

Finding a Route to Successful 'Free-from' Production

White Paper

Author: Barbara Hirst
Food Safety and Quality Consultant



Abstract

The 'free-from' sector represents an opportunity and a challenge for food manufacturers. To achieve a substantiated 'free-from' claim, manufacturers need to apply a risk-based approach to allergen management and consider issues such as staff training and appropriate testing. Help is available and this white paper gives some pointers on getting it right.

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Introduction

The 'free-from' market is growing and manufacturers are under increasing pressure to meet the demand. This commercial pressure brings challenges because, even where there are regulatory limits (as in the case of the 20mg/kg limit that applies to 'gluten-free'), these can be difficult to achieve. The challenge is even greater in the absence of regulatory limits for allergenic ingredients, where 'free-from' must mean exactly that - the products must not contain any trace of the allergen for which the 'free-from' claim is being made. These products, of course, are aimed at the most sensitive consumers. In a non-dedicated production facility, it is hard, though not impossible, to achieve this absolute position.

What is needed is a comprehensive review of all stages of the supply and production processes. There should be a focus on getting it right first time, coupled with the implementation of appropriate, validated controls to make sure the claim can be upheld each time. As some high-profile cases have demonstrated, the consequences of getting it wrong can be extremely damaging, both to the consumer and the brand. The good news is that there are tools available that will help food manufacturers to achieve a 'free-from' product for which the claim can be trusted.

The market for 'free-from'

According to market analysts from Mintel, the UK 'free-from' market is growing fast, following a slowdown in 2019. Research published by Mintel in February 2021 shows that sale of 'free-from' foods rose by 16.9% year on year, expected soon to break through the £1 billion ceiling. Sales in the targeted 'free-from' market grew to £652 million in 2020, with dairy-free and lactose-free sales reaching £455 million. A survey by Nielsen in the four weeks up to 16 May 2020 reported that an estimated 32% of UK households were buying dairy-free 'milk'.

The reasons for growth appear to be varied. It's partly due to consumers believing that a 'free-from' diet is a healthier option - which would clearly be the case of those with specific allergies and food intolerances. However, it is apparent that the general consumer, with no diagnosed medical condition, is also being convinced by the idea that their diet will be improved by eliminating specific ingredients such as gluten, milk and eggs.

In a 2020 survey by Product of the Year, the most popular trends were gluten-free and wheat-free options, with 35% of UK consumers saying they would be most likely to try the products that were free of these ingredients. This was closely followed by dairy-free, with 29% opting for products with this claim.

Mintel's survey in 2021 shows that the dairy-free market has been the primary growth engine in the 'free-from'

sector. This has partly been driven by increasing consumer awareness of the environmental benefits of eating more plants and fewer animal-derived foods. Mintel reported that four in ten adults now use or buy 'free-from' food or drink, with dairy substitutes being the most commonly used 'free-from' products. This shift towards more eco-friendly and dairy-free food has been closely linked with the media's growing attention on global warming and the impact that our diets can have on the environment. This increased focus is encouraging consumers to think more about what they eat and is driving them towards more sustainable eating habits.

Manufacturers of 'free-from' brands may use this to their advantage, changing their marketing to focus on environmental health, as well as personal health. However, 'free-from' brands are often seen as premium and more expensive, potentially causing a decrease in sales as people tighten their wallets as a result of the difficult economic times we are currently facing.

In October 2020, Asda made a pledge to lower the price of their 'free-from' Essential range so that consumers who need to buy these products would not have to pay more for them. This is a trend that is expected to grow.

Meeting the challenge

There is clearly a commercial incentive for the food industry to capitalise on the huge growth in demand for 'free-from' products. At the same time, there is a massive challenge that first needs to be overcome, and





that is that 'free-from' claims are absolute, unless there is a regulatory limit.

There are no regulatory limits for allergenic ingredients in 'free-from' products (except gluten-free). It is not sufficient to know that a recipe does not include the 'free-from' ingredient, especially when 'free-from' products are often manufactured in the same facility as products that do contain that allergen. Nor is it sufficient to have good clean down procedures alone, though these are, of course, necessary.

Rather, the whole supply and production process – from purchasing through to distribution – needs to be carefully considered, with all possible risks identified, controls put in place to mitigate those risks and those controls effectively validated. Some of this validation will be analytical testing, but most will be physical validation.

If a control system is in place to ensure that the right ingredients are picked from a store, both that system and the people operating it must be challenged to ensure that if an ingredient has been stored or labelled incorrectly, or could be picked incorrectly, the mistake is spotted and either the system or the people prevent the misuse. This involves training the right behaviours in staff to check every detail every time, altering supervisors/managers if an error has been made. This will allow manufacturers to be confident that they will get it right first time and every time. Businesses with a mature and robust food safety culture in place will be able to embed these systems of challenging, checking and reporting more easily.

2020 and 2021 recalls for free-from products

In 2020 and 2021, there were a number of FSA alerts that related to products making 'free-from' claims. A few examples are:

- Cake bars that contained a level of gluten above the regulatory limit but were labelled as gluten-free
- A ready meal that was labelled as free-from all 14 allergens, but it contained oats (that were gluten-free) but oats had not been declared as an allergen and emphasised in the ingredients list

- Wheat flour that had mistakenly been mis-labelled as gluten-free
- Ice cream that was labelled as milk-free but contained milk
- Bread that was labelled made without wheat, gluten-free but it contained wheat flour

These examples highlight that food manufacturers still face challenges in ensuring that their policies, standard operating procedures, systems and staff training are robust enough to meet the considerable challenges of 'free-from' food production. Any controls put in place to manage the production of 'free-from' need to be validated, both physically and sometimes analytically, to provide evidence that they are effective at reducing the probability of a risk arising. Unless they are validated in this way, 'free-from' is unlikely to really mean 'free-from' at all.



These recalls highlight some of the areas that can pose the biggest risks to consumers who have food allergies and intolerances. If prepacked foods have the incorrect label, by design, on the packet, a consumer is unlikely to notice this error and, if not corrected, the risk will occur each time the product is packed. If an incorrect label is applied in error, or one of the labels on a packet is incorrect, again the consumer is unlikely to notice. It is possible that a consumer may notice if the product looked very different to the label on the packet and therefore not consume it, but manufacturers should not rely on this. If an incorrect recipe is made because an incorrect ingredient is used, the consumer is very unlikely to notice.

All of these scenarios could deliver a high dose of allergen to a potentially highly sensitive consumer and the higher the dose of allergen protein a consumer receives, the greater the risk of them having a serious reaction. Of course, with products labelled 'free-from', the manufacturer is targeting the most sensitive consumers.



A tragic death in food service

An inquest was held following the tragic death on 22 April 2017 of Owen Carey who died after eating a burger at Byron Burger at The O2 Centre in Greenwich, London. Owen, who suffered from a number of allergies including to milk, was celebrating his 18th birthday. He selected grilled chicken breast and fries believing them to be free from milk. The chicken had, in fact, been marinated in buttermilk. Owen had made the serving staff aware of his allergies and he was also reassured that there was no mention of a marinade or any allergens on the menu. He was not informed of any allergens in the meal he had ordered by the serving staff. The presence of milk in the buttermilk marinated chicken caused him to have a severe anaphylactic reaction from which he died later that day.

This example illustrates the serious consequences of providing an allergic consumer a high dose of the allergen to which they are allergic and the potential for a tragic outcome. Communication is so critical in food service, where full ingredients listings is currently not required by law. Currently the requirement is that all allergen information must be available if requested by a consumer.

The legal perspective

It does matter that 'free-from' means what it says. If the label carries these words, then that is what consumers and legislators expect the product to be.

From a legal perspective, there is specific UK legislation (retained EU legislation) on the use of the term 'gluten-free'. Under the retained EU legislation General Food Law 178/2002, food should not be placed on the market if it is unsafe. The regulation also expects that those with food allergies or intolerances are considered and foods sold as 'free-from' and targeted at those individuals must not contain whatever they are claimed to be free from. Under the retained EU regulation 1169/2011 on the Provision of Food Information to Consumers, 'free-from' claims are covered in the

voluntary particulars section. All 'free-from' claims are voluntary and as such, must not mislead the consumer or be ambiguous or confusing. A 'free-from' claim must be completely free from those ingredients, unless there is a regulatory threshold set as there is for gluten.

There is of course, no obligation for a business to offer 'free-from'. Whether they are a food manufacturer or a food service business, these claims are voluntary and should only be made if the business can be completely confident that they can substantiate them. Consumers cannot demand that a business must supply them with a 100% guarantee of 'free-from' labelled foods.

The British Retail Consortium (BRC) and The Food and Drink Federation (FDF) jointly produced helpful guidance on the legalities of 'free-from' labelling in 2015. The FDF also produced guidance in 2020 on the distinction between allergen-free and vegan claims¹, noting that "A 'free-from' allergen claim is an absolute claim unless a regulatory threshold has been set and should only be used following a rigorous assessment of the ingredients, process and environment."²

In practice this puts several obligations onto the food business that wishes to make a 'free-from' claim.

If the manufacturer or caterer is unable to meet these obligations in full, then the product is unlikely to be free of the specified allergen. In such a situation, the manufacturer must be careful not to present its products in such a way that may mislead the consumer into believing the product does not contain any of the specified allergen and should avoid using the words 'free-from' or pictorials that might give the impression that the product is suitable for allergic individuals. RSSL was a key contributor to this guidance, specifically in the risk assessment section for pre-packed foods.

How does anyone get it right?

There are tools that manufacturers can use to help them in 'free-from' production. The emphasis here is on getting it right in the first place, having procedures and systems in place and good staff awareness. These controls need to have been robustly challenged and validated to ensure the likelihood of mistakes is minimised, or that errors will be picked up before a product leaves the factory.

To produce a 'free-from' product that is legitimate and safe, food manufacturers must begin by conducting a rigorous, stringent and comprehensive risk assessment that covers the entire production system including all incoming materials and every process step.

Any such assessment should cover all elements from raw materials to packing, assessing the probability of unintentional allergen presence occurring through all potential routes.

The first step in the risk assessment process is to map where allergens are present in all the possible materials coming onto the site. The next stage is then to assess whether there is a risk that those allergens may cause an unintentional presence in a product that does not contain them. This could be via a process step, production, environmental means or people.

The next step is to assess the probability that this risk might occur. This judgement should be based on evidence of how effective the controls that are currently in place to manage that risk are. If they are not effective enough, or there is insufficient evidence to show that the risk could not occur, then improvements to the existing controls or the introduction of new controls must be considered. These controls must be validated to provide this objective evidence.

It can be a mistake to focus on just the cross-contamination risks, such as those that could arise from ineffective cleaning or dust transfer through air movement. This could mean that some of the bigger risks to consumers are not assessed fully, or that the controls in place to manage them are not robustly validated.

For example, if a site focusses on the risk of airborne contamination into a product that is predominately made in an enclosed production environment versus the risk of using an incorrect ingredient that is not labelled correctly and could therefore be used in production, they could be spending resources on the lesser risks. An important aspect of this risk assessment and risk management is to consider how much allergen a consumer would be exposed to if the risk did occur. Of course, if a site is making 'free-from' claims, all the risks must be addressed to ensure the products do not contain the allergen that are labelled as 'free-from'.

If a quantitative approach to risk assessment is taken, it can allow a site to prioritise those that present the biggest risks in terms of unintentional exposure to vulnerable consumers. This way, the site's allergen management team can address those bigger risks as a matter of urgency, whilst not ignoring the risks that could lead to a smaller level of unintentional allergen presence.

The BRC/DFD guidance provides good advice for the scope of a risk assessment for pre-packed foods which RSSL were leading contributors for. The guidance is helpful to get manufacturers thinking. It is not designed to cover the detail for every scenario in manufacturing, more to ensure that all the possible areas have been carefully considered. It can be easy to focus either too much or too little on specific areas, so this guidance should help both to make sure no area is overlooked.

BRC/DFD guidance

1. Supplier quality assurance, raw material approval controls and supply agreements

- a.** Can the supplier consistently demonstrate that all raw materials are 'free-from' the specified allergen and is this covered in the terms of supply agreement?
- b.** Has the raw material supplier been initially approved and regularly audited to assess their ability to reliably maintain the 'free-from' status of the supplied raw materials?

2. Facility design

- a.** Is the production facility dedicated to excluding the allergen for which the 'free-from' claim is made?

- b.** If the production facility is not wholly dedicated, is it sufficiently physically or time segregated to eliminate the risk of cross-contamination (change of work clothing, storage, production scheduling, warehousing, material flows etc.)?

3. Production controls

- a.** Are defined control measures in place at the manufacturing facility and have these controls been validated?
- b.** Are these controls periodically verified and continuously monitored?
- c.** If those controls include cleaning and sanitation, have these been demonstrated reliably to remove the allergen(s) of concern to the required extent?

4. Product testing

- a.** Testing for the specified allergen in the product can be an effective way to verify allergen management controls. It is never a substitute for good allergen management. The necessity to test and how to implement a robust programme depends on a number of considerations. These include the way the product is produced, the type of product and the type and form of the allergen being tested for. Have you considered the role and purpose of testing and whether it would effectively verify allergen management controls?
- b.** Where testing is considered appropriate and necessary, have you considered:
 - What will be tested?
 - Where in the production process will the samples be taken?
 - What test method is most appropriate?
 - Based on risk, how frequently should samples be tested?
 - How much a sample should be and whether this is representative?
 - What action will be taken following results?
 - What positive release procedures can assure the 'free-from' status of the product?

5. Distribution and transport practices

- a.** Have distribution and transport practices been assessed in the risk assessment (considering off-site storage or third part hauliers)?

Testing

A brief word on testing is necessary because many manufacturers still rely on testing finished product to verify that it is indeed free of a particular allergen, rather than focussing on the controls and procedures to ensure the validity of the claim. Testing will play a part in 'free-from' production, but if the testing is not carried out by an independently accredited laboratory that has demonstrable expertise in the area and can advise on sampling as well as analysis and interpretation of results, testing could give a false level of assurance. Some manufacturers are using rapid test kits on site for ingredient verification and even finished product testing, for which they are not always reliable. Rapid tests are most suitable for cleaned surfaces and rinse waters and can be a useful tool as long as they have been fully



validated by the rapid kit manufacturer. If the site has not commissioned this validation, the rapid test may either not detect the contaminating allergen at all or may not be as sensitive as expected, leading to a false sense of assurance.

Getting advice from a laboratory with the right level of expertise on what to test, how many samples and from where, is key to using testing as an effective tool in 'free-from' manufacture. Tests that have not been validated can give rise to false negative or false positive

results. Allergen tests are particularly vulnerable to false results because there is potential for interference and cross-reactions in complex food matrices. An unvalidated test is as reliable as no test and could result in a poor decision.

It is therefore important to use test methods that have been validated for the specific allergen in the specific food. It also matters to know when and what to test, and how to obtain a sample. This observation applies as much to testing the finished product as it does to testing as part of a cleaning validation.

Training

Beyond the risk assessment and the resultant feedback into plant design and standard operating procedures, it is really important to have the buy-in of staff to the principles of 'free-from' production. Staff training and a mature food safety culture is key to the implementation of good working practices. Staff can be both the initiator of problems, and the first line in defence to protect against procedures going wrong. It is important that staff understand the implications of producing 'free-from' products that are not what they claim to be. Training should therefore include practical, challenge testing, as well as the theoretical understanding of what the consequences of contamination or incorrect ingredients or packaging might be.

Conclusion

Whilst it is impossible to give general advice that covers the specifics of every manufacturing facility, it is possible to observe that the 'free-from' sector requires the absolute gold-standard when it comes to allergen management. There is no option of a 'may-contain' statement on a 'free-from' product.

Risk assessment, physical validation, testing and training play key roles in helping manufacturers to achieve the standards required and to design procedures that not only work when things go well, but are quick (i.e., before product is released) to spot errors when something goes wrong.

By having a robust system for allergen management, manufacturers can be confident that every product made is packaged and labelled as it should be, and that 'free-from' really means 'free-from' every time the statement is used.

How RSSL can help

RSSL is an acknowledged expert in allergen management and was a key contributor to the BRC/FDF guidance on 'free-from' production. We offer consultancy and training that is highly practical and targeted to the specific production facility. Our practical allergen workshops showcase how a site can undertake a systematic approach to quantitative allergen risk assessment, assess the effectiveness of controls through validation and use the outcome of this to decide whether they can make free-from claims. Our expert laboratories partner with a wide range of food manufacturers to provide an allergen testing service using validated methods, to detect trace levels of allergens in a wide range of complex food matrices.

To find out more about our allergen management services please contact us on: **+44 (0)118 918 4076**, email enquiries@rssl.com, or visit www.rssl.com

References

1. FDF Guidance on 'Allergen'-Free & Vegan Claims:
www.fdf.org.uk/globalassets/resources/publications/fdf-guidance-allergen-free-and-vegan-claims.pdf
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About the author



Barbara Hirst
Food Safety and Quality Consultant

Barbara is a Food Safety and Quality Consultant at RSSL where she has worked for more than 20 years. In this role, she partners with customers and helps advise them on allergen management, both in risk assessment and validation of controls. This covers customers from a wide range of food manufacturing and food service backgrounds.

She is a Geneticist by education and she was previously heavily involved with the horse meat industry issue and the alleged contamination of spices with nuts. Using her scientific and technical knowledge, Barbara has helped advise regulators and industry on the best practice approaches to sampling, testing and control measures. Barbara was recognised in 2013 by SOFHT for her services to industry during the horse meat crisis by winning the 'Best Technologist of the Year' award.

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Reading Scientific Services Ltd
The Reading Science Centre,
Whiteknights Campus,
Pepper Lane,
Reading,
Berkshire RG6 6LA

Tel: **+44 (0)118 918 4076**
Email: **enquiries@rssl.com**
Web: **www.rssl.com**

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