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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health	
Virginia Administrative Code (VAC) citation	12 VAC 5-180	
Regulation title	State Plan for the Administration of the Virginia Shellfish Sanitation Program	
Action title	Deletion of the "State Plan" as a regulation	
Date this document prepared	December 12, 2007	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The "State Plan" was an agreement between the US Food and Drug Administration (FDA) and the State of Virginia to correct a number of deficiencies that had been cited by FDA as too severe to allow FDA's endorsement of Virginia's shellfish program. This agreement was formally signed in 1972. Those deficiencies were corrected in a timely manner and the Virginia shellfish program has been annually approved thereafter by FDA to ship shellfish interstate.

The "State Plan" no longer has any relevance to any agency in Virginia. It was listed as a regulation during the development of the Virginia Administrative Code when the prevailing concept was to be inclusive when listing significant documents as regulations. Since that time the "State Plan" has become obviously unnecessary and irrelevant.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly

chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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Code of Virginia §28.2-800

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The regulation has no relevance to any State agency and is unnecessary.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The regulation will be deleted in its entirety.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The only viable alternative is to leave the regulation in place.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable

effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Bob Croonenberghs, 109 Governor Street, Suite 614, Richmond, Virginia 23219, (804)864-7477 (phone), (804)864-7481 (fax), bob.croonenberghs@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

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In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.}

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

- 1) Deletion of this regulation will neither strengthen nor erode the authority and rights of parents in the education, nurturing, and supervision of their children.
- 2) Deletion of this regulation will neither encourage nor discourage economic self-sufficiency, self-pride, nor the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.
- 3) Deletion of this regulation will neither strengthen nor erode the marital commitment.
- 4) Deletion of this regulation will neither increase nor decrease disposable family income.

Periodic review - Public comment

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If this NOIRA is <u>not</u> the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 36, e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

Commenter	Comment	Agency response
No one	No comments received	none

The regulation does not meet some of the criteria set out in Executive Order 36, which must be met to be considered as a regulation worthy of retention. It does not have a bona fide purpose any more and it is not necessary for the protection of public health, safety and welfare.

Periodic review - Discussion

If this NOIRA is <u>not</u> the result of a periodic review of the regulation, please delete this entire section.

If this NOIRA is the result of a periodic review or if the periodic review is to be performed in combination with the NOIRA, please include a discussion of the agency's consideration of: (1) the continued need for the rule; (2) the complexity of the regulation; (3) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

- (1) The agency believes that there is no need for the continuation of this regulation because it no longer has any relevancy.
- (2) The regulation is extremely complex in its scope of items that had to be corrected by the State in the 1970s, in the source of funding and in the structure of the agencies conducting the work.
- (3) The regulation describes several agency organizational charts that were relevant in 1972 and may no longer be applicable, but it does not require that these structures be maintained. The regulation does not conflict with state or federal regulations or laws.
- (4) The regulation was last evaluated in 2003-2004.