewhere in wholesome conditions, conforming to food inspection requirements. All dead animals condemned carcasses, and parts thereof, shall be disposed of by the Director of Animal Industry. However, the owner may be required to dispose of the dead animals subject to the supervision of the Director of Animal Industry or his authorized representative pending the installation of suitable apparatus for disposing of same.

- 11. Bond to be filed by owner or importer. Each owner or importer of cattle for slaughter purposes upon arrival of the importation permit by the Secretary of Agriculture and Natural Resources shall deposit with the Bureau of Animal Industry a bond for the amount of PlO,000.00, fifty percent of which shall be in cash and the other fifty percent in surety bond for every approved shipment of not exceeding 1,000 head to head to guarantee the payment of the slaughter fees and other charges that may be due the Government from said owner or importer and the faithful compliance of the terms and conditions of the importation permit.
- 12. Power of the Director of Animal Industry to condemn diseased animals. The Director of Animal Industry reserves the right to destroy any diseased cattle or any animal that has been exposed to any dangerous and communicable animal diseases when in his judgment, this measure is necessary to protect the livestock interests of the Philippines. In such event all necessary precautions shall be taken to prevent losses from infectious diseases of cattle, but the government of the Philippines shall not be held responsible for such losses resulting from a cattle disease.

CATTLE OR CARABAGS IMPORTED FROM THE UNITED STATES AND OTHER COUNTRIES

- 13. Importation of cattle from the United States. Cattle imported from the United States shall be accompanied by a certificate of health issued by the inspector incharge of the Bureau of Animal Industry of the United States Department of Agriculture at the point of origin, certifying to the following facts:
 - (a) That all the animals are free from infectious livestock diseases or have not been exposed to such diseases for the last things down
 - (b) That each and every animal has been tuberculin tested by a veterinarian officially recognized by the Federal and/or State government within a period of sixty (60) days before shipment with negative result.
 - (c) That in case of non-vaccinated animals all have been tested trice for contagious abortion (Brucellosis) using the agglutination test at thirty days interval, the last having been performed five (5) days before shipment with negative results.
 - (d) That in case of vaccinated animals, said animals were vaccinated with Brucella abortus vaccine strain 19, when 4 to 8 months old and presently less than 36 months of age. The certificates of vaccination of each animal showing the brands or tattoos of vaccination should be attached with the health certificates.
- lh. Importation of cattle, carabaos and buffaloes from Burma, Hongkeng, Laos, Crategia, Vietnam, Indonada, India, Malay States, Thailand, Pakistan or other countries where dangerous communicable diseases exist. No cattle, carabaos or buffaloes shall be imported, brought or introduced into the Philippines from Burma, Cambodia, Laos, Vietnam, Hongkong, Ceylon, Indo-China, Indonesia, India, Malay States, Thailand, Pakistan or other countries there dangerous communicable diseases exist, unless:

- (a) Previous permission to this effect has been granted by the proper authorities of the Government of the Philippines.
- (b) The animals to be imported have been immunized by authorized government veterinarians from the point of origin against rinderpest by means of any of the following:
 - (1) avianized vaccine

 - (2) goat virus
 (3) lapinized vaccine, or
 - (h) tissuo vaccino
- (c) The immunization has been done in the presence of a veterinarian of the Philippine Government sent for the purpose. All expanses incident to travel by the Philippine representative shall be borne by the interested party.
- (d) The animals be certified by a government veterinarian from the point of origin that the said livestock are free from foot-and-mouth disease and other infectious animal disease at any time during twelve (12) months next preceding thedate of shipment and have not been exposed thereto.
- 15: Places of landing cattle, carabaos and Indian Buffaloes imported from Burma, Hongkong, India, Laos, Cambodia, Vietnam, Indonesia, Malay States, Thailand, Pakistan or other countries where dangerous communicable diseases exist. - Animals imported in accordance with the next preceding section shall, after inspection, be landed at either the Pandacan Quarantine Station in Manila or at any other place that the Director of Animal Industry may designate and shall be subjected to such tests and period of quarantine as the Director of Animal Industry may deem necessary.

In case any dangerous communicable animal disease, such as rinderpest, foot-and-mouth disease, contagious pleuro-pneumonia, etc. breaks out among the bovine animals on board any incoming vessel, the said vessel shall not be permitted to dock and the animals therein shall not be unloaded but shall be disposed of: (1) by returning them to the point of origin accompanied by a representative of the Bureau of Animal Industry) or (2) by destroying them on board and throwing over board in the high seas outside of the Philippine waters, witnessed by a veterinarian of the said Bureau; or (3) by killing or destroying the animals on board the boat and burning or burying their carcasses in an isolated place to be designated by the Director of Animal Industry in the presence of a representative of the Bureau of Animal Industry and at the expense of the owners, shippers, carriers or their agents.

The feces, litter or other dirts shall not be dumped or thrown over board within Philippine waters but shall be disposed of when the vessel is in the high seas, or incinerated on board. All persons in direct contact with the animals shall not be permitted to land unless their clothes are completely changed and their hands, changed clothes and shoes properly disinfected.

16. Importation of carabass and cattle from countries not declared infected with any dangerous and communicable animal diseases. - Jattle and carabaos imported from countries not declared by the Secretary of Agriculture and Natural Resources to be infected with any dangerous and communicable animal diseases shall be accompanied by a health certificate issued shortly before shipment by the proper veterinary authority of the country of origin, certifying to the fact that the same have not been exposed to any dangerous contagious animal diseases for at least three months before the issuance of the certificate.

17. Importation of horses, mules and assess. - Horses, mules and assess imported, brought or introduced into the Philippines from any foreign country shall be accompanied by a health certificate issued shortly before shipment by the proper veterinary authority of the country of origin, stating that such animal in the shipment is free from and has not recently been exposed to, any dangerous and communicable animal diseases.

In case of any doubt as to the presence of glanders or of any dangerous communicable livestock diseases among the animals in any shipment, the animals shall be placed in quarantine and tested with mallein or other officially accepted biologics, drugs or procedures at the expense of the owner. If an animal is positively found to be affected with glanders or incurable disease, it shall be destroyed and the owner thereof shall not be allowed compensation.

18. Importation of cattle, horses, mules and assess from South Africa. - Cattle, horses, mules and assess imported from South Africa shall, after inspection and tests and found free from trypanosomes and South African Horse sickness be landed at the Pandacan Quarantine Station in Manila or at any other place that the Director of Animal Industry may designate, and shall be subject to such tests and period of quarantine as the Director of Animal Industry may deem necessary.

SMALL ANIMALS

- 19. Importation of hogs. Hogs imported, brought or introduced from any foreign country into the Philippines either for breeding or slaughter purposes, shall be accompanied by a health certificate issued shortly before shipment by the proper veterinary authority of the country of origin, certifying to the fact:)
 - (a) That the hogs have been immunized to hog cholera using either simultaneous method or any of the modified hog cholera vaccines. In case of countries which are not infected with hog cholera, this requirement may be waived.
 - (b) That the hegs have been submitted to tubercullin and contagious abortion test shortly before shipment with satisfactory negative results.
 - (c) That the hogs have come from Brucellosis free hard and that two agglutination tests at thirty (30) days interval have been performed by government veterinarian or by any efficially recognized practising veterinarian at the point of origin both with negative results, the last having been performed five (5) days before shipment. This requirement may be modified by subjecting the animal to only one test at the discretion of the Director of Animal Industry.

- (d) That the animals are free from, or have not been exposed to, other dangerous communicable animal diseases, like vasicular exanthema, infectious praumonia, infectious enteritis or swine dysentery, infectious atropic rhinitis, African swine fever, toxoplasmosis, leptospirosis, and the like.
- (e) That the animals have been vaccinated against swine crysipelas within a month before shipment. In countries where the disease is not present this requirement may be waived.
- 20. Importation of goats and sheep. Goats and sheep to be imported, brought or introduced from any foreign country into the Philippines shall be accompanied by a health certificate issued shortly before shipment by the proper veterinary authority of the country of origin stating:
 - (a) That the goats come from brucellosis free herd and have been tested for brucellosis for two consequtive agglutination tests at thirty days interval with both negative results, the last one having been performed within five days before shipment.
 - (b) That the goals have been tuberculin tested with negative result, the test having been performed within a month before shipment by a government veterinarian or government licensed veterinarian of the country of origin.
 - (c) That the goats are free from any other dangerous communicable diseases and have not been exposed to such diseases.
 - (d) In case of the sheep, that the animals are free and have not been exposed to any dangerous communicable animal diseases shortly before shipment.
- 21. Importation of sheep and goats from South Africa. In addition to the requirements mentioned in Par. 20 above, sheep and goats imported from South Africa shall, after inspection with microscopic examinations of the blood for trypanosomes, be landed at the Pandacan quarantine Station in Manila or at any other place that the Director of Animal Industry may designate, and shall be subjected to such tests and period of quarantine as the Director of Animal Industry may deem necessary.
- 22. Importation of fowls. Fowls imported into the Philippines from any country thall be accompanied by a health certificate issued shortly before shipment by the proper veterinary authority at the port of embarkation, certifying to the fact:
 - (a) That the fools are free from, and have not been in contact with or exposed to, any dangerous and communicable diseases affecting aves for at least sixty days before the date of shipment.
 - (b) That the fowls have been tested against pullorum ten days before shipment with negative result; however, in the case of chicks a certification of the flock from whom they came from for freedom from pullorum disease will suffice,

- (c) That the fowls have come from flocks that are free from pullorum and leucosis complex.
- 23. Importation of hatching eggs. No hatching eggs shall be imported into the Philippines unless accompanied by a certificate issued shortly by the proper authorities from the point of origin certifying to the fact that such eggs come from pullorum and leucosis free flocks.
- 2h. Disposal of infected fowls. Should any shipment of fowls arrive infected with any dangerous and communicable diseases, all of the sick fowls shall be destroyed and cremated and apparently well ones held under quarantine for such time as the Director of Animal Industry may deem necessary. If such shipment is consigned to Manila the birds shall be quarantined at the Pandacan Quarantine Station or at any place that may be designated by the Director of Animal Industry and if consigned to any part of the Philippines, at the place that the said Director may designate!

No compensation shall be allowed for the birds destroyed and the expense for care and feed during the period of quarantine shall be defrayed by the owner.

CIRCUS AND PET ANIMALS

25. Requirements for incoming pets, circus or show animals. Dogs, cats, rabbits, circus and pet animals, and those intended
to be used for show or experimental purposes imported, brought
or introduced into the Philippine Islands from any foreign country shall be accompanied by a health certificate issued shortly
before shipment by the proper veterinary authority of the country of origin, stating that each of the animals is free from,
and has not recently been exposed to, any dangerous and communicable animal disease.

In case of dogs valid vaccination certificate against rabies must be included.

- 26. Circus and pet animals imported without health certificate. If any such animals shall arrive unaccompanied by said health certificate they may be placed in quarantine at the discretion of the Director of Animal Industry for a period of ten days. If a disease appears in one or more of them, they shall all be held in quarantine until after ten days have elapsed from the date of the disappearance of the disease.
- 27. Animals that may become agricultural pests. Cats, rabbits, squirrel and other animals intended for curiosities or pets, for experimental purposes, or for any other purposes, which might become agricultural pests or any way destructive to agriculture, shall be subject to inspection, certification and disposal by the Director of Plant Industry or his duly authorized agents under the Agricultural Pests Quarantine Act and the regulations promulgated hereunder (Act No. 3767).

28. Penalties. - Any person who shall contravene or violate any of the provisions of this Administrative Order, or who shall falsify, forge, counterfeit, alter, deface, or destroy any certificate, pass, tag, or any other legal paper issued by virtue of this Order shall be liable to prosecution, and upon conviction shall suffer the penalty provided in the second paragraph of Section 2747 of the Revised Administrative Code (Act No. 2711) which is a fine of not more than one hundred pesos (P100.00) or imprisonment for not more than thirty (30) days, or both, in the discretion of the court and such other penalties as are prescribed by the Penal Code.

REPEALING PROVISIONS AND EFFECTIVITY

- 29. Repealing paragraph. All order, rules, and regulations or parts thereof in conflict with the provisions of this order are hereby repealed.
- 30. Date of effectivity. This Administrative Order shall take effect on August 5, 1966.

(SGD.) FERNAMDO LOPEZ Vice-President and Concurrently Secretary of Agriculture and Natural Resources

RECOMMENDED BY:

(SGD.) ANACLETO B.CORONEL Director of Animal Industry

eja/

A true copy: laa & vra/1976-06-10

(輸入許可証フォーム)

Republic of the Philippines
Ministry of Agriculture and Food
DUREAU OF ANIMAL INDUSTRY
Diliman, Quezon City

IMPORT PERMIT (Wild Exotic and Other Pets)

Name of Importer: Office/Res./Address:				· · · · · · · · · · · · · · · · · · ·	State/Country of Origin: Purpose:		
					Date of Issuance;	· · · · · · · · · · · · · · · · · · ·	
					Expiry Date:		
Tel. No.		* * * * * * * * * * * * * * * * * * * *			Extension:	: :	
Farm Address:	•	• • •			Place of Quarantine :		
Tel. No.					n-m-p-Millinghyr (p-m)-		
DESERIPTION OF	ANIMALS:						
ITEM NO. :	SPEC	IES:	ТҮРЕ	:	SEX: NUMBER		
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•		•	•	•	*		
;		;		:	•		
TOTAL							

The importation of the animal(s) described above is hereby granted subject to the following conditions:

- 1. That a government Veterinary Officer/Surgeon at the point of origin shall declare under oath stating the following:
 - a. That said animals must come from or must have been raised in a government accredited farm/zoo/laboratory or have been confined in such establishment for not less than ninety (90) days from the date of capture from the wild state or since their birth.
 - b. That animals must have a valid vaccination against dangerous and infectious disease affecting their species.
 - c. That the animals should be accompanied by a Veterinary Health Certificate issued shortly (not more than 10 days) before shipment by the concerned government veterinary authority of the country of origin stating that the animals have been personnaly examined by an authorized government veterinarian and found to be free from dangerous communicable animal disease or exposure thereto, and further states that there has been no incidence of dangerous infectious animal disease at the farm/laboratory/zoo or establishment of origin for the last six months preceding shipment.
- 2. That the animals should be placed under quarantine for a period of 30 days from the date of arrival.

- 3. That the animals while in quarantine shall be subjected to periodic inspection and serological testing by the authorized representative of the Director of Animal Industry. The cost of the Testing shall be borne by the importer.
- 4. Should any disease break out during the quarantine period, all the infected animals are to be burned and/or buried at the expense of the owner. No compensation shall be paid for any animals destroyed.
- 5. That upon termination of the quarantine period, the removal of the animals shall be duly authorized by the Director of Animal Industry.
- 6. That this permit is subject to cancellation should any dangerous communicable disease break out at the country of oragin, or maybe revoked at anytime before the expiration date if the interest of the government so requires.
- 7. That a CITIES (Conventionoun International Trade in Endangered Species) Permit should accompany the shipment of endangered species.
- 8. The permitee shall pay to the Bureau of Animal Industry the following feest
 - a) For the issuance of this Import Permit P15.00 (Sec. VII, Animal Ind. Adm. Order No. 6-14).
 - b) For the inspection and issuace of landing permit upon arrival of the animals at the port of entry P

CONFORME;

Importer/Authorized Representative

CLASSIFICATIONS OF RESTRICTED PESTICIDES

The List of Restricted Pesticides is categorized as follows:

- 1. Those which are not for importation except in case of emergency. Such cases are to be determined by the Authority
- 2. Those to be used for termite control only
- 3. Those to be used under specified limitations
- 4. Fumigants and other chemicals for use only by certified fumigators

STOP SALE, STOP USE, REMOVAL AND HOLD ORDERS

When a pesticide is being offered for sale or used in violation of this Restriction Notice, the FPA through its authorized representative, may issue and enforce stop sale, stop use, removal or hold order to the owner or custodian of said pesticide, ordering it to be held at a designated place until the law or the Rules and Regulations of this Authority shall have been complied with; the said pesticide is released in writing by the FPA or its authorized representative; or until all said violations have been disposed by the proper authorities.

The provisions of Presidential Decree 1144 and the FPA Rules and Regulations and their penal provisions shall apply for violations of this circular.

BANNED AND RESTRICTED PESTICIDES IN THE PHILIPPINES

Banned Pesticides

- Parathion-ethyl
- Copper Aceto-arsenite (Paris Green)
- 3. DDT containing mosquito coils
- 4. DBCP
- 5. Nitrofen
- 6. Leptophos
- 7. EPN
- d. Endrin
- 9. Mercuric fungicides
- 10. Toxaphene
- 11. Elemental phosphorous (White & Yellow)
- 12. Thalium sulfate
- 13. 1-Napthylthiourea (ANTU)
- 14. Gophacide
- 15. Sodium Flouroacetate

- 16. Sodium Flouroacetamide (1081)
- 17. Strychnine

VII. Restricted Pesticides

- A. Importation Not Allowed Except in Cases of Emergency as Determined by the Authority.
 - 1. 2,4,5-T
 - 1. Heptachlor only allowed use in agriculture is for pineapple plantations under conditions enumerated in Pesticide Circular No. 9, Series of 1982.
 - 3. DDT- the only allowed use is for malarial eradication program.
 - 4. Aldicarb
 - 5. Technical HCH or BHC For direct importation in sugar plantation stipulated in Pesticide Circular No. 4 S. 1983
 - 6. Chlorobenzilate
- B. For Termite Control Only
 - 1. Alarin
 - 2. Dieldrin
 - 3. Chlordane
 - 4. Heptachlor
- C. For Use Under Specified Limitations
 - 1. Not for Use Near Aquatic Ecosystem
 - a. Aldrin
 - b. Chlordane
 - c. Dieldrin
 - d. Endosulfan
 - 2. Too Hazardous for General Use (For Institutional Use Only)
 - a. Paraquat (Pillarquat; Gramoxone) for use in banana and other plantations granted written permits by FPA.
 - b. Phenamifos (Nemacur) for use in banana and pineapple plantations only.
 - c. Ethoprop (Mocap) for use in banana plantations only.

- d. Methidathion (Supracide) for use in banana plantations only.
- e. <u>Inorganic Arsenicals</u> (Arsenic Trioxide) for use in wood preserving and treatment plants only.

D. Funigants and Other Chemicals for Use Only by Certified Funigators

Adequate time for aeration is required after treatment before commodities are processed into food or feeds.

- 1. Methyl Bromide
- 2. Ethylene Dibromide
- 3. Carbon Disulfide
- 4. Phosphine generating compounds
- 5. HCN generating materials
- 6. Chloroform
- 7. Carbon Tetrachloride
- 8. Ethylformate

BRAND NAMES FOR ACTIVE INGREDIENTS IN THE LIST OF BANNED AND RESTRICTED PESTICIDES

Active Ingredient

Brand Name

I. Banned Pesticides

Parathion- ethyl Copper Acetoarsenite	Parathion Paris Green		
DDT-containing mosquito coils	Panda; Double Swallow;		
bor-concarning mosquito corrs	Antelope; Ccck		
DECP			
DECF	Nemagon; Fumazone;		
	Femalour L		
Nitrofen	Tok		
Lepthophos	Phosvel		
E P.N	EPN 45 EC		
Endrin	Endrin 19.5 EC; Endrin 2G		
Mercuric Fungicides	Agallol; Calocure;		
	Cerasan; Aretan; Funchex;		
	Panogen; Quicksan;		
•	Semesan; Setret; Upsulum		
Toxaphene	_		
Elemental Phosphorus	<u>-</u>		
Thalium Sulfate	***		
ANTU	-		
Gophacide	-		
Sodium fluoracetate	- 1080		

Sodium fluoracetamide Strychnine - 1081

II. Restricted Pesticides

A. 2,4,5-T

Heptachlor
D D T

Aldicarb
Technical HCH or BHC
Chlorobenzilate

Heptachlor 2E -Temik -Akar

B. Aldrin

Dieldrin Chlordane Aldrex, Aldrin 40 EC; Aldrite Dieldrex; Dieldrin 50WP Chlordane 75 EC; Chlordane H

C. 1. Aldrin

Chlordane

Dieldrin Endosulfan Aldrex; Aldrin 40EC/WP; Aldrite Chlordane 75EC; Chlordane H Dieldrex; Dieldrin 50WP Thionex; Thiodan; Endox; Endosulfan 5G; 35EC

2. Paraquat
Phenamifos
Ethoprop
Methidathion
Inorganic Arsenicals

Gramoxone; Pillarquat Nemacur Mocap Supracide Lead arsenate; Tanalith; Kemira 33; Osmose K-33; Celure; Boliden K-33

D. Methyl Bramide

Ethylene Dibromide

Carbon Disulfide Phosphine-generating compounds Brom-O-Gas; Dowfume; MC-2; Methybron; Metabrom Dowfume W-85; Bromofume; EDB

HCN-generating material Carbon tetrachloride Chloroform Ethylformate Quickphos; Phostoxin Magtoxin; Delicia Gastoxin; Detia Gas EX-B; Gastion

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資料W 保健省食品医薬品局行政命令第88号のA

(食品添加物に関する規制ガイドライン)

REPUBLIC OF THE PHILIPPINES
Ministry of Health
BURLAU OF FOOD AND DRUGS
Manila

May 25, 1984

ALMINISTRATIVE ORDER No. 38-A s. 1984

SUBJECT: Regulatory Guidelines Concerning Food Additives

This regulation prescribes the guidelines on the use of food additives in all foodstuffs sold in the Philippines whether ranufactured locally or imported.

1. Definition of Terms

Food Additive refers to any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has natritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packaging, transport, or holding of such food results, or may be reasonably expected to result (directly or indirectly) in its or its by-products becoming a component of (or otherwise affecting the characteristics of) such food.

Processing Aids was additives that are used in the processing of food to achieve a specified technological purpose and which may or may not result in the presence of residues or derivatives in the final product.

Flavoring substances refer to flavor preparations composed of substances derived from plant/animal products and/or chemically synthesized substances whose significant function in food is flavoring rather than nutritional.

2. List of Fermissible Food additives

- 2.1 a mist of remeissible Food additives, duly approved by the Minister of Health upon the recommendation of the Bureau of food and Drugs, shall be the official reference for additives that are allowed for use in food products. Poodstuffs containing additives not found in the list shall be considered illegal and their local distribution shall not be permitted.
- 2.2 The additives are listed in separate tables according to their functional categories.
- 2.3 Every food additive included in the list small meet the specification for identity and purity set for that particular substance in any of the latest edition of the following publication:

- a) U.S. Code of Federal Regulations
- b) Food Chemicals Codex.
- c) JECFA Specifications (published in FaO Food and Nutrition Paper)
- 2.4 The use of additives shall be in accordance with the specified restrictions, e.g., the type of food where the substance may be added and/or the quantitative limitations prescribed thereto. Whenever GMP is indicated, it means that the additives in question are self-limiting in food for technological, organoleptic, or other reasons and that, therefore, the additives need not be subject to maximum limits but must be used according to good manufacturing practice.
- 2.5 The list of permissible additives shall be subject to permodic review and the use of any substance may later be banned when circumstances render such action necessary.
- 3. Requirements for Approval of Other Additives
 - 3.1 Any person or entity who wish to use a food additive that is not included in the approved list may file with the Minister of Health, through the Bureau of Food and Drugs, a petition proposing the approval of such additive.
 - 3.2 Petitions shall be accompanied by pertinent information concerning the food additive including, but not limited to, the following:
 - a) the chemical identity and composition of the additive, its physical, chemical and biological properties and specifications for its purity;
 - by a description of the method of manufacture and a list of substances used in the synthesis, extraction or other method of preparation,
 - c) the amount of the food additive proposed for use and the purposes for which it is proposed, together with all directions and recommendations regarding the proposed use;
 - d, data establishing that the food additive will have the intended physical or other technical effect or that it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food and the amount necessary to accomplish this,
 - e, assay method(s) for determining the amount of the food additive in the raw, processed and/or finished food and of any substance formed in or on such food because of its use;
 - f) proposed tolerance or maximum level of use, if required to ensure its safety;
 - g) full reports of investigation made with respect to the safety of the additive, including information as to the methods and controls used in conducting such investigations;

- h) or in lieu of clause (g) official documents from the country of origin containing the standard procedure adopted in evaluating the safety of food additives and a certification from the Health authorities in that country indicating the present status of the additive and these documents shall be duly authenticated by the Philippine Consulate; and
- i) a sample of the food additive and a sample of food containing the additive.
- 3.3 The bureau of Food and Drugs shall, within ninety days after filing of a petition, notify the person or entity concerned whether or not the food additive in question shall be recommended for the approval of the Minister of health.

This regulation shall take effect immediately upon approval and publication in the Official Gazette.

Recommending Approval:

APPROVED:

(SGD.) CATALINA C. SANCHEZ Director

(5Gu.) J. C. AZUAIN
Minister of Health

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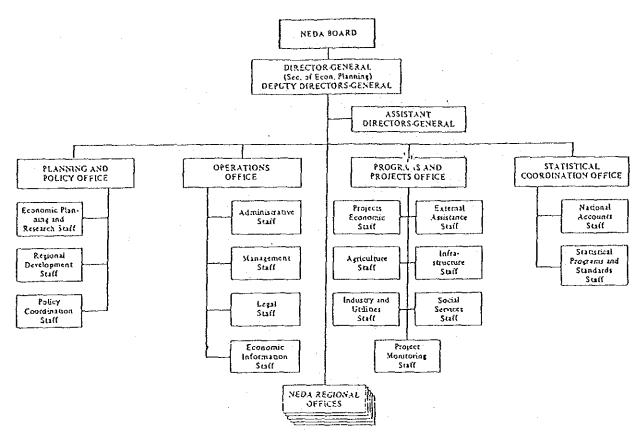


CHART 1. - THE INTERNAL ORGANIZATION OF NEDA (as of December 1977)

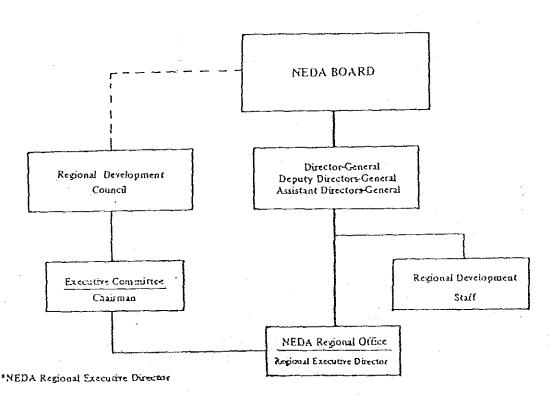


CHART 2. - ORGANIZATION FOR REGIONAL DEVELOPMENT PLANNING

