Never Events

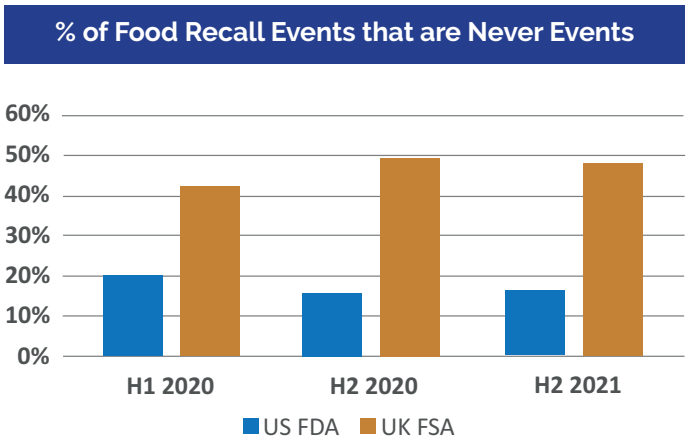
Could almost half of all food recalls be prevented?

"to err is human, to cover up is unforgivable, and to fail to learn is inexcusable"

Sir Liam Donaldson, former Chief Medical Officer for England.

Imagine you are a surgeon and you operated on the wrong leg. Now imagine if the equivalent or worse happened in the food industry, such as an undeclared allergen in your product causing a serious allergic reaction or even death. The healthcare sector has taken action to prevent awful scenarios like this and called them "Never Events". It is now time for the food industry to take action to prevent easily avoidable, dangerous and costly mistakes that lead to recalls. In order to assist with this, in 2019 we defined a Never Event recall principle and, in this article, we highlight the latest Never Event recall numbers, the key risks and how we help companies to mitigate those risks.

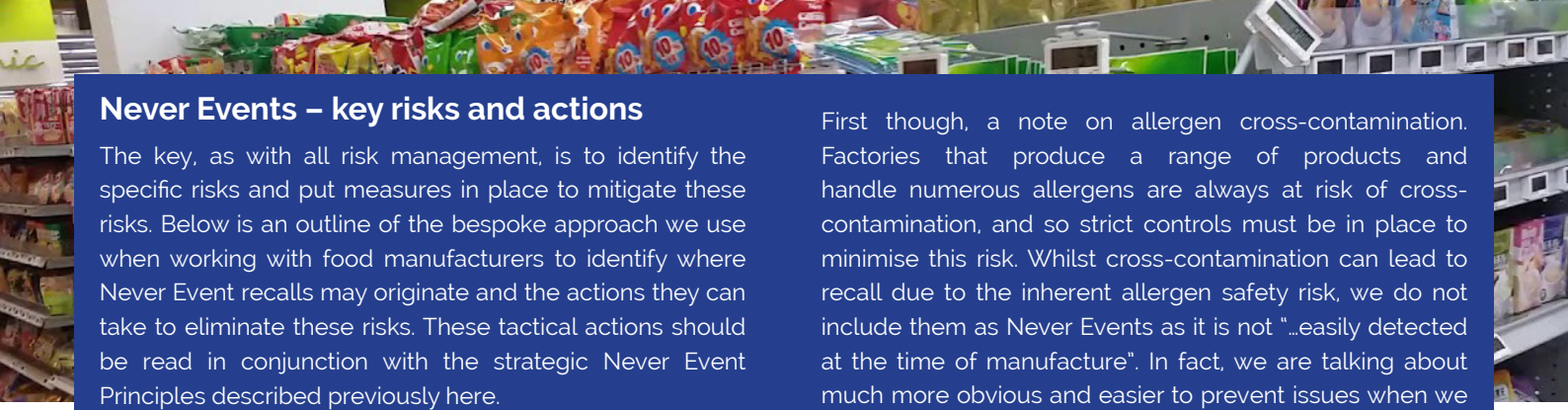
How many Never Event recalls are there?



As a business we track global recall data and we noticed a significant number of product recalls that are totally unnecessary and we believe could be prevented. As a reminder, we class packing food products in the wrong packaging or with errors on the label that trigger a recall as Never Events for the food industry because these mistakes are totally avoidable and should never happen. For a reminder of the principles of Never Events and our definitions, click here.

Unbelievably, in 2020 46% of all food recalls reported by the UK Food Standards Agency could be classed as Never Events as they had labelling or packaging errors, and this rose to 48% in the first 6 months of 2021. In the US, 18% of food recall events reported by the FDA in 2020 could be classed as Never Events and between January and June 2021, it was 16%, still a significant number of recalls. This isn't just a problem restricted to smaller companies with limited budgets either, Never Event recalls occur in companies of all sizes including the largest multinationals.

The key to preventing these Never Events is to identify specific risk areas within food manufacturing where Never Event recalls originate and mitigate those risks. By taking specific actions, it should be possible to eliminate these unnecessary, costly recalls, and most importantly provide improved protection to the consumer.



Never Events – key risks and actions

The key, as with all risk management, is to identify the specific risks and put measures in place to mitigate these risks. Below is an outline of the bespoke approach we use when working with food manufacturers to identify where Never Event recalls may originate and the actions they can take to eliminate these risks. These tactical actions should be read in conjunction with the strategic Never Event Principles described previously here.

First though, a note on allergen cross-contamination. Factories that produce a range of products and handle numerous allergens are always at risk of cross-contamination, and so strict controls must be in place to minimise this risk. Whilst cross-contamination can lead to recall due to the inherent allergen safety risk, we do not include them as Never Events as it is not "…easily detected at the time of manufacture". In fact, we are talking about much more obvious and easier to prevent issues when we classify an incident as a Never Event.

RISK – NPD

Never Event errors can start as early as the NPD (new product development) stage with the packaging / label artwork design, such as not highlighting allergens appropriately. This may be due to a lack of knowledge within the business of the importance of allergen labelling or not being aware of regulations for all territories where the product is to be sold. There are differences in allergen legislation from country to country as to what constitutes a food allergen and how the product is to be labelled, so errors can easily happen if thorough checks aren't made.

ACTION

Good practice in this regard is to ensure there is a robust approvals process built into the NPD activity for new packaging designs and clear information available on specific regulatory requirements for all of the sales regions. Some businesses will want to deliberately restrict the number of allergens they handle within their operation to minimise these risks, and if this is the case, the NPD process must ensure new products keep within these constraints.

RISK – Similar packaging

In some cases, the reason for a recall is a product being put in the wrong packaging. This may be caused by a number of reasons. The business may have many different but similar items of packaging, and through complacency or lack of training, the operator selects what they believe to be the correct one, but do not have the time to properly check it. This may be combined with a lack of an adequate start-up validation process.

ACTION

Implement a start-up validation process to confirm the product, the packaging and other requirements before the production run is permitted to commence.

This validation would also help to ensure that not only have the correct materials been selected for the current production run, but any materials left-over from the previous run have been removed and correctly returned to stock.

You may already have this, but have you checked that it is robust and always followed?

Is there an opportunity for a final check at the end of the line to ensure the product in the packaging matches the description on the packaging?

RISK – Disorganised packaging storage

Some errors come from the poorly organised storage of packaging materials. Packaging storage often doesn't receive the same focus and attention that, for example, raw material storage may get. As such, packaging materials can be poorly labelled or mis-located. The risk here, is greater if the business often has packaging materials from a batch left-over and it is common practice to return unused items back to stock. People, often in a hurry, to get the next production run underway do not take the time and care needed to replace the unused material correctly, and so increase the risk of using the wrong packaging next time around.

ACTION

Such situations can be avoided if there is a clear process and responsibility for this activity, and that packaging stores are kept clean, tidy and organised. Packaging must be clearly identified, and if there are similar products there needs to be a robust method for distinguishing one from another. A second level of control could then come in the form of thorough start-up checks including bar code scanning and visual ID that would provide an additional assurance that packaging materials have been properly selected.

RISK – "Last minute" production changes

A possible reason why controls that normally work perfectly well may fail is when there are "last minute" changes to production schedules. This may be as a result of a sudden demand for a particular product or an error in scheduling either by the business or their customer. Such changes are often implemented in a hurry, and this disrupts the normal flow of the process. Perhaps, materials that had been allocated by the stores for the intended job are not removed and the new materials are then also made available at the packing process, and so an error is just waiting to happen.

ACTION

Food manufacture is a fast-moving process and changes like these are inevitable from time to time. The company must have a suitable process for implementing and controlling changes to the original production plan.

RISK – Product for export

Businesses that manufacture products for export to multiple countries often face issues with languages on packaging. In some cases, if the product they are handling was not originally intended for that country, they have to over-sticker the product. This is another opportunity for an error to occur, particularly if there are several, similar products that require such rework to be performed.

The error could be that the product has simply not been subject to the relabelling operation and exported with incorrect allergen information for that country and even in the wrong language. Mistranslation could also be a risk; for example, we have seen a raw seafood product mistranslated on the label as 'Ready-to-eat" rather than "Ready-to-cook", which had to be recalled as a result

ACTION

This again comes down to poor handling, storage, labelling and validation of the labels. Therefore, robust start-up validation is required as well as label checks prior to dispatch.

Rework including relabelling operations are often outsourced and so if there is a lack of adequate control over the selection of the service provider, then it is possible that poor practices may be in place. Ensure any outsourced relabelling or contract packing facility is fully compliant with your expectations and processes. Basic errors at this late stage in the process could be highly costly. Where translation is involved ensure the translation is carried out by those fluent in the relevant language and labelling specialists knowledgeable in all the regulatory requirements check the final packaging.

Summary

Almost half of UK FSA and around 20% of US FDA food recalls are due to products being put in the wrong packaging or errors on the label (mostly related to allergens). These Never Event product recalls, as the name suggests, are easily avoided if the appropriate controls are put in place. Businesses should do simple checks as described above and then consider more thoroughly the implementation of the strategic Never Event principles as used successfully in the Healthcare sector.

With effective checks and validation, improved systems, commitment from senior management and a general culture of unfettered reporting, these recalls can be fully prevented and the numbers of recalls in a year would be dramatically reduced. This would protect consumers and avoid the unnecessary and very high costs accompanied by negative brand impact that a recall can have on a food business.

RQA are here to help you assess your risks and put measures in place to mitigate those risks and ensure these Events NEVER happen again.

Vince Shiers Ph.D.
Managing Director
RQA Group

If you require assistance with reviewing and implementing new procedures to prevent Never Events, click here or get in touch with us on: contact@rqa-group.com or call +44 (0)118 935 7242.