"Never Events" and Product Recall

Applying the "Never Events" Principle to the Food Manufacturing Sector.

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"For several years, I have been looking into how some serious food safety related product recalls could be prevented. In this paper, I describe how I applied the "Never Events" principle, used in the health care sector, to food manufacturing. The number of food "Never Event" recalls has reached up to 50% in some territories. I therefore propose that there must be more that can be done to reduce these dangerous and yet surely preventable product recalls. Read on to see if you can make small differences in your business, applying the Never Events principle, to significantly reduce the potential for these recalls and thereby improve consumer safety across the industry. Remember, Never Events should never happen "

Vince Shiers Ph.D., Managing Director, RQA Group.

"Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes". NHS England

Allergen related recalls are almost always due to cross-contamination of allergens or using incorrect packaging or errors on the label being applied. In February 2024, there were 9 allergen alerts issued by the UK Food Standards Agency. Of those, at least 6 were due to using incorrect packaging. In the US, in the same period, 15 out of 34 FDA enforcement notices with an allergernic cause were recalled as a result of products that were packed in the completely wrong packaging or had errors on the label. I propose that packing food products in the wrong packaging or with errors on the label should be classed as a "Never Event" because these sorts of errors are totally avoidable and should never happen.

But What is a "Never Event"?

"Never Events" are defined by the National Health Service England (NHS) as a particular type of serious incident that meets all the following criteria:

1. They are wholly preventable
2. Each "Never Event" type has the potential to cause serious patient harm or death
3. The category of "Never Event" has occurred in the past... and a risk of recurrence remains
4. Occurrence of the "Never Event" is easily recognisedand clearly defined

Examples of a "Never Event" in the health sector include, a surgical intervention performed on the wrong patient or wrong site (for example wrong knee, wrong eye). It can be seen that putting the wrong label on a food product resulting in allergen safety risks could meet all the above criteria.

How do "Never Events" help the Health Service?

In the words of the NHS: "*Learning lessons from incidents requires timely incident reporting, which in turn requires a fair, open, and just culture that rejects blame as a tool. In part this is because: "…a patient safety incident cannot simply be linked to the actions of the individual healthcare staff involved. All incidents are also linked to the system in which the individuals were working. Looking at what was wrong in the system helps organisations to learn lessons that can prevent the incident recurring."*

So "Never Events" are not simply the result of an error of an individual but can be linked to failures in the system where the individual works. Improving the system will help a company to learn lessons and prevent reoccurrence. Success of systems in businesses relies on employees following them, all of the time. This is only achieved by senior management developing a culture of identifying, investigating and correcting failures in the system with an open, evidence-based decision making and fair approach that encourages zero tolerance for "Never Events".

What is a "Never Event" in Food Manufacturing?

This is clearly open to discussion and I welcome a debate on this, but a first draft goes like this:

1. They are wholly preventable
2. Each "Never Event" type has the potential to cause serious harm or death to consumers
3. The category of "Never Event" has occurred in the past…and a risk of recurrence remains
4. Occurrence of the "Never Event" is easily detected at the time of manufacture and clearly defined

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Examples of "Never Events" in the food manufacturing sector could include:

- Putting the product in the wrong packaging
- Using a label that includes erroneous information. E.g. The product contains peanut, but this is not stated correctly on he label (not cross contamination – see side box)
- Foreign material, specifically metal pieces (e.g. filings from machinery) in finished product
- Unauthorised release of quarantined products

Cross contamination of allergens in production or the supply chain is a more difficult issue and whilst highly undesirable, it is not easily detected and would probably not be considered wholly preventable. It therefore does not meet the above criteria of a "Never Event".

How Does That Apply to Food Manufacture?

There are already many controls in food manufacture including pre-requisite programmes and HACCP but the frequency of serious and avoidable product recalls is still high and increasing. So perhaps an additional approach is required using principles learnt from the health care industry.

If the wrong label is put on a food product do we believe that blaming the operator responsible will prevent the same issue happening again? Probably not. Using the "Never Events" principle we need to look holistically at the system within which the operator is working and identify gaps in that system that enabled the error to occur. This may involve re-training, but it should also require senior management to look at their responsibilities to see if they have engendered an environment that allows "Never Events". Much of this will already happen, but there is a need for a new focus to ensure the company culture prevents serious incidents rather than allowing them to occur. For example, is there too much pressure on production targets that passively encourages short cuts. Is there an environment where basic training of operators is seen as optional when budgets are stretched? In short, Senior management must see themselves as responsible for the actions of their employees, even if those employees are many levels of seniority below them. So, the occurrence of a "Never Event" in a food factory is therefore much more than an error at operator level; it is a failure of senior management and ultimately the culture they have developed in their company.

"Never Events" and Food Safety Culture

Food Safety Culture is the phrase of the moment with organisations such as the Global Food Safety Initiative and BRC. For "Never Events", food safety culture gets to the heart of the issue. Classifying specific food safety incidents as "Never Events" and senior management providing leadership to identifying and eliminating these events reinforces the Food Safety Culture throughout the organisation.

12 Steps to Implement "Never Events" Principle

1. Look back at previous incidents in your company and your sector. Agree "Never Events" for your company.
2. Include "Never Events" in the senior management meeting agenda.
3. Identify gaps in current systems that allow "Never Events" to occur.
4. Develop a policy that reinforces senior management commitment to creating a culture where "Never Events" are understood and will always be prevented.
5. Allow a culture of unfettered reporting of "Never Events" including whistleblowing.
6. Develop a plan that covers identifying, investigating, responding and managing "Never Events". Include senior management responsibilities and the approach required to investigating and managing an event. This may link into existing policies and plans but should be given extra emphasis.
7. Introduce steps to reduce the possibility of "Never Events" to an absolute minimum.
8. Ensure training is provided specifically addressing causes and prevention of "Never Events". (This is not just aimed at operators). Include in induction training.
9. Include "Never Events" elimination steps in the internal audit programme to ensure ongoing system compliance.
10. Seek external challenge of your "Never Events" to ensure the elimination steps are robust.
11. Introduce governance mechanisms with respect to regular reporting on "Never Events" and "near misses"[1] at senior management meetings. Include reporting at company level as well as site level.
12. Once principle is embedded, review the "Never Events" list annually and consider including other areas of the business, such as health and safety

[1] A "near miss" is a "Never Event" that was detected and stopped just in time before the event occurred

> "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.

Finally...

Ultimately by applying the "Never Events" principle, changes can be made to reduce the occurrence of product recalls caused by careless and unnecessary errors. After all, "Never Events", should never happen…

If you find this article interesting or if you would like to explore applying the "Never Events" principle in your business, click the button below or visit our website to get in touch.

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