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Proposal No.	13-107

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting		 a. ⊠ Growing Area b. □ Harvesting/Handling/Distribution c. □ Administrative
Submitter	Robert Rheault	c. — Administrative
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Proposal Subject	Sources of Seed for Aquaculture	
Specific NSSP	Section II. Model Ordinance	
Guide Reference	Chapter VI. Shellfish Aquaculture	
Text of Proposal/	.03 Seed Shellstock	
Requested Action		
1	Seed may come from any classification, provided that	growing area, or from any growing area in any t:
	B. Seed from growing prohibited classificated deleterious substance C. Seed from growing classification are cultivated by the classification are considered by	ed is sanctioned by the Authority g areas or growing areas in the restricted or ation have acceptable levels of poisonous or es; and g areas or growing areas in the prohibited tured for a minimum of six (6) months one month water temperatures are above 50 degrees F.
Public Health Significance	prohibited classification have beed deleterious substances (John Mul Rice unpub. data, Leavitt unput adequate to purge viral and bacter high enough to maintain active degrees C) (Richards 1988). Once the Authority is satisfied the seed have "acceptable levels of culture in open waters should be contaminants to ensure that publicity right to deny seed collection and for deleterious substances, or to necessary. The original intent of this section contamination prior to harvest for substances were at acceptable level six-month requirement was implement was implement of the section month.	tured in certain growing areas that are in the en shown through repeated sampling to be free of the RI DOH, unpub. data, Rheault unpubl. data, b. data). A period of one month is typically rial contaminants provided water temperatures are metabolic activity (above 60 degrees F or 15 that adequate sampling has demonstrated that the deleterious substances", then a 30 day period of adequate to allow purging of bacterial and viral ic health is protected. The Authority retains the culture in any area, or to require additional testing require longer periods to purge contaminants as a was to provide for purging of viral and bacterial r consumption on the assumption that deleterious els prior to moving the seed to grow out areas The emented as a short-hand way to ensure that seed a when water temperatures exceeded 60 degrees F.

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	typically more than six months from harvest size when shellstock relay times as short as two weeks are common.
	References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251.
	Supporting Information: RI DOH metals data (oyster seed grown in Billington Cove Marina) Unpublished data from Rd. Dale Leavitt (clam seed grown in Warwick Cove Marina)
Cost Information	This change should facilitate record keeping and documentation efforts required to ensure that seed from prohibited waters do not get harvested until bacterial and viral contamination has been purged.
Action by 2013 Task Force I	Recommended referral of Proposal 13-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-107.
Action by 2015 Aquaculture Facility Inspection Committee	Recommended the following: (1) Referral of Proposal 13-107 back to Committee as appointed by the Conference Chair. (2) The charge of the Committee be expanded to include updating and revising the Aquaculture Chapter of the Model Ordinance to reflect current practices and methods and submit proposals for the next Annual Meeting.
Action by 2015 Task Force I	Recommended adoption of Aquaculture Facility Inspection Committee recommendations on Proposal 13-107.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-107.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-107.
Action by 2017 Aquaculture Facilities Inspection Committee	Recommended adoption of Proposal 13-107 as substituted. Section I. Definitions Replace definition 9. in Section I of the Model Ordinance as follows:
	9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration, wet storage or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.
	Modify definition 93. in Section I of the Model Ordinance as follows: (93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering or nursery culture of seed for aquaculture, is not permitted.

Section IV. Chapter IV. Shellstock Growing Areas

Change @03 E. (2)(a) to read:

- (2) General. The Authority shall:
- (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed <u>or nursery culture</u> for aquaculture or the depletion of the areas classified as prohibited; and

Replace Chapter VI. Aquaculture in its entirety as follows:

Chapter VI. Aquaculture

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]
@ .01 General.

- A. Activities which have been determined to pose a significant public health concern and need regulation outlined in this Chapter include, but are not limited to:
 - (1) Seed production in waters classified as Prohibited or Unclassified;
 - (2) Aquaculture that attracts birds or mammals; and
 - (3) Land based aquaculture
- B. The Authority shall:
 - (1) Approve the written operational plan for operations as outlined in @.01A above.
 - (2) Inspect operations outlined in @.01A above at least annually; and
 - (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A(1). are being implemented.
 - (4) Consistent with Chapter IV @ .01 (D)(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals their presence should be considered for possible adverse effects on growing area water quality

@ .02 Seed Shellstock.

- A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.
- B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.
- C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

Requirements for the Harvester/Dealer

.01 Exceptions.

Hatcheries and nurseries rearing larvae and/or seed that are located in:

- A. Approved or conditionally approved growing areas are exempt from these requirements.
- B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.

.02 General.

- A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
 - (1) A permit from the Authority for the activity and functioning of his facility;
 - (2) A harvester's license; and
 - (3) Certification as a dealer, where necessary.
- B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.
- C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.
- D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
 - (1) The closed status of the conditionally approved classification;
 - (2) The restricted classification;
 - (3) The open status of the conditionally restricted classification; or
- E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
- F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII., and XIV.
- G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
 - (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;
 - (2) Water source, its treatment method, if necessary, and its quality in land based systems.
- .03 Seed Production in Water Classified as Prohibited or Unclassified.

<u>Seed may come from any growing area, or from any growing area in any classification, provided that:</u>

- A. The source of the seed if from waters classified as prohibited or unclassified is sanctioned by the Authority; and
- B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

- (1) A description of the design and activities of the culture facility;
- (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
- (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;
- (6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.

.04 Aquaculture that attracts birds or mammals.

- A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
 - (1) A description of the design and activities of the culture facility;
 - (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
 - (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
 - (4) The species of shellfish to be cultured and harvested;
 - (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;
 - (6) Maintenance of the required records

.05 Land Based Aquaculture.

- A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:
 - (1) A description of the design and activities of the culture facility;
 - (2) The specific site and boundaries in which shellfish culture activities will be conducted;
 - (3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
 - (4) The species of shellfish to be cultured and harvested;
 - (5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
 - (6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;
 - (7) A description of the water source, including the details of any water treatment process or method;
 - (8) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
 - (9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
 - (10) Maintenance of the required records.

- B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues.
 - (1) Construction and remodeling plans for any permitted aquaculture facility;
 - (2) Aquaculture operational plans; and
 - (3) Aquaculture permits.

C. Water Systems.

(1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

D. Water Quality.

- (1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.
- (2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.

.06 Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in Section .05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
- C. Include in its operational plan requirements to:
 - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
 - (2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

Move Chapter VI Section .07 to a new Chapter:

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening.

If a State recognizes shellfish gardening the Authority:

- A. Shall permit or register shellfish gardening activities.
- B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.
- C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct

consumption.

- <u>D.</u> May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.
- @ . 02 Requirements for the Shellfish Gardener.
- A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.
- C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.

Action by 2017 Task Force I

Recommended adoption of Aquaculture Committee recommendation on Proposal 13-107 as amended.

Section I. Definitions

Replace definition 9. in Section I of the Model Ordinance as follows:

9. Aquaculture means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed_collection, production, cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration_or, wet storage_or the broadcasting of spat or seed shellfish being left to mature the same as wild shellfish.

Modify definition 93. in Section I of the Model Ordinance as follows:

(93) Prohibited means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering or nursery culture of seed for aquaculture, is not permitted.

Section IV. Chapter IV. Shellstock Growing Areas

Change @03 E. (2)(a) to read:

- (2) General. The Authority shall:
- (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

Replace Chapter VI. Aquaculture in its entirety as follows:

Change @03 E. (2)(a) to read:

- (2) General. The Authority shall:
 - (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

Chapter VI. Aquaculture

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@ .01 General.

- A. <u>Aquaculture Aactivities which may have been determined to pose a significant public health concern and are regulated need regulation outlined in this Chapter include, but are not limited to:</u>
 - (1) Seed production in waters classified as Prohibited or Unclassified;
 - (2) Aquaculture structures that attracts birds or mammals; and
 - (3) Land based aquaculture
- B. The Authority shall:
 - (1) Approve the written operational plan for operations as outlined in @.01A above.
 - (2) Inspect operations outlined in @.01A above at least annually; and
 - (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A(1). are being implemented.
 - (4) Consistent with Chapter IV @ .01 (D)(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals their presence should be considered for possible adverse effects on growing area water quality

@ .02 Seed Shellstock.

- A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.
- B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.
- C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

Requirements for the Harvester/Dealer

- .1 Exceptions.
 - Hatcheries and nurseries rearing larvae and/or seed that are located in:
- A. Approved or conditionally approved growing areas are exempt from these requirements.
- B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.
- .2 General.
- A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
 - (1) A permit from the Authority for the activity and functioning of his facility:
 - (2) A harvester's license; and
 - (3) Certification as a dealer, where necessary.
- B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced

- only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.
- C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.
- D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
 - (1) The closed status of the conditionally approved classification;
 - (2) The restricted classification;
 - (3) The open status of the conditionally restricted classification; or
- E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
- F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.
- G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
 - (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification;
 - (2) Water source, its treatment method, if necessary, and its quality in land based systems.
- .3 Seed Production in Water Classified as Prohibited or Unclassified. Seed may come from any growing area, or from any growing area in any classification, provided that:
- A. The source of the seed if from waters classified as prohibited or unclassified is sanctioned by the Authority; and
- B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
 - (1) A description of the design and activities of the culture facility;
 - (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
 - (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
 - (4) The species of shellfish to be cultured and harvested;
 - (5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities;
 - (6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.
- .4 Aquaculture that attracts birds or mammals.
- A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

- (1) A description of the design and activities of the culture facility;
- (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
- (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
- (4) The species of shellfish to be cultured and harvested;
- (5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;
- (6) Maintenance of the required records
- .5 Land Based Aquaculture.
- A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:
 - (1) A description of the design and activities of the culture facility;
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 - (4) The species of shellfish to be cultured and harvested;
 - (5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
 - (6) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;
 - (7) A description of the water source, including the details of any water treatment process or method;
 - (8) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring. The bacterial indicator monitored shall be the same as used for monitoring growing areas;
 - (9) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
 - (10) Maintenance of the required records.
- B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues.
 - (1) Construction and remodeling plans for any permitted aquaculture facility;
 - (2) Aquaculture operational plans; and
 - (3) Aquaculture permits.
- C. Water Systems.
 - (1) If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.
- D. Water Quality.
 - (1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size shall meet the requirements for water

- quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.
- (2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements of Section D. (1) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.
- .6 Polyculture Systems.

A polyculture system shall:

- A. Meet all requirements in Section .05 Land Based Systems;
- B. Provide information concerning all sources of and species of all organisms to be cultivated, cultured, and harvested;
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 - (1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
 - (2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

Move Chapter VI Section .07 to a new Chapter:

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening.

If a State recognizes shellfish gardening the Authority:

- A. Shall permit or register shellfish gardening activities.
- B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation.
- C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption.
- D. May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.
- @ . 02 Requirements for the Shellfish Gardener.
- A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
- B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.
- C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish

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	garden site and provide these records to the Authority upon request. Recommends a committee be appointed by the Conference Chair to review and revise existing guidance documents related to the Aquaculture Chapter.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-107.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-107.