

Indiana State Department of Health Food Protection Program

Policy for Processing Variance Requests

Purpose

This policy describes the process for submitting a request for a variance and for approving, denying and revoking a variance of certain Indiana State Department of Health rules.

Scope

This policy applies to each request for a variance submitted by a person on behalf of a food establishment(s) or proposed food establishment(s) operated or intending to operate in the State of Indiana, except that variances shall not be considered for temporary food establishments. It also applies to persons to whom a variance has been granted or revoked.

Law

IC 16-19-3-4.3

Sec 4.3. Upon a showing of good cause, the executive board may grant a variance from one (1) or more of the state rules concerning;

- (1) food handling machinery; or
- (2) sanitary standards for the operation of food establishments.

IC 16-42-5-5.2

Sec. 5.2. The state department may grant a variance from one (1) or more of the state rules concerning:

- (1) food handling machinery; or
- (2) sanitary standards for the operation of food establishments in accordance with IC 16-19-3-4.3.

Definitions

Agency	The term “agency” means the Indiana State Department of Health
Assistant Commissioner	The term “assistant commissioner” means the person most immediately responsible for the operations of the Public Health and Preparedness Commission of the Indiana State Department of Health. The term also means his/her designee.

Director	The term “director” means the manager of the Indiana State Department of Health, Food Protection Program
Food Handling	<p>The term “food handling machinery” means any of the following used for and in food handling:</p> <ol style="list-style-type: none"> (1) Equipment; (2) Appliances; (3) Tools; (4) Plumbing and related fixtures; (5) Refrigeration devices; (6) Heating, ventilation, and cooling equipment; or (7) Any other piece of equipment used for and in food handling.
Physical Location	The term “physical location” means the place where food is produced, or the site where the actions or features involved in a granted variance will actually occur. This is recognition that a food establishment’s physical location may be different from a mailing or business location.
Regulatory Authority	The term “regulatory authority” means the state or local enforcement body or authorized representative having jurisdiction over a food establishment, including, as appropriate, the Indiana State Department of Health, county or city health departments, U.S. Food & Drug Administration, or the United States Department of Agriculture.
Variance	The term “variance” means a written document issued by the assistant commissioner upon demonstration of good cause by the person requesting the variance which authorizes a waiver, modification or deviation from one (1) or more of the state rules concerning food handling machinery, or sanitary standards for the operation of food establishments.

Policy

- (a) The agency shall treat as confidential in accordance with state law any information that meets the criteria for a trade secret that is included with a request for a variance.
- (b) A request for a variance under this policy shall contain at least the following information:
1. name, mailing information, electronic mail address and telephone number of the individual submitting the request;
 2. name and address of the person or organization seeking the variance;
 3. a complete listing of food establishments for which the variance is sought, including physical locations, (if different than the mailing address in #2 above), mailing addresses, telephone numbers and name of the person most responsible for supervising the food establishments;
 4. a statement of the proposed variance from the rule requirement citing relevant rule section numbers;
 5. an explanation of how the potential public health hazards and/or nuisances will be alternatively addressed by the proposal including supporting studies from accredited laboratories, Hazard Analysis Critical Control Point (HACCP) plan, standard sanitation operating procedures, or other evidence. The explanation must be based on generally accepted scientific principles;
 6. the request must demonstrate the following:
 - how the proposal differs from what is common and usual in similar industry situations;
 - how the proposal may be unique in dealing with a situation not addressed in existing rules or law;
 - how the proposal does not diminish the protection of public health;
 - if the proposal is based on new science and technology; and
 - how implementation of the variance would be practical.
 7. an explanation as to how the request will assure that all provisions of the variance, if granted, will be enacted at each of the establishments for which a variance has been granted;
 8. a list of all affected parties known by the requester; and
 9. copies of any related variances, waivers, denials or opinions issued by other governmental agencies.
- (c) A request for a variance shall be delivered to the assistant commissioner by United States mail, private carrier, electronic transmission, or by personal service. Upon receipt, a request for a variance delivered by United States mail, private carrier, or by

personal service shall be marked with an official Food Protection Program date stamp. A request for a variance delivered by electronic transmission shall be printed immediately upon receipt and marked with an official Food Protection Program date stamp. The submission of a variance request indicates acceptance of the terms of this policy.

- (d) Upon receipt of a request for a variance and in consideration of available agency resources, the assistant commissioner shall convene a variance review committee consisting of at least the director and two senior food specialists of the Food Protection Program and an epidemiology specialist to analyze the request and make recommendations to the assistant commissioner regarding its approval or denial.
- (e) Within 15 business days of receipt of a request for a variance, the assistant commissioner shall provide written notice of the request to all affected regulatory authorities and to any other affected parties. The regulatory authority will also make a determination within this time frame as to the need to hold a public meeting to hear comments on the proposed variance request.
- (f) A period of 30 business days shall be allowed to receive comments from affected regulatory authorities and other affected or interested parties. The variance review committee shall consider any comments received.
- (g) The variance review committee may request additional information, as needed, from the requestor or any other individual or entity that they believe could have additional pertinent information.
- (h) Unless additional time is requested, the variance review committee shall make a recommendation regarding approval or denial of the variance to the assistant commissioner as soon as possible, or within 30 business days, if resources allow. The variance review committee may submit to the assistant commissioner a request for additional time, as needed, and will notify the requester in writing if the time extension is granted.
- (i) Upon demonstration of good cause, the assistant commissioner may grant the request for a variance. A demonstration of good cause must have its basis in generally accepted scientific fact and principles and shall include consideration of whether this will result in deviation from nationally recognized standards and protocols for food safety. The desire not to comply with a rule will not

be considered as a justifiable reason for granting a variance. The past compliance history with existing rules and variances will also be considered in making a final determination on the request.

- (j) The assistant commissioner shall deny the request for a variance when good cause has not been demonstrated by the requester. To satisfy the good cause requirement, evidence must be shown that potential public health hazards and nuisances will not occur as a result of the proposal being granted.
- (k) No variance will be granted when doing so would conflict with state statutes or rules (other than the rule at issue in the variance request). A granted variance later determined to be in conflict with state law shall be considered invalid and the holder of the variance will be notified.
- (l) The assistant commissioner shall provide a written notice of the grant or denial to the person requesting the variance and to all affected regulatory authorities and affected parties.
- (m) Prior to implementing a granted variance at any food establishment, guidelines will be provided by the agency that will explain the regulatory authority responsibilities. The agency reserves the right to require the grantee to bear the cost for any and all notification and training to all affected regulatory authorities regarding the granted variance.
- (n) Each establishment listed in the request for variance shall comply with this policy, as well as any plans and/or procedures that are submitted and approved as a basis for the variance. Failure to do so shall be considered a violation of the rule that was varied and may result in revocation of the variance.
- (o) Each establishment for which a variance is granted shall have on the premises a copy of the variance at the physical location of the establishment.
- (p) Upon learning of a failure to comply with this policy or the plans or procedures in a variance, the assistant commissioner shall provide written notice that the variance will be revoked to:

1. the person granted the variance;
2. the establishment(s) which failed to comply with this policy or the plans or procedures in a variance;
3. the affected regulatory authority(s); and
4. any other affected party;

unless the variance grantee can immediately demonstrate the ability and willingness to comply with the terms of the variance.

- (q) Features, factors, conditions, records, and principles involved in a granted variance shall be subject to periodic verification during routine establishment inspections and surveys conducted by the agency, another regulatory authority, or both.
- (r) If at anytime the assistant commissioner becomes aware that new science or technology and/or epidemiological data demonstrates that the basis for the existing variance has changed, then the variance may be revoked.
- (s) Any time existing laws are amended or repealed, the existing variance may be revoked to comply with new law or to protect public health.
- (t) The agency shall maintain a public list of all variances granted. The list shall contain the following:
1. name, mailing information, electronic mail address and telephone number of the individual submitting the request;
 2. name and address of the person or organization seeking the variance;
 3. a listing of the rule sections which were varied; and
 4. the nature of the variance described in general terms.
- (u) The assistant commissioner shall provide a report to the Indiana State Department of Health Executive Board at a regularly scheduled meeting of the board of any approvals and/or denials of variance applications and revocations and/or reinstatements of previous variance approvals. The assistant commissioner shall also notify the Executive Board when a request is received.