

# Form 15.1: Recall Hazard/Risk Analysis

Date Notified: \_\_\_\_\_

## Using this Form:

The decision to recall can be somewhat subjective at times. There are some situations where the hazard is known to be potentially life threatening, and the decision to recall is clear. In other situations it may be necessary to separate public perception of risk from scientific analysis of risk, and the decision to recall can be more difficult. This form is designed to clarify the thought process when making a decision to recall, and to provide a record of recall decisions for future reference.

1. <b>Brand/Product Name</b>	
2. <b>Company Contact Details</b>	
3. <b>Contact Person</b>	
4. <b>Product Information</b> What batch(es) is suspected? Are batches before and after affected? Quantity of product Product size Use-by or best before date?	
<p style="text-align: center;"><b>Is ALL the product still in company/distribution control (not yet with consumers)?</b></p> <p><input type="checkbox"/> Yes – Product Hold or Withdrawal (see Note 1)</p> <p><input type="checkbox"/> No – Recall possible, proceed with risk analysis</p>	
5. <b>Details of Hazard/Non Compliance</b> <input type="checkbox"/> Microbiological contamination <input type="checkbox"/> Chemical contamination <input type="checkbox"/> Foreign matter <input type="checkbox"/> Undeclared allergen <input type="checkbox"/> Labelling incorrect <input type="checkbox"/> Other Has any testing been done? Does the product contravene a regulatory limit or standard?	
<p style="text-align: center;"><b>Does the hazard/non-compliance have the potential to cause risk to health?</b></p> <p><input type="checkbox"/> Yes – recall possible, proceed with risk analysis</p> <p><input type="checkbox"/> No – recall not required, unless other factors indicate otherwise (see section 10). Company's own commercial risk to recall or not. Corrective action to prevent reoccurrence to be undertaken and documented.</p>	
6. <b>Distribution Data (Note 2)</b> Where is product sold? Has product entered the retail chain? Approximately how much product has been sold? Has product been exported (if yes, to where)?	
7. <b>Consumption Information (Note 3)</b> How is this product commonly used (e.g eaten immediately, stored for a few days, stored for a long period of time in freezer/pantry)? How much of this product is eaten and how often? Is it Ready-To-Eat?	
8. <b>Consumer/Medical Reporting (Note 4)</b> Have there been consumer complaints relating to this product? Any reports of illness?	

<p><b>9. Expert Opinion (Note 5)</b> Note experts consulted, and results of consultation.</p>	
<p><b>10. Any other relevant factors</b> This section should be used to record anything else that influences the recall decision.</p>	
<p style="text-align: center;"><b>Hazard/Risk Assessment indicates Recall Required?</b></p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Maybe – insufficient information to make accurate scientific assessment. Precautionary principle to be used.</p>	
<p><b>Precautionary Principle:</b> Where assessment of available information indicates the possibility of harmful effects on health but scientific uncertainty exists, assume the product presents a risk to human health and take appropriate control action.</p>	
<p><b>Final recall decision</b> <i>(including the extent of the finalised scope of the recall (batches, distribution etc))</i> <b>and key reasons:</b></p>	

## Notes:

1. Risk analysis may be required to determine whether product is suitable for reconditioning and release for sale or must be disposed of (destroyed).
2. Distribution contributes to the risk analysis, as it assists in identifying the potential exposure of consumers to the hazard. Widespread distribution to many people carries greater risk than limited local distribution. However, New Zealand has no specified acceptable level of protection, therefore if one person may be exposed to significant risk recall may be required.
3. Consumption information contributes to risk and the recall decision in the following ways:
  - a. Recall is more likely to be indicated if product is in the hands of the consumers but not yet eaten, i.e. is still in pantries, fridges or freezers. If product is consumed immediately or shortly after purchase, recall information is unlikely to be able to be communicated to the consumer in time to prevent exposure to the hazard. In this situation consideration will need to be given to whether the consumer needs to be informed that they have been exposed to the hazard and should seek medical advice.
  - b. The hazard may only present a risk when product consumption exceeds a specific threshold, sometimes within a particular timeframe. National Nutrition Survey data can be used to provide an indication of average consumption of many products.
4. Consumer/Medical reporting: Where two or more consumer complaints or reports of illness implicate the same product or manufacturer the likelihood of a hazard being associated with the product is high and therefore likelihood of recall is high, particularly if the reports have originated from different households or otherwise unrelated sources. Confirmed reports of illness take precedence over consumer complaints. Recall is not automatic on suggestion of illness, unless there is additional evidence that confirms a causal link with a particular food product, however reports of illness must be taken seriously. Product may need to be put on hold, or withdrawn pending further investigation.
5. Expert Opinion becomes very important when differentiating between 'real' risk based on scientific evidence versus perceived risk. Expert opinion may also be a source of recent, unpublished, advances in scientific understanding of risks associated with particular hazards, that may impact on the decision to recall.