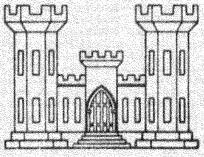
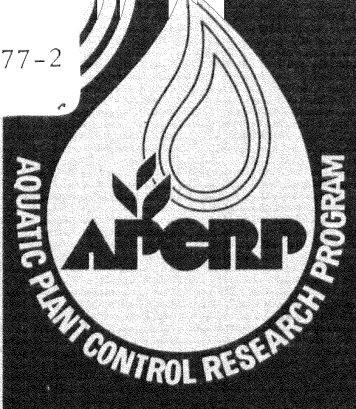


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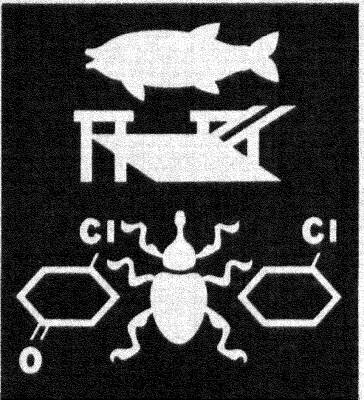
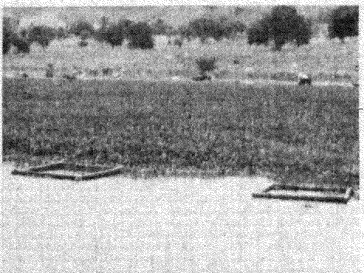
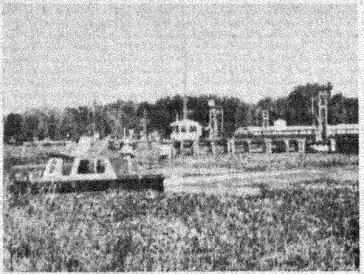
A MANAGEMENT PROCEDURE FOR THE INTRODUCTION OF BIOLOGICAL AGENTS FOR CONTROL OF AQUATIC PLANTS

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Preface

On 7 July 1976 a meeting was called by the Aquatic Plant Research Branch (APRB), Environmental Systems Division (ESD), Mobility and Environmental Systems Laboratory (MESL), U. S. Army Engineer Waterways Experiment Station (WES). The purpose of this meeting was to identify a systematic process that would allow the Corps of Engineers to intensify their efforts to introduce and use effective biological control agents to control problem aquatic plants. Accordingly and in cooperation with personnel of the U. S. Department of Agriculture (USDA), Agricultural Research Service (ARS), Biocontrol Research Laboratory in Gainesville, Florida, and the USDA Aquatic Plant Management Laboratory (APML), Ft. Lauderdale, Florida, the process of searching for, introducing, testing, and evaluating biological agents for control of aquatic plants in the United States was systematized.

This report explains the process and was prepared by Mr. W. E. Grabau, Special Assistant, MESL, who occupied the lead role in the development of the process.

Acknowledgment is made to the following who made significant contributions to the development of this process, both during and after the meeting:

Dr. L. W. Larson, USDA, ARS	Mr. W. E. Grabau, WES
Mr. N. R. Spencer, USDA, ARS	Mr. J. L. Decell, WES
Dr. David Perkins, USDA, APML	Mr. B. O. Benn, WES
	Mr. R. F. Theriot, WES

Funds were provided by the Office, Chief of Engineers (OCE), Department of the Army, under authorization 96X3122. The work was conducted under the general supervision of Mr. B. O. Benn, Chief, ESD, and Mr. W. G. Shockley, Chief, MESL, and under the direct supervision of Mr. J. L. Decell, Chief, APRB. The OCE Technical Monitor was Mr. H. Roger Hamilton.

Commander and Director of the WES during conduct of this work and preparation of the report was COL J. L. Cannon, CE. Technical Director was Mr. F. R. Brown.

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A MANAGEMENT PROCEDURE FOR THE INTRODUCTION OF BIOLOGICAL
AGENTS FOR CONTROL OF AQUATIC PLANTS

Introduction

1. The control of weeds by means of biological agents is an attractive concept. If effective control can be obtained with an agent that will survive perennially, then the cost of control consists only of the capital costs of finding, evaluating, and releasing the agent. For all practical purposes, there will be no continuing operational costs. This can be compared with chemical and mechanical control procedures, for which yearly operational costs involve many millions of dollars. This factor will grow increasingly important as fuel costs rise. Even if the biocontrol agent must be reintroduced from time to time, the idea remains feasible, chiefly because it involves few or none of the problems of environmental contamination that are so common with chemical control methods.

2. However, biological control should not be viewed as a panacea, or as a complete replacement for other methods of control. Despite the fact that the first biocontrol agents were introduced in 1888, the technology for using biocontrol agents is still in its infancy. There is little reliable data to indicate that biocontrol agents can be developed for the control of all weed species. If nature has not produced an adequate control, no amount of searching or testing will produce one. Thus, a program in biocontrol is almost by definition a high-risk proposition. Nevertheless, the recent success with the introduction of the alligatorweed flea beetle, Agasicles hygrophila Selmunto Vogt and Vogtia malloi Pastrana, and their resulting control of the aquatic weed, alligatorweed (Alternanthera philoxeroides (Mart.) Griesb.), indicates the potential of biological control.

3. The general problem of finding, evaluating, and eventually introducing a biological agent for control of a plant pest is a complex process formed of unequal parts--administration, science, engineering,

and politics. So complicated is the process that participants not uncommonly find that they have forgotten exactly where they are in the procedure. Sometimes this means that some things are done twice. Sometimes it means that a critical step is inadvertently omitted, only to surface later amid detrimental effects.

4. The lack of a more-or-less standard procedure can also result in serious inefficiencies, simply because a lack of context makes it difficult to assign an appropriate amount of time and effort to each stage. In the absence of a way of looking at the entire problem, there is a tendency to overkill or underkill, neither of which makes for overall economy.

5. The U. S. Army Corps of Engineers (CE), through one of its research laboratories, the U. S. Army Engineer Waterways Experiment Station (WES), had decided to intensify efforts to find and introduce into the United States effective biological control agents against several aquatic plant pests. In view of the considerations previously cited, WES personnel decided to systematize the process as much as possible, hoping thereby to reduce materially the time required to find and process biocontrol agents for a number of aquatic plant pest species. Accordingly and in cooperation with personnel of the U. S. Department of Agriculture Biocontrol Research Laboratory in Gainesville, Florida, a systematization of the entire process was formulated. A discussion of the resultant procedure constitutes the body of this paper.

6. The outline of the procedure was developed in the form of a flow diagram (Figure 1). Flow diagrams are widely used in many branches of science and engineering to portray very complicated processes and thus make them comprehensible. They are especially valuable when the process incorporates decision points that trigger two or more alternative procedures, depending upon the nature of the decision. There need not be many sets of decision-induced branches before the overall pattern becomes elusive indeed. The same may also be said for processes in which two or more things must necessarily go on concurrently, all timed in such a way that the resultants of the concurrent subprocesses materialize at the proper time to be incorporated in some future step.

7. The procedure for finding, evaluating, and introducing a bio-control agent into the United States includes both kinds of complexities. As a consequence, it is indeed difficult to keep all of the parts in mind and in balance. It was the author's hope that the flow diagram would help accomplish that and thus manage the effort with a minimum of confusion.

Procedure

8. The flow diagram (Figure 1) and the following discussion are each divided into four parts, reflecting the fact that the process of finding and introducing a biocontrol agent falls into four distinct phases. These four phases are:

- a. Phase I: Search and Preliminary Evaluation.
- b. Phase II: Agent Assessment.
- c. Phase III: Operational Evaluation.
- d. Phase IV: Operational Deployment.

These phases are identified by subheadings in the following discussion.

9. It will also be noted that each procedural step identified in the flow diagram (Figure 1) has been labeled with a number. By convention, each step is a "block," and thus there is a number for each block. In the following discussion, the block number refers to the similarly numbered procedural step in Figure 1. The flow diagram is not arranged according to a rigorous time line. While, in general, the flow of time is from left to right, no uniform time scale is implied, and one should not assume that blocks placed one under the other imply that the steps are necessarily to be done concurrently. Time flows with the arrows between blocks, not with position in the diagram. The small circled numbers in the arrows leading to or from the edges of the pages indicate the blocks to which the arrows are directed on a subsequent page, or from whence they come on a previous page.

Phase I: Search and Preliminary Evaluation

10. Phase I is primarily a field exercise in which biologists go into the field and search for organisms that are preying on, or are

parasitic on, the target plant species. This phase involves as much evaluation of such things as host specificity, life cycle characteristics, etc., as is possible in the field in the geographic region in which the search is conducted. If the region happens to contain institutions with modern research facilities, such investigations may be exhaustive. However, if the region of search is such that no such facilities are available, the in-region evaluations may be quite superficial.

11. Block 1. The first management decision is to decide which plant species is the object of attack. In general, a plant species selected for attention is one that will have been the subject of complaint by some substantial number of people. That is, people in the public sector have made it clear that they would like the plant species to be controlled.

12. Block 2. The geographical distribution of the selected plant species must be delineated and certain attributes of its occurrences documented. At this stage, it is of critical importance to determine to what extent the species has beneficial uses and in what situations the species is harmful. Almost without exception, a harmful species has some benefits. The information collected at this point may be relatively superficial, but it will normally include a preliminary determination of such factors as to whether the plant is indigenous or introduced, the identification of close taxonomic relatives (since such relatives might make it unlikely that a host-specific agent could be found), its potential susceptibility to direct biocontrol agents (if known), etc.

13. Block 3. With all relevant information assembled, a decision must be made as to whether the plant species is dominantly beneficial or baneful.

14. Block 4. If it is decided that the beneficial aspects outweigh the baneful, then direct biocontrol agents, such as insects or pathogens, cannot be used, since it can be assumed that no biocontrol agent will discriminate between plants in beneficial locations and those in harmful locations.

15. Block 5. If biocontrol cannot be used, the only recourse is to investigate other control methods in which discrimination can be exercised, such as chemical control, mechanical removal, and so on. For example, such indirect methods as water-level control or the introduction of a beneficial competitive plant species might well be investigated.

16. Block 6. If it is decided that the harm outweighs the good, the search for biocontrol agents can proceed. At this point, the decision is highly tentative. In effect, the conclusion is that a control for the plant is needed, and, therefore, a search of available knowledge of the plant and its associations should be conducted to determine whether it would or would not be worthwhile to conduct a deliberate search for a biocontrol agent.

17. Block 7. The information that was assembled to provide the basis for the decision to proceed with a search for biocontrol agents must be appropriately formatted and the resulting document transmitted to the Working Group on Biological Control of Weeds (WGBCW).* It is the function of the Working Group to make recommendations as to the propriety of introducing biocontrol agents, and it is normally beneficial to inform them as early as possible of any plans that may mature into a request for an introduction. They will also normally make recommendations as to the feasibility of conducting a search for biocontrol agents for the target species.

18. Block 8. As soon as the decision to proceed is made, an effort can be initiated to assemble all possible information on the target plant species. The search for data should be as exhaustive as possible and should encompass extant literature, scientists, and other agencies with possible information or experience. The information sought should include:

* The WGBCW is made up of representatives from the U. S. Departments of Agriculture and Interior and the Environmental Protection Agency. Its function is to advise the Plant Introduction and Technical Support Staff of the Animal and Plant Health Inspection Service (APHIS) on the importation and release of biotic agents for the biological control of weeds.

- a. Taxonomy. The current taxonomic placement is critically important, since it provides insight into general characteristics, helps to locate sources of data, etc.
- b. Point of radiation. The geographical region in which the target species originated is likely to have the largest number of "enemies" of the target species, as well as the highest potential for finding host-specific enemies.
- c. Physiology. This is important, because it helps to define the general environmental conditions in which the target species is likely to be found and thus helps to limit the areas of search.
- d. Ecology. This rather general term includes information on plant and animal associations of which the target plant is a member, population dynamics, and potential enemies.

19. Block 9. At this point the exhaustive search of all available knowledge (conducted in block 8) may make it possible to decide whether or not the target plant species has natural enemies that could be exploited as a control agent. Thus, a critical decision is made at this point: Does data justify search for possible biocontrol agents? While it is not mandatory that this decision be made in coordination with the WGBCW, it is normally helpful to do so for at least two reasons. First, the WGBCW members possess a very substantial amount of experience that can be helpful. Second, it is politically expedient to keep review authorities informed of progress. The decision is normally based on indications within the assembled data that the target species has one or more natural enemies that exhibit some indication of being host specific. If the decision is that a search for a biocontrol agent would not be worthwhile, attention must shift to block 5.

20. Block 10. If the decision is that a search for a biocontrol agent does appear to be worthwhile, the development of guidance for the search can be initiated immediately. The guidance is normally derived more-or-less directly from the information collected previously (block 8). Elements of primary concern are:

- a. The geographic regions in which searches will be concentrated.
- b. Identification of known enemies to the target species, if any are mentioned in the data.

- c. Specifications for the collection of supplementary data, especially on physiology of the target species, environmental conditions under which it is found, and biological associations.

21. Block 11. As soon as guidance is developed, organization of the search can be undertaken. This will include such things as making contractual arrangements to perform the search, provide logistic support to field parties, etc. It also includes such details as making certain of funding arrangements and specifying chains of responsibility.

22. Block 12. It is probable that the collection teams who actually do the searching will in fact find some potential biocontrol agents. A mechanism must be established to process the collected material and make a judgment as to which items seem promising. The essential element is a laboratory where the evaluations can be made. The chosen laboratory must be located, its responsibilities defined, and its services financed. This laboratory may be in the United States or overseas. A logistic system must also be established to transmit specimens and data from the field to the laboratory. Ideally, these details should all be taken care of before the collection teams leave for the field.

23. Block 13. The teams can now head for the field to begin their search. At this stage specimens will consist only of dead material and written data.

24. Block 14. As soon as a significant amount of data and/or number of specimens have been collected, the collection teams will transmit them to the evaluation laboratory (block 12). The material will, in general, consist of specimens of possible biocontrol agents, samples of the plants on which the specimens were captured (to help in making preliminary evaluations of host specificity, feeding habits, types of damage, etc.); and supplementary data on the characteristics of the ecosystem in which the specimens were collected.

25. Block 15. The laboratory (block 12) will conduct preliminary evaluations of specimens. The evaluation will include careful attention to taxonomy so that realistic searches of the literature, museum collections, etc., can be as efficient as possible. This background search will be focused on collective known data on the potential biocontrol

agents, such as life system, population ecology, and relations of specimens to target plant species.

26. Block 16. The laboratory will select (usually in coordination with the sponsoring agency) the most promising of the collected specimens for further study. At this point, there may be many candidate agents that have survived preliminary analysis, since the only data available will be observations from the field. Thus, such important details as host specificity may be entirely lacking. In many instances, the decision to include an organism in the list of candidate control agents must be made almost exclusively on the amount of damage the agent has done to the target plant species.

Phase II: Agent Assessment

27. This phase is concerned with laboratory assessment of the organisms collected in Phase I. It is primarily an exercise in pure biological science aimed at finding out as much as possible about the organisms within the laboratory. The objective is to screen all of the collected organisms and select the most promising for candidate biocontrol agents. At the end of Phase II, the selection of candidate agents will be based on laboratory tests with live agents, as opposed to the Phase I evaluation based on dead specimens and field observations. The Phase II list of candidate agents can, therefore, be expected to be very much shorter than the Phase I list.

28. Block 17. Now that there is some assurance that the search will result in some potential biocontrol agents, arrangements must be made for one or more laboratories to perform a preliminary evaluation with live specimens. Ideally, this laboratory should be in-region (i.e., in the region where both the target weed and the potential biotic agents occur) to eliminate the administrative problems of shipping potentially noxious plants and/or animals into regions where they do not already exist. If such a laboratory already exists in-region, the problem is usually quite simple. If one does not, it may be necessary to establish one, which may be quite expensive. If that cannot be done, there may be no option but to proceed with administrative policy and obtain permission to import the live samples into another region. The

arrangements must also include logistics to efficiently transmit live materials from the field to the evaluation laboratory.

29. Block 18. The teams can now begin the collection of live specimens of the promising biocontrol agents. The collection of supplementary ecosystem data should continue. Of perhaps even greater importance is the collection of data on breeding habits and life-cycle characteristics, including any environmental constraints (temperature, humidity, light intensity, etc.) that can be recognized. This information will be invaluable later on, if the biocontrol agent is selected for intensive study. At that time it will be necessary to establish breeding colonies.

30. Block 19. The collected live specimens are transmitted to the evaluation laboratory as collected (assuming that it is an in-region laboratory).

31. Block 20. The in-region laboratory will then perform a preliminary evaluation of the promising biocontrol agents. This evaluation will attempt to perform the following determinations:

- a. Life system, including environmental constraints, individual life span, breeding cycle, morphological stages, etc.
- b. Detailed taxonomy.
- c. Population ecology, including seasonal variations.
- d. Relation of agents to target plant species. At this stage, the investigation is intended to establish that the candidate agent significantly attacks and damages the target plant species and identify the mode of damage and the life stage of the candidate biocontrol agent during which damage is caused.
- e. Host specificity. At this preliminary stage, only common and economically important food plants are exposed to the candidate biocontrol agent.
- f. Preliminary screening for pathogens and parasites, so that the risk of accidentally introducing a disease or parasite can be minimized.

32. Block 21. While the initial evaluations (block 20) are commonly made with "wild" specimens, it is usually good practice to begin the development of rearing procedures as soon as possible, in

anticipation that the candidate biocontrol agent will prove to be useful if introduced.

33. Block 22. One thing that must be avoided at all costs is the accidental introduction of a parasite or pathogen along with the biocontrol agent. There are two reasons. First, the parasite or pathogen may wipe out, or at least materially reduce, the effectiveness of the agent being introduced. Second, the parasite or pathogen may not be host specific. One of the potential problems is the fact that an insect introduced to control waterhyacinth might, for example, carry a virus that kills domestic honeybees. Thus, it is very important that the candidate biocontrol agents be screened for the presence of pathogens and parasites as early as possible, and that the development of sanitization procedures be initiated if any are found.

34. Block 23. On the basis of the preliminary evaluation with live specimens (block 20), the most promising species are selected as candidate biocontrol agents. The candidates are, of course, only those that have demonstrated some degree of effectiveness (block 21) and have not attacked nontarget plant species (block 22).

35. Block 24. Using the data on life systems, environmental constraints, breeding cycles, etc., gathered during the field searches for potential biocontrol agents (blocks 13 and 18), and on the basis of in-region laboratory tests and evaluations (blocks 15 and 20), the development of mathematical performance prediction models of the most promising candidate biocontrol agents can be initiated. The initial versions will be very generalized and largely conjectural and will not, at this stage, be useful for predicting the effectiveness of the agents in the United States. Instead, the models will serve to help in the identification of gaps of knowledge and thus aid in designing future data collection and in the design of test programs.

36. Block 25. Upon completion of the preliminary in-region evaluations, reports describing the evaluation tests and procedures must be prepared. The reports covering the rejected species need only summarize the state of knowledge, but the reports covering those species selected as candidate biocontrol agents must be in great detail, since they will

ultimately be the basis for further action.

37. Block 26. As soon as the candidate biocontrol agents have been selected, action must be initiated to obtain the necessary clearances to import them, under quarantine, into the United States for more exhaustive testing and evaluation or, in some cases, for immediate release via a quarantine facility. One of the essential steps is to seek concurrence on importation from the state in which the research quarantine facility is located. The usual state response is to make importation contingent upon Federal approval. In all cases the request for concurrence must be accompanied by a detailed report of the preliminary evaluation tests.

38. Block 27. The action reports (block 25) must be submitted to the WGBCW, along with a notification that the APHIS has been requested for permission to import the candidate agents under quarantine into the United States. It is usually good practice to accompany the request with documentation indicating that the concerned states have given conditional approval. The WGBCW is not empowered to issue import licenses, that power is reserved by the APHIS. However, it is the function of the WGBCW to make recommendations to the APHIS, and such recommendations are usually honored.

39. Block 28. At the same time that the documentation is forwarded to the WGBCW, the APHIS is requested to grant a license to import the candidate agent into quarantine in the United States.

40. Block 29. The WGBCW will, in the course of time, transmit its recommendations to the APHIS.

41. Block 30. Upon receipt of the recommendation from the WGBCW, the APHIS will make one of four possible decisions: see blocks 31, 34, 39, and 57.

42. Block 31. The first possible APHIS decision is that the candidate agent is dangerous or otherwise unsuitable and thus rejects the importation request without qualification.

43. Block 32. In the event that the importation request is denied without qualification, the only management alternative is to investigate alternatives, of which there are three: first, find an alternative

biocontrol agent, in which case procedure cycles back to block 13; second, investigate other methods of control, in which case the procedure cycles back to block 5; and third, drop all further investigation of control means for the target plant species.

44. Block 33. The rejected colony of agents is destroyed.

45. Block 34. The second possible APHIS action is to reject the application for importation on the grounds of insufficient data and require the acquisition of additional data before resubmission of the importation request.

46. Block 35. In this event, the procedure is to coordinate with the APHIS and the WGBCW and obtain in detail the reasons for the request for additional data, with emphasis on obtaining specifications for the data required to satisfy the objections.

47. Block 36. With the data specifications required, it is then possible to design a new series of tests to be conducted in the in-region laboratory. It is necessary to coordinate the test plans very carefully with the WGBCW and the APHIS to ensure that the proposed tests will suffice. Usually the additional tests will consist of more rigorous examinations of host specificity and effectiveness.

48. Block 37. As soon as the APHIS requirement for additional data is known, the in-region laboratory is alerted, so that it does not inadvertently demobilize. Then, as soon as the details of the new test plan are available (block 36), the in-region laboratory is informed, and arrangements are made for the conduct of the tests. In most instances the new tests are only extensions of the old, and no serious problems arise. However, if the test program is such that it cannot be accommodated by the original laboratory, steps may have to be taken to upgrade the laboratory, or to make new arrangements with a different laboratory.

49. Block 38. The laboratory then performs the required tests with the new specifications and designs. Upon completion, the procedure cycles back to block 25.

50. Block 39. The third possible APHIS action may be the issuance of an importation permit after receipt of the necessary state permit,

but only with the proviso that additional tests be conducted under quarantine in an APHIS-approved laboratory.

51. Block 40. In this event, arrangements must be made with a laboratory in the United States to accept the candidate agents and to perform the necessary tests. If APHIS approval is confidently expected, time can be saved by making arrangements for a laboratory as soon as the decision is made to seek an importation permit (block 28).

52. Block 41. As soon as those arrangements have been made, the agents can be transmitted to the designated laboratory.

53. Block 42. In the meantime, as soon as the APHIS action is known, steps must be taken to obtain from the APHIS and the WGBCW the specifications of the tests to be conducted under quarantine.

54. Block 43. With the specifications known, the tests may then be designed. The test designs should be carefully coordinated with the APHIS and the WGBCW to ensure that they provide all of the information required.

55. Block 44. When the test plans have been satisfactorily completed, the tests can be conducted, with rigorous attention paid to the quarantine restrictions. In general, these tests will incorporate rigorous examinations of the following:

- a. Host specificity. A wide spectrum of economic plants, as well as plants of scientific and cultural interest, will be exposed to the candidate agents at all stages of the life cycles of both plants and agents. Special attention will be given to species taxonomically close to the target species.
- b. Environmental limits. These tests are normally intended to ensure that the agent will survive and reproduce under environmental conditions in the United States and to establish the geographical limits of survivability, if possible.
- c. Effectiveness. These tests are intended to provide a basis for estimating the degree of control that would result from the operational release of the agent into the United States.

56. Block 45. As soon as the agents are safely delivered to the quarantine laboratory, work can continue, if necessary, on the development of rearing procedures. This is not only to ensure an adequate

supply of agents for test purposes, but also in anticipation of the need for substantial numbers to serve as the basis of a colony for release.

57. Block 46. Concurrently with the rearing program, candidate agents will be subjected to a detailed screening for pathogens and/or parasites. This may include electron microscope examinations of tissues and germ plasm, if necessary.

58. Block 47. If any pathogens or parasites are found, the development of procedures for sanitization will continue to ensure that the colonies finally released will be free of all diseases or parasites.

59. Block 48. The additional data arising from the laboratory tests (block 44), added to those previously acquired through in-region data collection (blocks 13 and 18) and laboratory tests (block 20), are used to improve and refine the mathematical performance prediction models of candidate biocontrol agents. In the absence of data from field trials, the models will still be largely conceptual, but the general nature of the interactions among significant factors can probably be formalized. The primary use at this point will be as a framework on which to base the design of field trials (block 58), although some use may also be made during the process of deciding whether the candidate agent is or is not sufficiently promising to warrant continuation (block 49).

60. Block 49. With all of the test data from the United States laboratory available, a decision must be made as to whether each candidate agent that has survived evaluation up to this point is sufficiently promising to warrant continuing development. This decision will be largely subjective, although the mathematical performance prediction models may be helpful if they are regarded as sufficiently realistic in the absence of any form of field validation. If the decision is that a candidate agent is not sufficiently promising, further development is dropped, and the procedure cycles back to block 32.

61. Block 50. However, if the decision is that the candidate is promising, the next step is to prepare a detailed report providing all acquired data as an action report to justify a request to the APHIS for a permit to release the agent into the open environment. Assuming that

permission to release will be granted, it is usually worthwhile also to prepare a somewhat popularized information report for wide public dissemination.

62. Block 51. The detailed action report is transmitted to the APHIS and the WGBCW with a request for a permit to release the agent. The same report is simultaneously submitted to all states where target plant species occurs with a request (PPQ 526) for permission to release biocontrol agents.

63. Block 52. Upon receipt of the report and the accompanying request, the matter will be considered by the WGBCW, and it will forward its recommendation to the APHIS. The APHIS will then make one of two decisions. It may decide that additional testing is necessary before a permit to release can be granted, in which case procedure cycles back to block 42.

64. Block 53. The WGBCW also sends a copy of all relevant documentation to appropriate agencies of the Governments of Canada and Mexico, with a request for concurrence in the proposed release. This international coordination is essential because insects and pathogens released in the United States will probably spread to neighboring countries.

65. Block 54. In all cases to date, both Canada and Mexico have concurred in proposed releases of biocontrol agents.

66. Block 55. There is, of course, always the possibility that either Canada and/or Mexico will object to a planned introduction. In that event, it is assumed that some form of negotiation would occur, but the precise nature of such discussions is not within the purview of this plan.

67. Block 56. The second possibility is that the APHIS will issue an unconditional release for the agent after state and foreign concurrence. This is essentially the same as the fourth category of decision that the APHIS can make upon receipt of the initial recommendation from the WGBCW at the conclusion of in-region testing (blocks 28 and 29). See block 57.

68. Block 57. If the tests in the in-region laboratory (block 20)

have been done exhaustively and with great care, or if there is some other over-riding consideration, the APHIS can issue a permit for unconditional importation and release of a biocontrol agent without any further testing or without a period of quarantine (see block 56).

Phase III: Operational Evaluation

69. When the APHIS authorizes release of the biocontrol agent, the procedure shifts from a research orientation to a technology exploitation orientation. The problem is no longer to find an agent that appears to be effective and safe to release; instead, the emphasis is now on the development of operational procedures by which the agent will be used in the field to bring the target plant species under control.

70. Block 58. As soon as release of a biocontrol agent is authorized, work can begin on the design of a small-scale field test. The program is small scale for at least two reasons. First, the performance of an agent under laboratory conditions is not always an indication of the performance under natural conditions in the open. It is by no means unknown for an agent to be very promising in the laboratory, only to fail completely upon release, and, of course, the converse can also occur. Thus, one reason for a small test is simple economics: it is better to make a small preliminary investment to confirm promising results than to make a large investment with a high risk of failure. Second, it is possible that an undesirable attribute will emerge in the open that remained undetected in the laboratory. If the initial release is small and made under close observation, there is at least the possibility of repairing the situation before it becomes irreversible.

71. The design of a small-scale test must include three basic elements. First, the test sites must be selected. The specifications will, of course, depend upon the target plant species, the nature of the candidate control agent, and economic and socio-political considerations. Second, the procedures to be used for monitoring the effectiveness of the agent and its effects on the ambient environment must be developed in detail. Third, the plan must include preliminary guidance for the procedure to be used to release the agent. In effect, this is a first-generation cut at a field deployment manual.

72. Block 59. As soon as the test site is fixed, work should begin on compiling a detailed description of the environmental conditions in the test areas prior to the release of the candidate agent. This assessment of the existing ecosystem is the datum against which the effectiveness of the candidate agent will be made.

73. Block 60. After the baseline environmental conditions are known, but prior to release, the mathematical performance prediction model (block 48) should be used to predict the effects of the agent on the target plant species. This should also be used later to assess the validity of the mathematical model, though it is also useful as an aid in planning the actual release.

74. Block 61. As soon as preliminary plans have been made, care should be taken to coordinate with all concerned agencies, both public and private. This includes State and local governments, citizens groups, other interested Federal agencies, and the appropriate CE Districts and Divisions. A carefully conducted program of coordination and education at this point may prevent serious difficulties at a later date.

75. Block 62. The rearing procedures developed in the course of the various laboratory programs are now exploited to rear a sufficient population of the selected agent to supply the needs of the small-scale field test. During the course of the rearing process, the agent should be put through a final check for parasites and pathogens.

76. Block 63. When data begin coming in from the environmental characterization effort (block 59), work can be initiated on the preparation of Environmental Impact Assessments (EIA) and Environmental Impact Statements (EIS), if they are determined to be necessary.

77. Block 64. When all preparations are complete, the candidate agent is released at the site chosen for the small-scale field test.

78. Block 65. As soon as release is effected, the planned monitoring and analysis program (block 58) is put into motion. This program is intended to measure the effectiveness of the agent, its survivability under natural conditions, and the long-term effects on the environment, if any.

79. Block 66. After the monitoring program has run long enough

to give reasonable confidence that all major effects are understood, the test and its consequences must be documented. This will normally consist of a technical report and a popularized report.

80. Block 67. As soon as enough data are available from the monitoring program, a decision must be made as to whether the candidate agent is sufficiently effective as a control to be worth pursuing, while at the same time free of unsuspected baneful effects.

81. Blocks 68 and 69. If for some reason the candidate agent is determined to be not sufficiently effective, the program is terminated, as in block 32. In this event, all populations or colonies of the candidate agent are destroyed.

82. However, if the agent is declared useful, a series of actions are triggered that are strongly dependent upon the characteristics of the biocontrol agent. There are two basic variants:

- a. Type I agents are those that survive perennially and spread automatically. With such agents, an initial introduction will likely result in the irreversible establishment of the agent as a permanent part of the ecosystem.
- b. Type II agents are those that survive only a single season, in which case they must be reintroduced from time to time. Such agents do not become a part of the permanent ecosystem, although their continued use may cause long-term or even permanent changes in the ecosystems in which they are deployed.

83. There are many variations and degrees. For example, some Type I agents spread very rapidly, so a single introduction, however small, may result in the spread of the agent to the limits of range of the target plant species in a very short time. On the other hand, some Type I agents may spread autonomically only very slowly, in which case it may be necessary to plant many colonies in order to obtain complete coverage within a reasonable time frame.

84. Some agents may be combinations of Type I and Type II. For example, an introduced species may survive perennially in the southern states, but not in the northern, even though the range of the target plant species encompasses both.

85. In the following discussion, the management sequence relevant

to Type I agents is given in blocks 69-74, and that for Type II agents in blocks 75-98.

86. Block 70. If it was possible to conduct a small-scale test of a Type I agent in a sufficiently isolated location, the agent may not be able to spread autonomically. In this case, a decision must be made as to whether or not an additional release is required.

87. Block 71. If it is decided that an additional release of the Type I agent is required to ensure timely spread, then a large-scale release must be designed. Since the agent is already present in the environment and will presumably eventually spread throughout the United States, the design of the second release need not be as carefully formulated as the first. Nevertheless, it is wise to go through the same basic steps (blocks 59-65) as for the initial small-scale field test, if only to provide adequate documentation, perform the necessary inter-agency coordination, etc.

88. Block 72. The small-scale field test has provided the first realistic validation data for the mathematical performance prediction model. Thus, the data from the small-scale field test should be used to update and refine the mathematical performance prediction model, so that reasonable estimates of the long-term effectiveness of the agent can be made.

89. Block 73. If it is decided that the release made in the course of the small-scale field test is sufficient to ensure the spread and control of the target plant species, then detailed documentation of the entire program must be prepared. Normally this will consist of a technical report for the scientific community and a somewhat popularized report for general dissemination. At the same time, the mathematical performance prediction model should be updated, as described in block 72.

90. Block 74. Upon dissemination of the documentation, the development program can be terminated. In this context, termination may not be absolute for some time, since it is good policy to monitor the control exercised by the agent for at least several years, albeit at a very low level of effort.

91. Block 75. If the candidate is a Type II agent (seasonal survival only), the next step is to design and conduct a large-scale field test. The objective is no longer to establish effectiveness, as in the small-scale test; instead, it is to develop operational procedures. This is critical with Type II agents, since they must be reintroduced at the beginning of each growing season. Despite the difference in objective, the general procedure is very similar to that used for the small-scale tests (blocks 58-62). The sites must be selected, and the monitoring and analysis procedure must be updated. The most important difference from previous test plans is in the matter of deployment guidance. For the large-scale tests, guidance must be developed for the use of the agent in an operational, as opposed to scientific or investigatory, mode. In effect, a first-generation manual for the field crews must be developed.

92. Block 76. The baseline environmental conditions at the test sites must be established. It may be expected that this effort can be made more efficient than before, since the designers will have the benefit of the experience gained in the small-scale tests.

93. Block 77. The mathematical performance prediction model must be updated and refined on the basis of the results of the small-scale test. This is especially critical for Type II agents, because the performance prediction model will be one of the principal tools used by the operational crews to establish criteria for the application of the agent under different environmental situations.

94. Block 78. With the updated model, the performance of the biocontrol agent and the response of the ecosystem in the test site is predicted.

95. Block 79. Concurrent with the design of the large-scale test, all necessary coordination with private, local, State, and Federal agencies must be maintained. Permits will be obtained from the APHIS to move biocontrol agent(s) to the state(s) in which the test site(s) occurs.

96. Block 80. Because control of the target species with a Type II biocontrol agent will require a continuous supply of agent,

provision must be made for the establishment of a rearing facility. The first step is to establish criteria for such a facility. This will include production rate, location, and probable cost. Obviously one of the primary sources of data for estimating the required production rate will be the mathematical performance prediction model.

97. Block 81. If the rearing facility used to produce the bio-control agent for the small-scale test proves to be inadequate to supply the quantities required for the large-scale test, a new rearing facility will have to be established. If a new facility is required, it must be completed early enough to produce a population for release according to the schedule for the large-scale test. Normally, this means that the decision as to the need for a new facility must be made very early in the planning cycle.

98. Block 82. A quantity of the agent sufficient to meet the needs of the large-scale test must be produced.

99. Block 83. When an adequate population of the agent is grown, the release is made in the test area according to the procedures set forth in the first-generation field manual (block 75).

100. Block 84. The deployment process must be carefully monitored to determine the adequacy of the deployment instructions. In addition, the activity of the biocontrol agent, the effect of the agent on the target plant species, and the ecosystem response must also be closely monitored.

101. Block 85. Complete documentation of the large-scale test must be prepared. This will generally consist of a technical report and a popularized report.

102. Block 86. As soon as a period of time has elapsed such that the responses of agent, target plant species, and ecosystem can be established with reasonable confidence, a decision must be made as to whether the agent is useful enough to develop methodology to reintroduce each year. This decision may not depend completely upon effectiveness and safety; it may also depend on the economics of the system. It may be, for example, that the agent is so costly to produce and disseminate that the solution is more expensive than the problem.

103. Block 87. If it is decided that the agent is not acceptable, the program with respect to the candidate agent is terminated.

104. Block 88. The mathematical performance prediction model must be updated and refined on the basis of the findings during the large-scale tests. This is essential for the preparation of the second-generation field manuals (block 89) if revised versions are required prior to operational deployment.

105. Block 89. Manuals for the guidance of the operational deployment of the agent must be prepared. These manuals may (depending on the agent) include specifications of biological constraints, weather and climate conditions required for successful release, logistics requirements, rearing procedures, etc.

Phase IV: Operational Deployment

106. With the beginning of Phase IV, the action moves out of the direction of the research and development community and into the direction of the operational community. The role of the scientist in this stage is that of observer.

107. Block 90. It is almost certain that the biocontrol agent will be in short supply for at least some time, simply because of the time required to create adequate rearing facilities and logistics systems. Thus, it is probable that release priorities will have to be established. The procedure can be expected to be closely analogous to that used to establish schedules for herbicide applications.

108. Block 91. Permits must be obtained from State and local governments for the use of the agent. If proper coordination has been maintained (block 79), this procedure may go smoothly. If not, difficulties may be expected. In addition, a permit must be obtained from the APHIS for each state in which the agent is to be operationally deployed.

109. Block 92. The general environmental conditions in each candidate release site must be established at least to the level required by the mathematical performance prediction model.

110. Block 93. The actual operational release sites are selected on the basis of anticipated effectiveness of the agent, as predicted by

the mathematical performance prediction model, but conditioned by local and State needs. Thus, it should be noted that the actual release sites are not necessarily identical to the priorities previously selected (block 90), since the local and State agencies may have special problems of their own.

111. Block 94. The actual deployment of the agent is now planned, with emphasis on rearing schedules, logistics, and cost.

112. Block 95. In the meantime, steps must be taken to prepare the necessary populations of the biocontrol agent for release.

113. Block 96. The agent is deployed according to the operational release plan.

114. Block 97. The results of the operational releases should be carefully monitored, both to ensure that control is achieved and to determine whether unexpected ecological effects develop in any of the release areas. In this regard, it should be noted that the test program cannot possibly have included all possible environmental conditions, and thus the possibility remains, even at the conclusion of the large-scale test, that a special combination of environmental conditions could trigger an unexpected response in an ecosystem. The data from the monitoring program should also be used to validate and update the mathematical performance prediction model, if necessary.

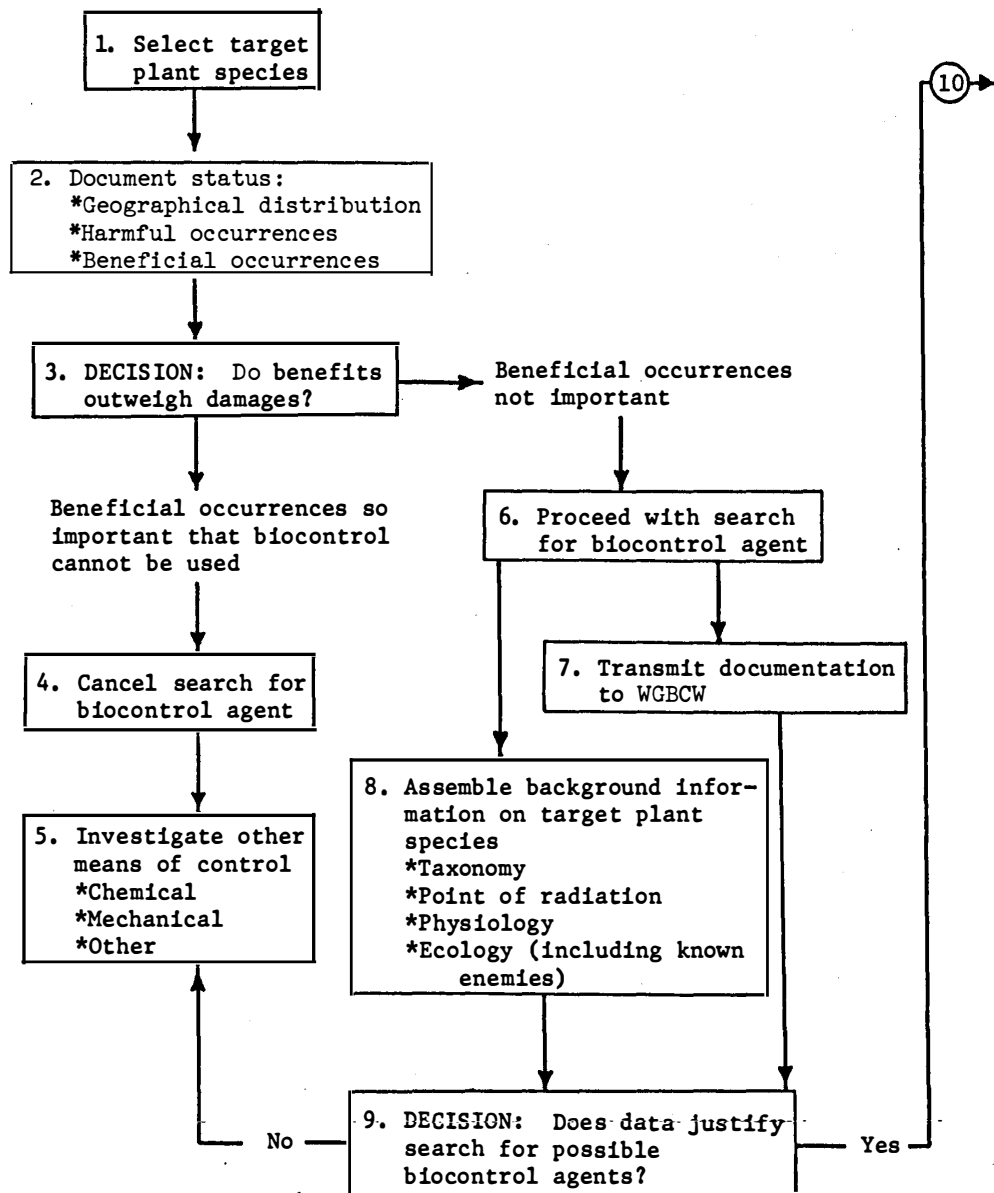
115. Block 98. Finally, the results of the initial operational deployment of the agent should be documented and made a matter of public record.

Conclusions

116. Many interrelated tasks must be successfully completed before a biological control agent can be used operationally. The complexity of the interrelations emphasizes the unavoidable fact that the introduction of a biocontrol agent can be expected to be a lengthy process. In the unlikely event that all tasks go smoothly and well, the entire process will still require a minimum of about 4 years. If serious snags develop, such as the finding of a pathogen late in the test cycle or

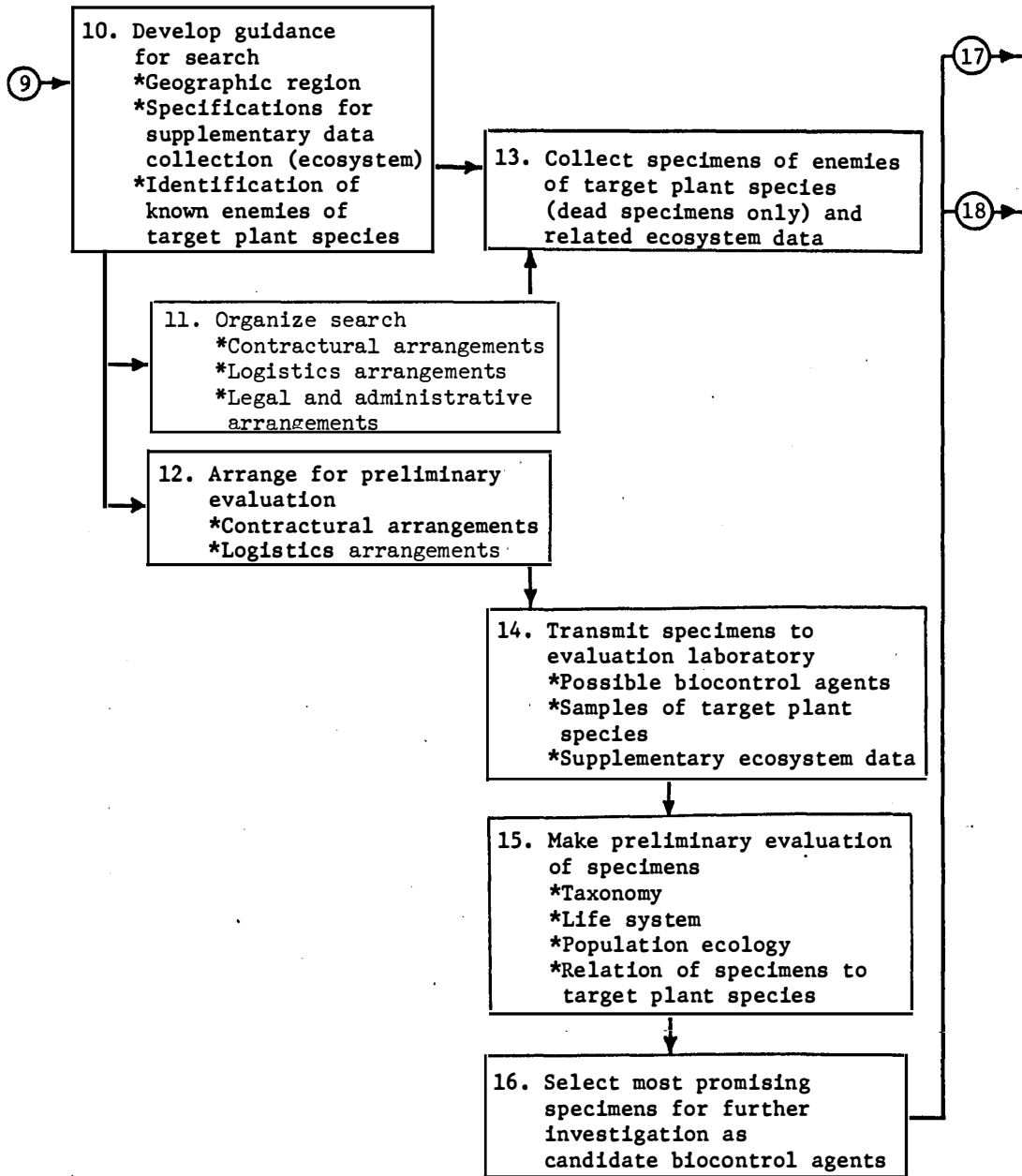
uncertainties as to host specificity, the process may take as long as 7 or 8 years. And, of course, it may fail completely, if the difficulties are such that they cannot be eliminated.

117. One of the remaining problems of management is to assemble factual data on the lengths of time required to complete each component task. Until such data are available, there is no way to reliably predict the time required to produce a biocontrol agent for operational use. Given this situation, it is all too easy for research people to unintentionally misrepresent, to both high-level management and the public, the time required to achieve effective control with biological agents.



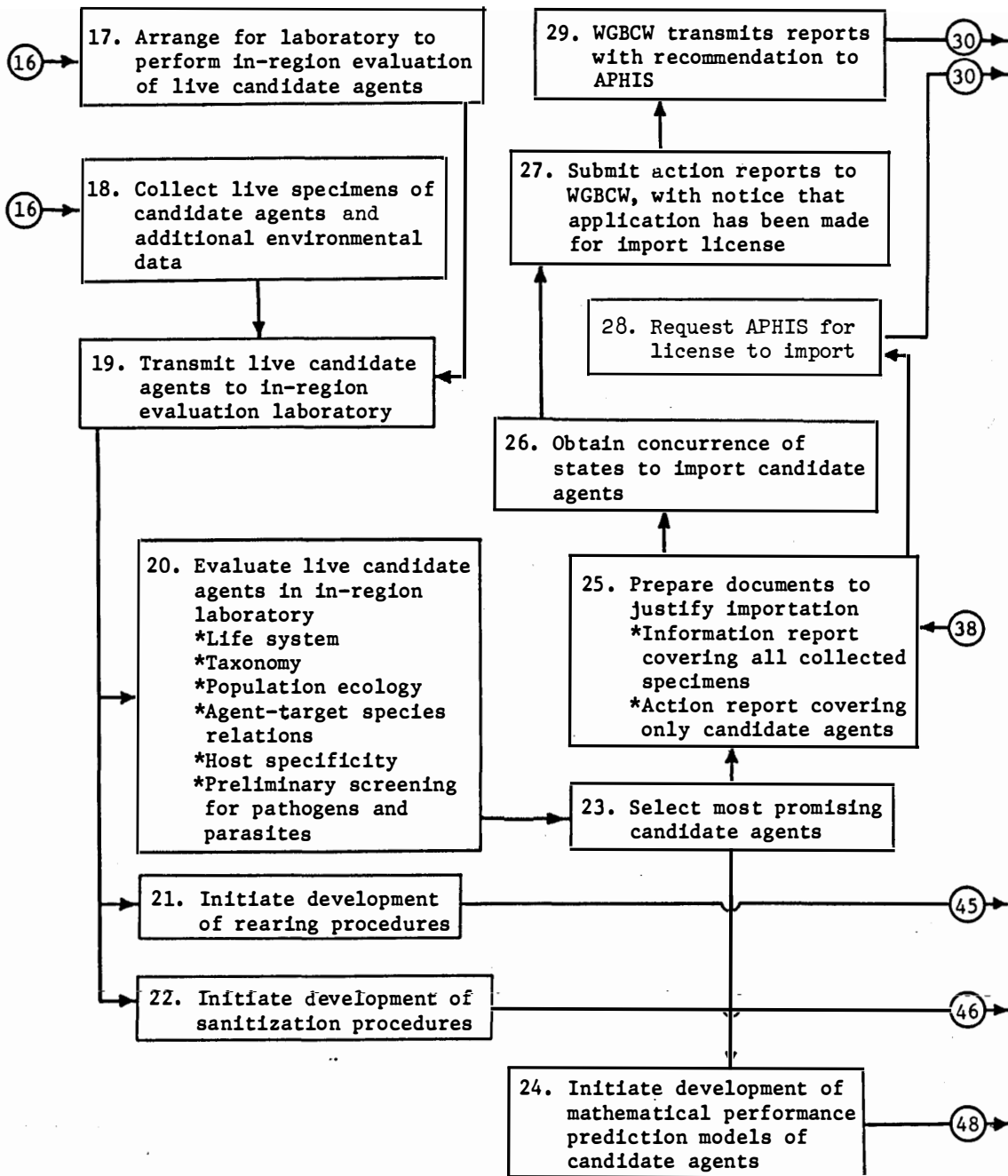
Phase I: Search and Preliminary Evaluation

Figure 1. Flow diagram of management plan for introduction of a biocontrol agent (sheet 1 of 10)



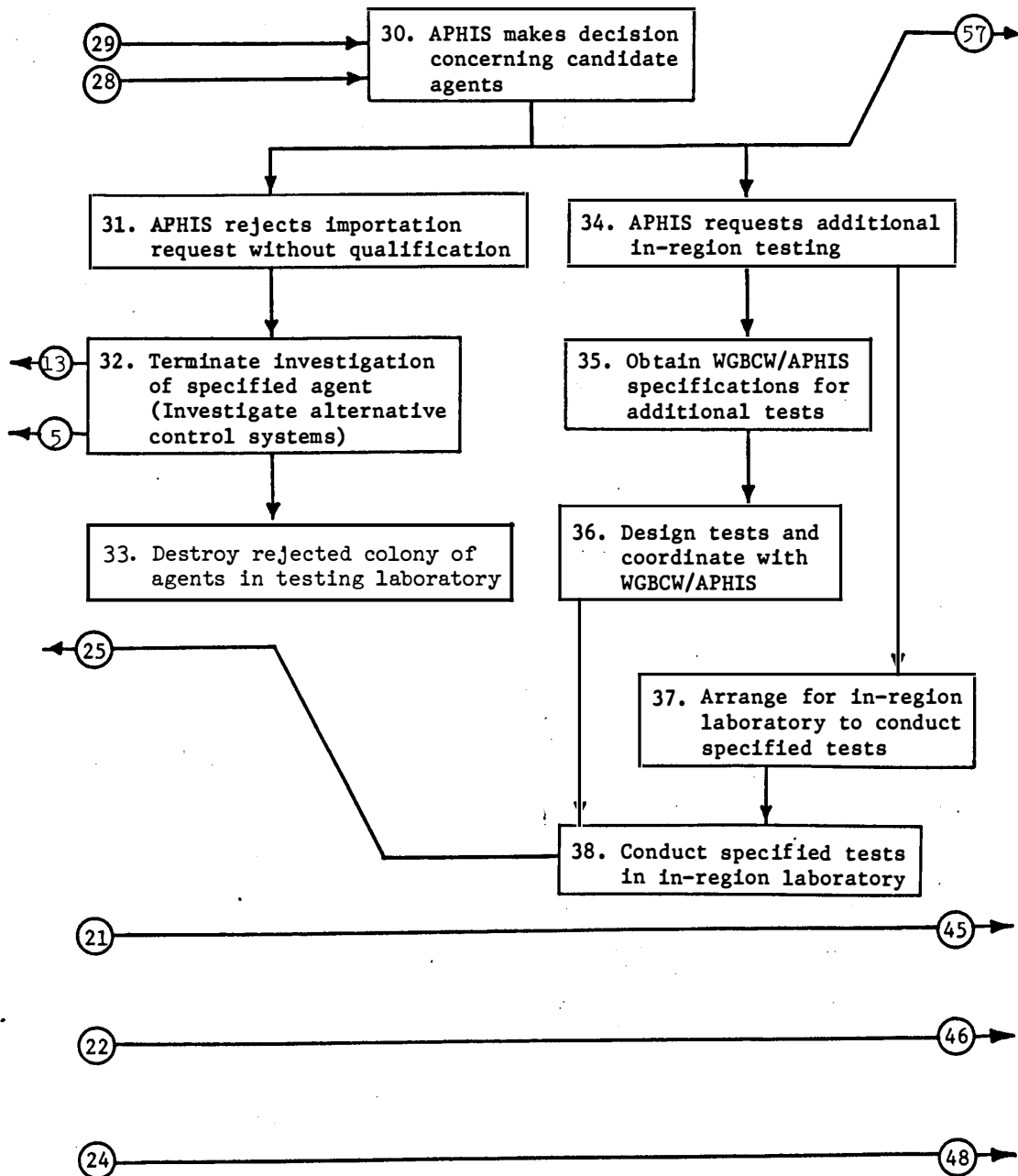
Phase I: (continued)

Figure 1 (sheet 2 of 10)



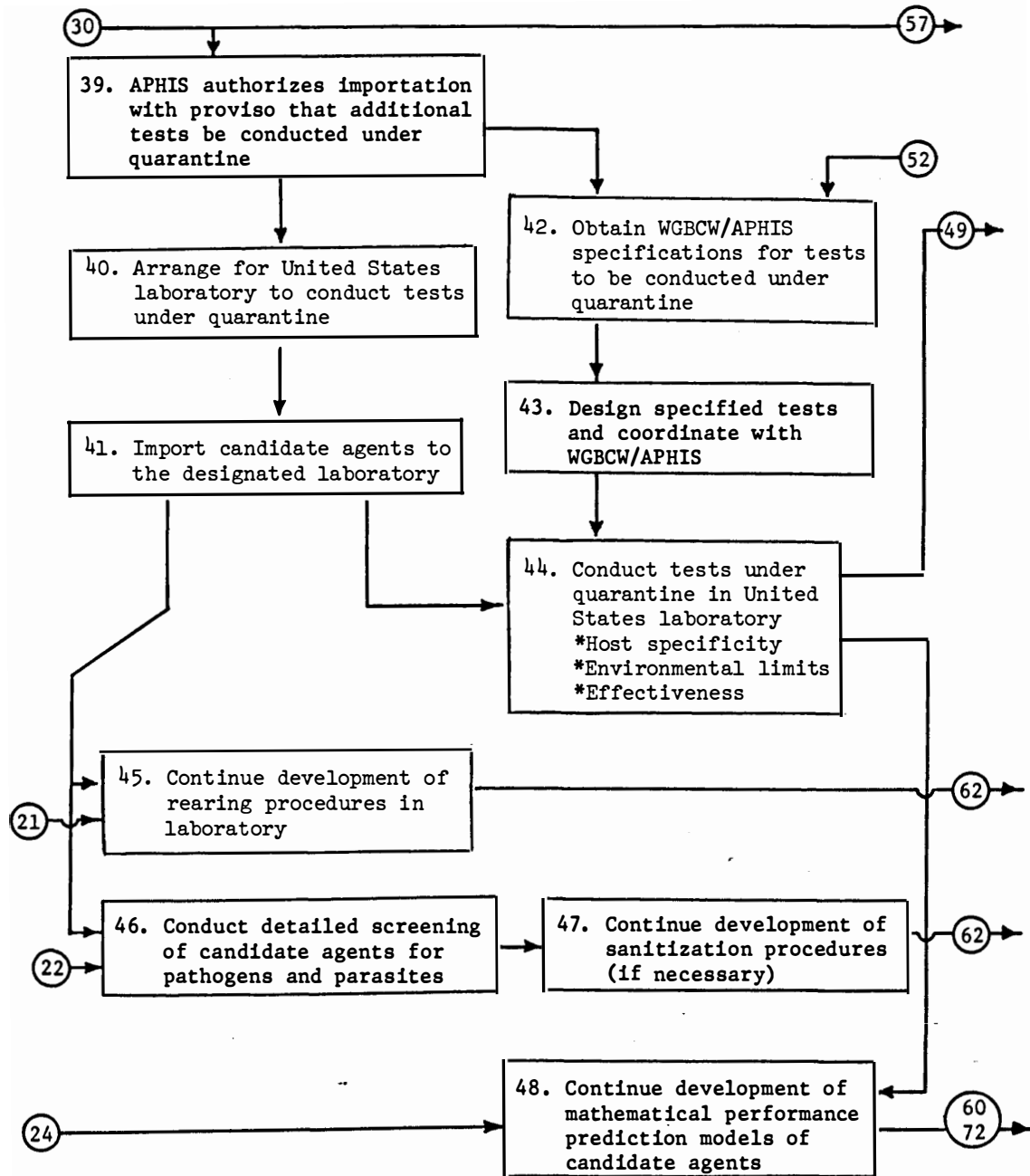
Phase II: Agent Assessment

Figure 1 (sheet 3 of 10)



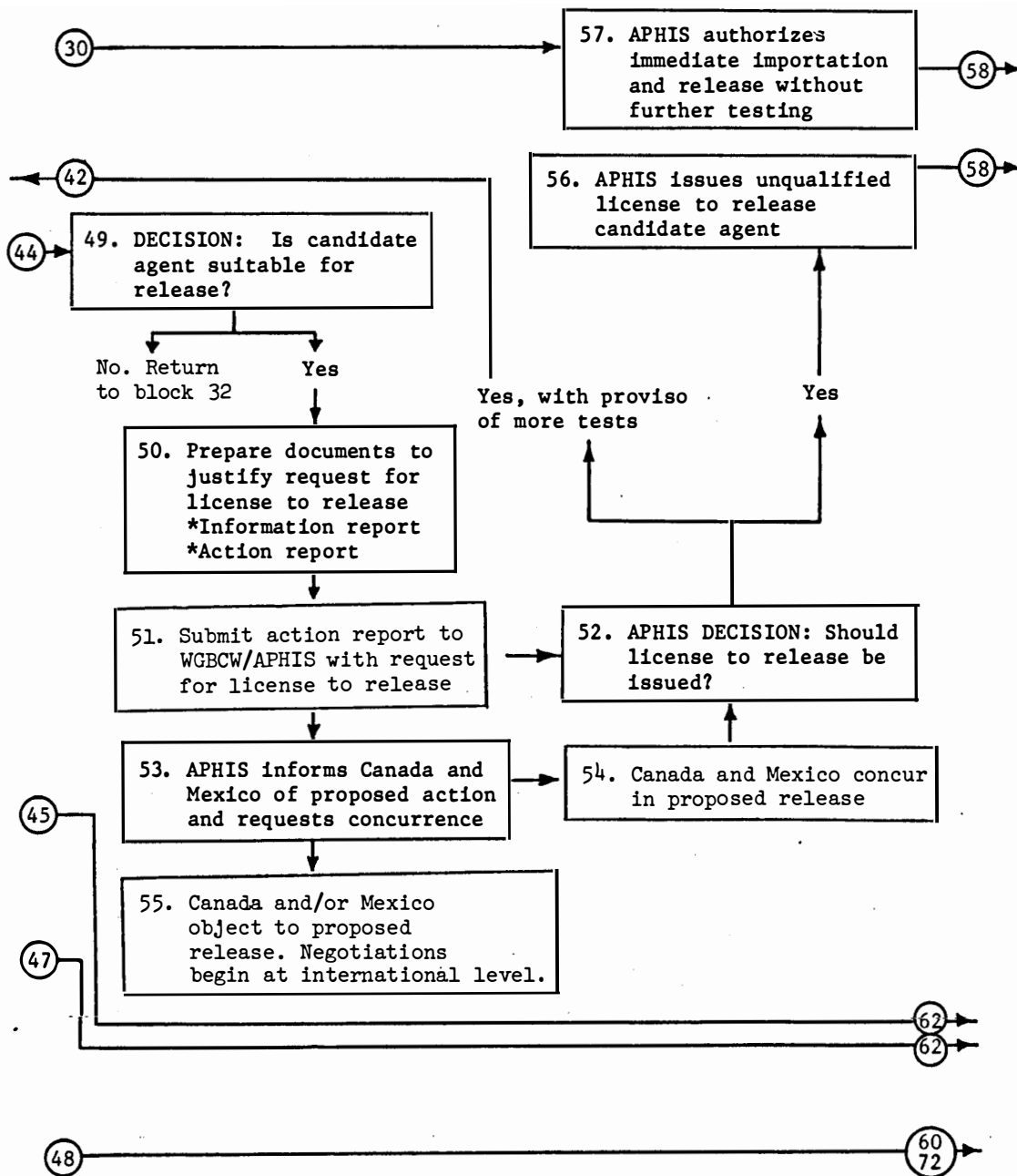
Phase II: (continued)

Figure 1 (sheet 4 of 10)



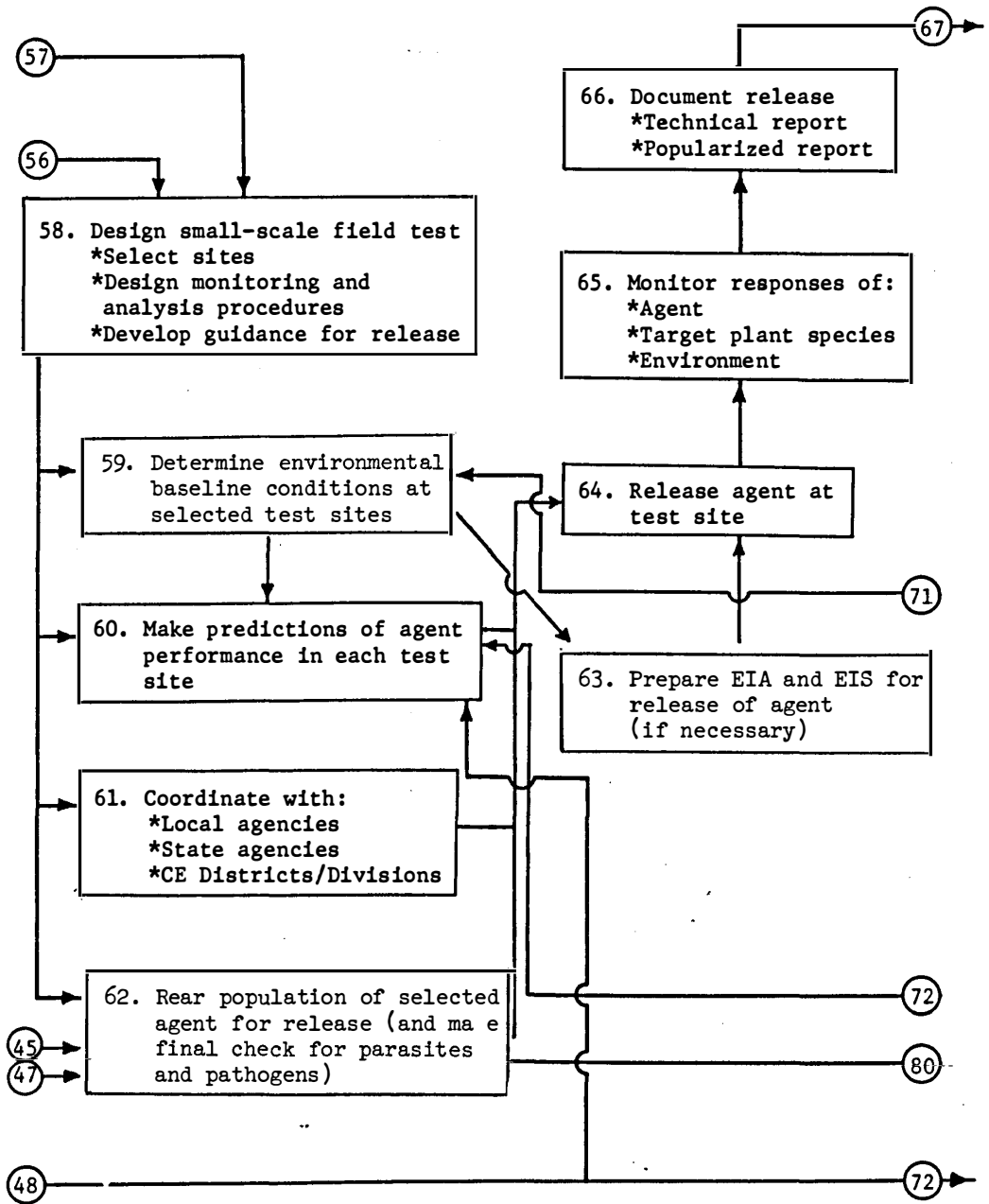
Phase II: (continued)

Figure 1 (sheet 5 of 10)



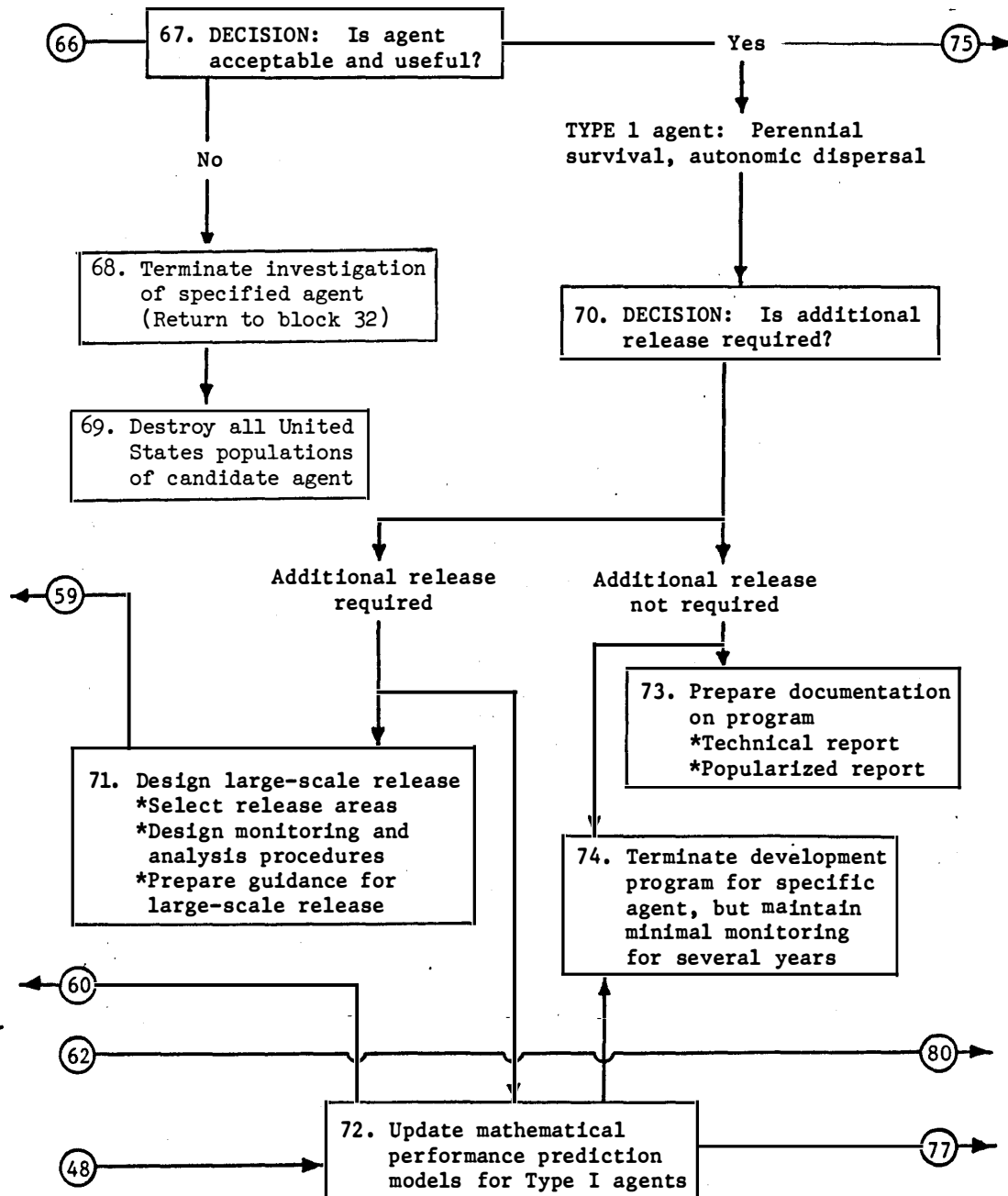
Phase II: (continued)

Figure 1 (sheet 6 of 10)



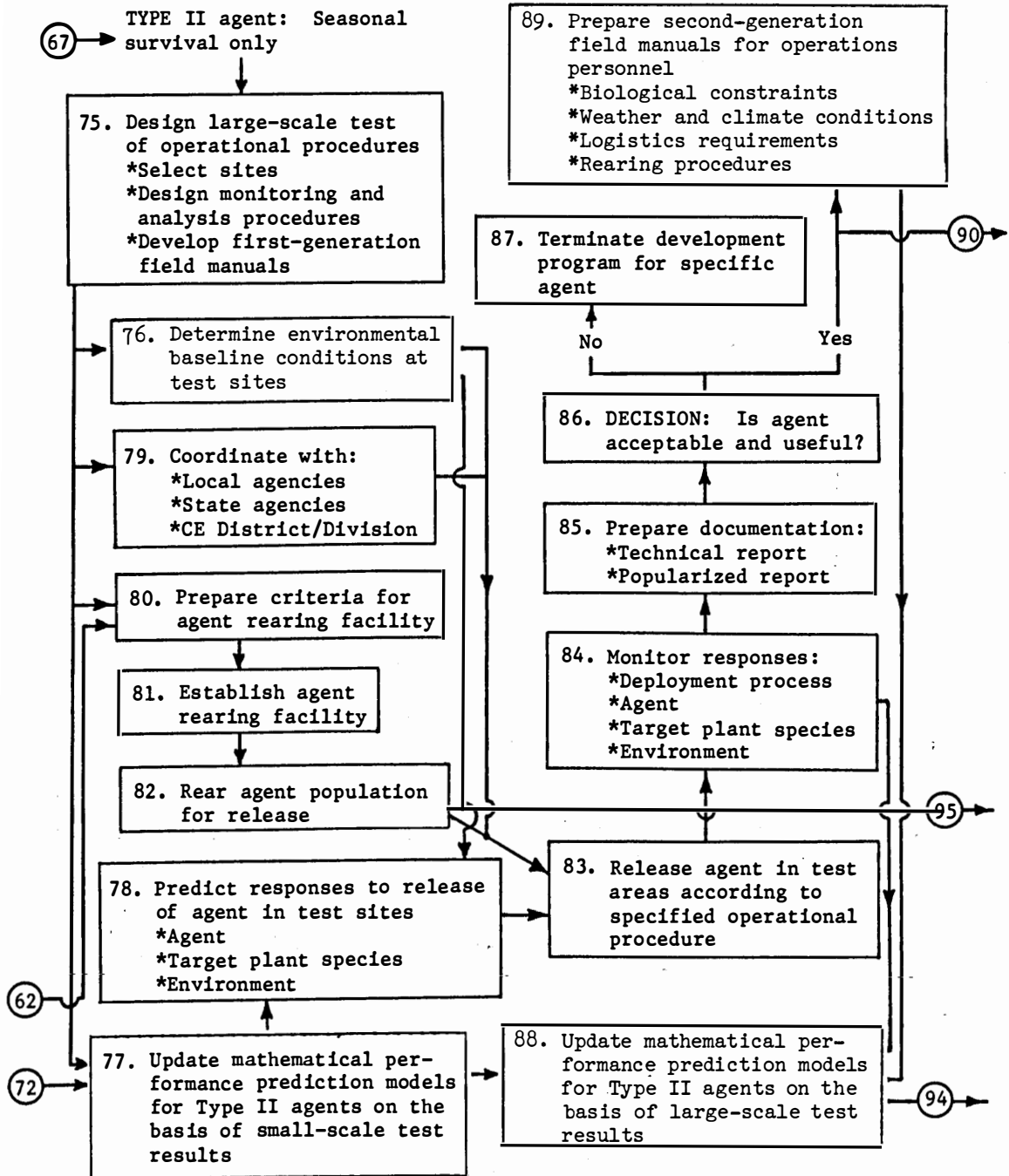
Phase III: Operational Evaluation

Figure 1 (sheet 7 of 10)



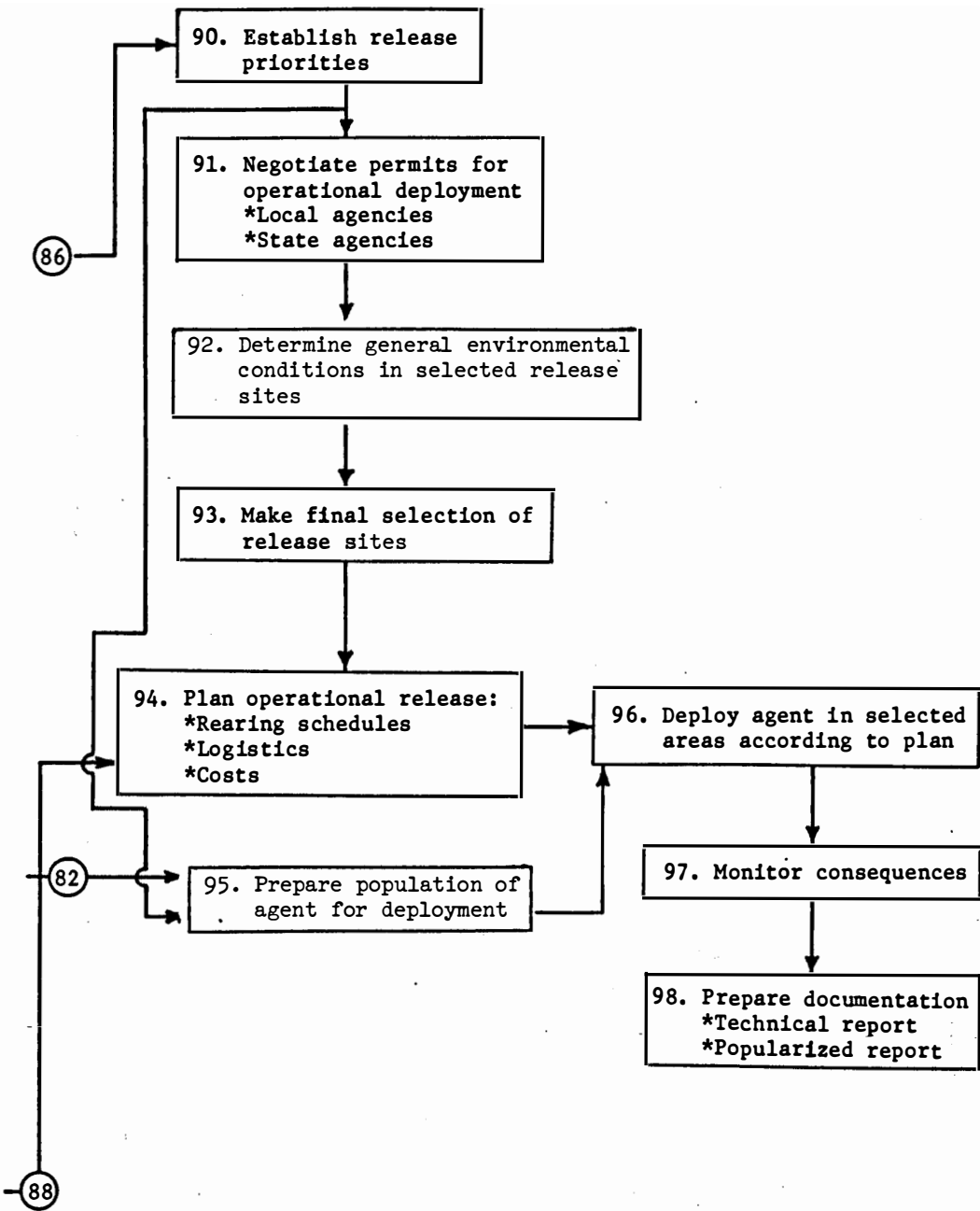
Phase III: (continued)

Figure 1 (sheet 8 of 10)



Phase III: (continued)

Figure 1 (sheet 9 of 10)



Phase IV: Operational deployment

Figure 1. (sheet 10 of 10)