

## Tips for Requesting a Variance

Variations allow food establishment operators to be innovative in creating processes, procedures and equipment which benefit their facility while still providing safe food. They may also allow establishments with unique circumstances to address public health concerns in ways which fit those specific circumstances. Indiana law, IC 16-19-3-4.3, allows the Indiana State Department of Health to grant a variance from state rules “upon a showing of good cause”. The following are some tips to help a variance request to be successful:

- Make sure your proposal cannot be accommodated under an existing food rule provision. There have been variance requests which were not necessary because there was sufficient latitude in the existing food rule to allow the establishment to do what they desired without a variance.
- Make sure all of the application information which applies to the proposal is included. Applications have been denied or unnecessary waiting has occurred because requests lacked essential information such as:
  - The section(s) of rule to be varied, complete HACCP plans, flow charts, ingredient lists, a full listing of foods covered by the proposal, scientific studies which support the request, results of laboratory tests, photos or schematics of equipment to be used, time/temperature parameters for the product. A simple, clear and concise description of the new process or equipment is essential to understanding and effectively acting on a proposal.
- Make sure information can be provided as timely as possible. The variance protocol specifies certain time frames for actions to occur. At least one variance request has had to be denied because the information exchange took too long to be acted upon.
- Some VRs require a period of testing to occur during the variance review committees’ deliberation & prior to granting a variance so that lab samples can be collected or to observe a unique procedure being performed. For example, if a variance request is submitted which proposes to use a special process to turn a potentially hazardous food into a non-potentially hazardous food by acidification, or if a proposal includes putting additives in a food to preserve it or increase shelf life, it would be critically important during the testing period, as well as after the variance is granted, that there be no variation from the submitted procedure, HACCP Plan, or standard operating procedure (SOP). Variations have been denied when lab samples showed a final product not to have the proposed pH or  $a_w$  (water activity).
- Variance requests which involve using reduced oxygen packaging in any of its various forms should provide a full explanation of what barriers will be used to prevent the growth of *C. botulinum* (*L. monocytogenes* is also included in the FDA Model Food Code and is recommended to be addressed). If an alternative to the common double barrier method is proposed, there must be a detailed explanation of how the alternative method provides a level

of safety at least equal to having two barriers. The use of resources, such as the FDA Model Food Code is encouraged, but proposals that deviate from the provisions stated in such documents must be accompanied by a detailed explanation as to why the deviations were made and how your proposal addresses the underlying reason for the stated requirement.

- Discuss ideas for proposals with your State or Local Health Inspector. They are a good source for information and can assist in assessing the need for a variance.
- Variance requests are reviewed “as resources are available”, meaning there may be times when other ISDH Food Program activities and responsibilities will take precedence and have higher priority and the stated protocol time frames may not be met by the Program.

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