

Legal Aspects of Product Development

To Support the
Development of Healthy
Food & Drink Products

 **Interreg**
Atlantic Area
European Regional Development Fund



Note on the Scope of this Training

As you will see during this training module, there are numerous legal considerations that you will need to bear in mind as you develop or reformulate your healthy food and drink products.

Given this diversity, it is not possible for us to provide you with an exhaustive list of legislation in this short training session. Please do not rely upon it as your only source of legal reference.

We do hope however, that it will serve to raise your awareness of this important aspect of Product Development and prompt you to either investigate legal considerations more fully yourself, or to seek professional legal advice to ensure your compliance.

Please be aware also, that legislation is often subject to amendments and updates, or may be superseded by new regulations. This training refers to legislation in place in January 2021.

So please remember, it is always important to check that you are using the most up to date legislation as your reference.

For a more in-depth overview of labelling regulations, please see our [Legal Labelling](#) training module.

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1. Introduction to Legal Responsibilities in Product Development

- Legal obligations of product development
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- Why a defence of Due Diligence is important

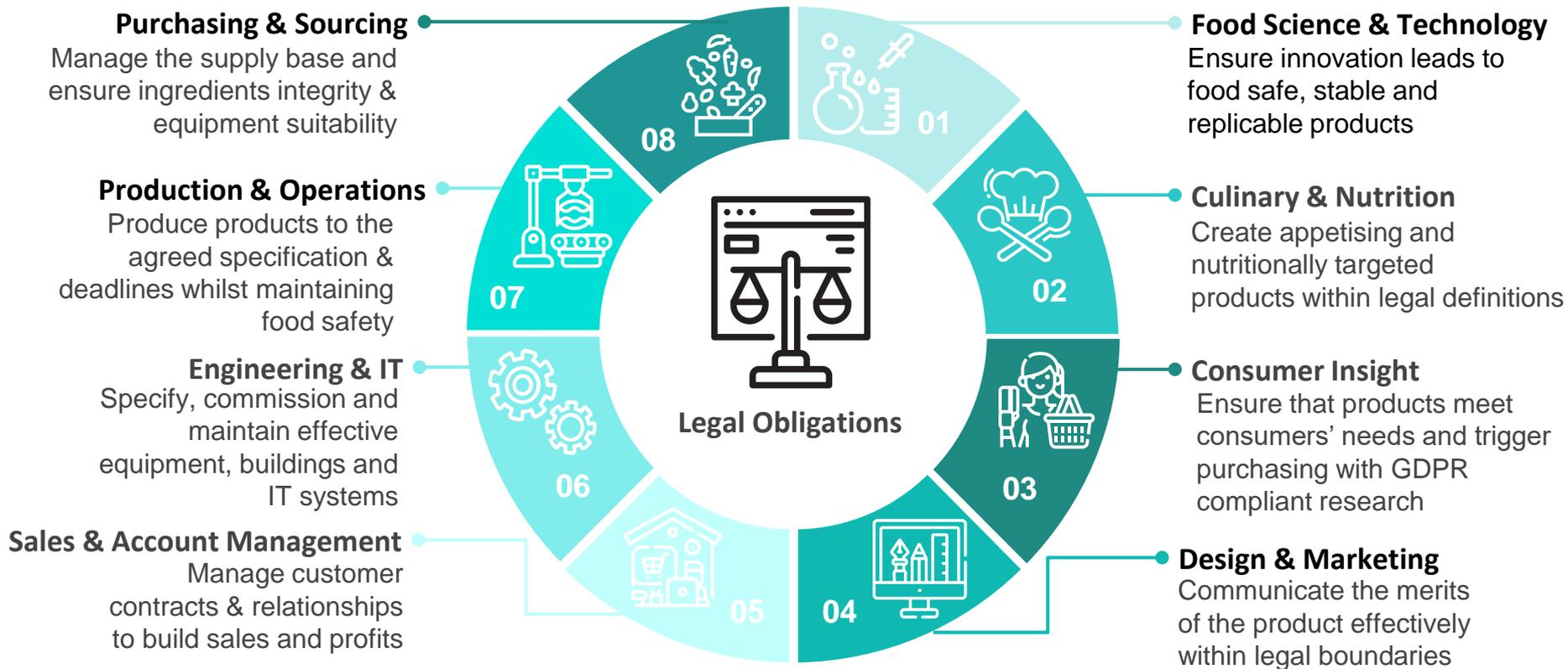
2. Areas of Product Development to be Considered

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- Recipes
- Allergens
- Labelling & Packaging
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- Social & Environmental Responsibilities

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There are many legal obligations underpinning all aspects of product development



Duty of Care

- A fundamental principle surrounding the manufacture and sale of food stuffs is that all manufacturers have “**a duty of care**” to everyone who consumes their products.
- **Laws** exist which stipulate your obligations as a manufacturer to achieve this duty of care.
- **Administrative agencies** are assigned to enforce these laws and they set **regulations** which **provide** standards and define the rules under which the laws will be enforced.
- These **enforcement bodies** are responsible for ensuring that every business complies with the law and they can exercise the power to **prosecute** any which fail to do so.
- **Laws and regulations** which apply to food manufacture relate to many aspects of bringing food to market, and you will need to think about them as you develop or reformulate your products.
- These include the rules around **ingredients, composition & quality** of foods, the **hygiene conditions** under which products are produced, stored & sold and the manner in which food is **labelled, advertised & presented**. Also legal contracts, **health & safety & environmental obligations**.

Your Fundamental Obligations



PROTECTING HEALTH

01

You must not **include** anything in food, **remove** anything from food or **treat** food in any way which means it would be **damaging to the health** of people eating it. **Food must not be “injurious to health”**.



ENSURING QUALITY

02

You must ensure that the food you serve or sell is of **the nature, substance or quality which consumers would expect**. All food **“placed on the market”** must be **“fit for human consumption”**



PREVENTING FRAUD

03

You must ensure that your food products **are labelled, advertised and presented** in a way which is **not false or misleading**.

Document Your Development

It is important to be able to demonstrate that you have a robust product development process which proves your products are **safe to consume**.

Also that it has been conducted in a **methodical, well documented** way, that fully takes into account your **legal obligations** to produce **safe, wholesome and correctly communicated** products.

If you pursue your development project using this approach you will be able to **gather evidence** that you have taken all possible care and **shown “due diligence”** in creating your new product, which you could offer as **a defence** if you are accused of a breach of food related laws.



Why A Due Diligence Defence is Important



- “Due Diligence” refers to being able to **prove** that your business has done everything **reasonably possible** to comply with current legislation and regulations, and that you **applied all reasonable precautions** to avoid committing an offence.
- For example in terms of food safety, your business must prove that it has done everything reasonably possible to **anticipate** risks and **prevent** food safety breaches from occurring.
- A due diligence defence is the best way to prevent legal repercussions if an incident takes place that involves your business and is designed to protect the right of traders so that they will not be convicted of an offence if they took all **reasonable care** to prevent an incident.

We'll take a more detailed look at when you need to think about specific legal implications during product development



SUPPLIERS

INGREDIENTS



RECIPES

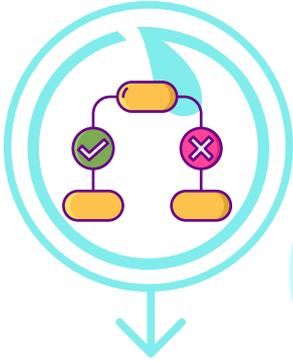
ALLERGENS



LABELLING

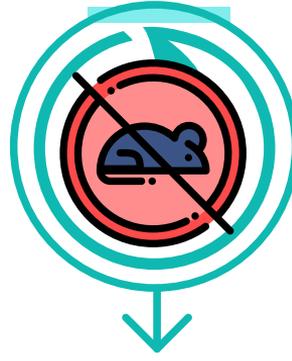


Embed new products within your food safety systems



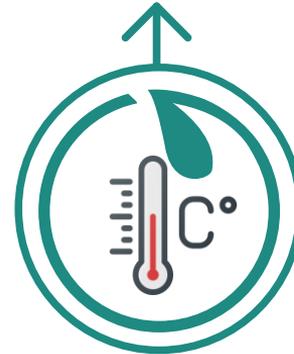
HACCP
ASSESSMENT

PREVENTING
CROSS
CONTAMINATION



CLEANING
& PEST
CONTROL

TEMPERATURE
CONTROLS



STAFF
TRAINING

What do I need to think about ... Suppliers



Create a pool of reputable suppliers and try select what you need from them. Record all information provided by them.



Auditing your supply base to ensure that they can supply safe, consistent products takes time, money and effort, so focus is beneficial



Legally you must be able to trace at least your direct supplier and direct customer for every ingredient.



Many supply chains are complex and international but your supplier, and in turn their suppliers, must be able to trace all the way back along the supply chain.



Terms and conditions are an important component of your contracts with suppliers - so ensure you understand your rights and responsibilities



For example - can you return goods which are not to specification and in what timescale – only on receipt or after storage in your business ?



Consider what ongoing support you may need from suppliers – such as updates on ingredients or allergens, food safety advice or engineers for safe maintenance of equipment



Choose suppliers who can give you the level of support you need to fulfil your legal obligations as part of the supply agreements or at affordable fees. Ensure your contracts have a clause requiring notification of ingredient changes or product substitutes for all items.



Some suppliers such as designers and photographers will generate Intellectual Property so ensure contacts are clear who owns the rights to this IP



Check our **Intellectual Property** training module for more information



What do I need to think about ... Ingredients



You must ensure that your products are of a consistent quality and as declared on your packaging

You need your ingredients to be supplied with attributes of a consistent, agreed specification to achieve this



Ensure you have agreed detailed, documented specifications for ingredients. These should be signed and up to date as, along with associated documents, they will form the basis of the contract for supply for all your ingredients.

These should include precise commitments on all product attributes such as composition, appearance, size & shape, texture, odour, nutritional profile etc - as well as guaranteeing origins, being free from contamination such as chemical residues or foreign bodies.



Allergen control is key in the safe supply and handling of ingredients, so specifications must capture critical information needed for food safety and allow you to provide accurate and up to date allergen advisory labelling.

The presence of any allergens whether in the ingredient itself or the potential for cross contamination to have occurred in the supply chain must be explicitly stated so you can reflect these in your allergen declarations.



If any ingredients are being relied upon for your business to guarantee a legal on pack claim, you must prove that you have shown due diligence in achieving this claim, including ingredients.

You should explicitly explain and formally document the requirement with the supplier & ensure that certificates of conformance accompany deliveries and are scrutinised as part of your ingredients intakes inspections. Review regularly as changes occur in your products, production processes, premises & staff.



What do I need to think about ... Recipes



When constructing your recipe you must not include or exclude anything or treat the food in any way that would be damaging to the health of consumers or make it unfit for human consumption



This is a wide subject from ranging from physical properties like sharp edges, choking hazards in children's foods or excessive acidity to the correct use of preservatives to prevent pathogens or products going stale or decomposing



Certain product categories have legal standards for their composition in relation to how you must label them. So your recipes must be carefully constructed to meet the standards for the product names you plan to use.



These categories are very diverse and include meat products such as burgers, bread, jams & marmalades, milk and chocolate products as well as others – so be sure to check with your national authorities if your products are included in these laws.



New & innovative ingredients of animal and plant origin and novel manufacturing processes must have “Novel Foods” authorisation before use, designed to protect consumers from any adverse consequences of consuming uncommon substances.



Check if any “new to market” ingredients or those only commonly eaten outside of the EU that you want to use are on the [Novel Foods Catalogue](#) or may require to be formally authorised before you can use them



Your recipes are a key business asset, so think about how you might protect them via confidentiality or non-disclosure agreements, copyrights or trade secrets precautions.



Check our **Intellectual Property** training module for more information as to how your valuable recipe intellectual assets could be protected



What do I need to think about ... Allergens



Living with a food allergy is incurable and constantly stressful for sufferers, including fear of consuming an allergen accidentally and limitations on what they can eat

How could you help ? As you develop your products challenge every allergen that might be in your recipe – could you remove it without negatively affecting your product ?



Allergens must be rigorously controlled at every step of the procurement, handling, processing, packing, storage, distribution and placing on the market to ensure that their presence is documented and potential for cross contamination avoided

Ensure that any components containing allergens are strictly segregated and managed in a controlled way – this applies not only in the factory environment but when you are preparing samples or testing products during the development process



For anyone suffering from food allergies incorrectly labelled food can at best cause illness and discomfort and at worse can be truly life-threatening. Always highlight changes to allergens in any existing products.

Precise and informative labelling of allergens is crucial to protect allergy sufferers and must meet the relevant legislation – see the **Legal Labelling** training module for details.



There are 14 legally declarable allergens – see the next slides for details but individual people may also have allergic reactions to other foods.

Precisely documenting all the components in your recipes allows you to provide vulnerable consumers with the information they need to stay safe and well.



14 Declarable Allergens



Celery

This includes celery stalks, leaves, seeds and the root called celeriac.

You can often find celery in celery salt, salads, some meat products, soups and stock cubes



Cereals containing gluten

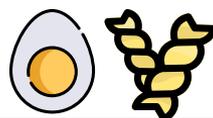
Wheat (such as spelt, Khorasan wheat, Kamut), rye, barley and oats. Often found in foods which contain flour, such as breadcrumbs, bread, cakes, batter, couscous, meat products, pasta, pastry, some baking powders, sauces, soups and fried foods which are dusted with flour.



Crustaceans

Crabs, lobster, prawns and scampi are crustaceans.

Shrimp paste, often used in Thai and south-east Asian curries or salads, is an ingredient to look out for.



Eggs

Eggs are often found in cakes, some meat products, mayonnaise, mousses, pasta, quiche, sauces and pastries or foods brushed or glazed with egg.



Fish

You will find this in some fish sauces, pizzas, relishes, salad dressings, stock cubes and Worcestershire sauce.



Lupin

Although lupin is a flower, it is also used to make flour.

Lupin flour and seeds can be used in some types of bread, pastries and even in pasta.

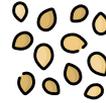


Milk

Milk is a common ingredient in butter, cheese, cream, milk powders and yoghurt.

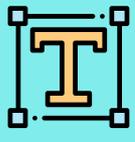
It can also be found in foods brushed or glazed with milk, and in powdered soups and sauces.

14 Declarable Allergens



<p>Molluscs These include mussels, land snails, squid and whelks, but can also often be found in oyster sauce or as an ingredient in fish stews</p>	<p>Mustard Liquid mustard, mustard powder and mustard seeds fall into this category.</p> <p>This ingredient can also be found in breads, curries, marinades, meat products, salad dressings, sauces and soups.</p>	<p>Nuts Nuts which grow on trees, like cashew nuts, almonds and hazelnuts.</p> <p>You can find nuts in breads, biscuits, crackers, desserts, nut powders (often used in Asian curries), stir-fried dishes, ice cream, marzipan (almond paste), nut oils and sauces</p>	<p>Peanuts Peanuts are actually a legume which grow below ground, which is why it's sometimes called a groundnut. Peanuts are often used as an ingredient in biscuits, cakes, curries, desserts, sauces (such as satay sauce), as well as in groundnut oil and peanut flour</p>	<p>Sesame seeds These seeds can often be found in bread (on hamburger buns for example), breadsticks, houmous, sesame oil and tahini.</p> <p>They are sometimes toasted and used in salads.</p>	<p>Soya Often found in bean curd, edamame beans, miso paste, textured soya protein, soya flour or tofu. Soya is a staple ingredient in oriental food. It can also be found in sauces, desserts, ice cream, meat products, and vegetarian products.</p>	<p>Sulphur dioxide (Sulphites) Often used in dried fruit such as raisins, dried apricots & prunes. Also used in meat products, soft drinks, vegetables as well as in wine and beer. If you have asthma, you have a higher risk of developing a reaction to sulphur dioxide.</p>
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What do I need to think about ... Labelling & Packaging

	<p>There are specific legal requirements that all business must comply with regarding the information that must be stated on all food packaging in terms of location, formats and font sizes</p>		<p>Our Legal Labelling training module will give you detailed information about what you need to consider when labelling your products</p>	
	<p>No information or images that appear on your food packaging or advertising and marketing must be misleading to the consumer. So you must choose your wording and images carefully & check these against the end product.</p>		<p>Ensure you do not mention or even imply something that is not true – e.g. you use diced ingredients but show them as chunky or suggest that a product is authentically Italian when it is not made in Italy</p>	
	<p>Your declared weight or volume on pack must be accurate and there are a number of regulations which advise how you should weigh & label your products.</p>		<p>Your development trials must demonstrate that whether you choose to pack to either minimum or to average weights that products will be within the acceptable tolerances permitted</p>	
	<p>Your packaging materials must be clean, undamaged, approved for food contact, stored and handled in a way that prevents any risk of contaminating the product</p>		<p>Ensure you test that foods do not interact causing packaging materials to deteriorate over shelf life. Also that packaging storage and use during production is carefully controlled</p>	
	<p>The size of your packaging must be proportionate to the contents and not mislead the consumer</p>		<p>So you cannot put a small amount of product in a large packet with lots of empty space, because the large pack would be misleading as to the amount of product actually inside</p>	

What do I need to think about ... Health & Nutrition Claims

As we have seen, protecting consumers from being misled about what they are buying is a core principle of regulations governing labelling, advertising and marketing of products.

With this aim, there are specific regulations which set out what you are allowed, and forbidden, to claim about your products in relation to their nutritional profiles and health benefits.

Health Claims



A health claim is defined as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. Health claims are different from nutrition claims as they refer to, or imply, a function in the body.

Any claims are required to have been authorised by the EFSA (European Food Standard Agency) and will be subject to rigorous scrutiny of the scientific evidence that the claim is proven to be true.

Very few such claims submitted for approval are successful and consequently permitted to be added to the official EU Register.

Nutrition Claims



Nutrition claims are defined as any claim, which states, suggests or implies that a food has particular beneficial nutritional properties due to the presence, absence, increased or reduced levels of energy or of a particular nutrient or other substance.

Nutrition claims provide factual information about the nutritional composition of the food. Some examples of nutrition claims are “reduced energy”, “contains calcium”, “low fat”, “high fibre” and “contains lycopene”.

As the basis upon which each nutrient is permitted to make a claim varies, you should take care to apply the correct assessment criteria for the nutrient you are highlighting in your claim.

For [the list of approved claims in the EU click here](#).

UK businesses can find relevant information [here](#).

Any claims you make must be proven using representative samples and by appropriate testing methods during your development process. For more information see our **Legal Labelling** training module.

What do I need to think about ... Changes in Labelling Laws

You should always check that you are basing your packaging design and information on the most up to date requirements for the market in which you will be selling your products.

Food labelling regulations are subject to frequent reviews by the authorities in different countries. These reviews may lead to changes in the way that products must be labelled.

Changes may affect the information required or the on pack position or the format in which this information must be presented.

For example, UK regulations may diverge from EU equivalents once the UK exits the European Union.

Also in 2020 the UK government held a consultation on the most advantageous way to present nutritional information on front of packaging, which may change requirements in the future.

In France, the French authorities have implemented the Nutri-Score labelling scheme and in the USA a new format for the Nutrition Facts labels is now required.

So it pays to ensure you are using up to date information in your plans.

NUTRIENT-SPECIFIC LABELS		SUMMARY LABELS	
NUMERIC Guideline Daily Amounts Une portion contient : 		SIMPLE Green Tick Keyhole Choices 	
COLOUR-CODED (Traffic lights) 		GRADED 5-colour nutrition label/NutriScore Logo Nutri-Score/Santé Publique France 2017	
Warning symbols Chilean system 		NuVal SENS Health Star Rating 	

Note: the circled images were used in the comparative study on perception, understanding and use of front-of-pack systems.

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	Calories 230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

What do I need to think about ... Health & Safety

Equipment

Equipment must meet all safety regulations, for example guarding and safe power supply, audible warnings.

Appropriate certification must be in place.

It must be food grade and not present foreign body risks.

It must be able to be cleaned rigorously to prevent cross contamination and build up of pathogens

All equipment should be trialled during development to ensure there are no health & safety issues arising during production

These trials should be documented and if issues are identified, demonstrate how they will be prevented, mitigated or overcome



This is a wide area of responsibilities, so, in order to ensure that you are legally compliant, consider taking professional advice from a Health & Safety specialist if you are implementing significant new or innovative equipment or major changes to work procedures.

Production & Associated Tasks

Production methods and all ancillary handling must not pose a risk to the health & safety of any staff or other persons

This covers a wide range of risk but might include such things as the risk of repetitive strain injuries, the danger from knives or blades, risk of inhalation which might lead to lung illnesses, slashing of substances which could cause damaged to skin, decibel levels of noise being above legal standards.

As with equipment, trial and document how health & safety will be ensured to prove your due diligence.

What do I need to think about ... Social & Environmental Responsibility

Responsible Sourcing

All resources such as ingredients, equipment & packaging need to be sourced from legally compliant sources.



Producer Responsibility

You should investigate and comply with any producer responsibility regulations that apply to your products, packaging and operations.



Good Neighbours

Actions by your business should not adversely affect your neighbours – excessive noise or traffic pollution for example.



Natural Environment

Products, production processes, packaging and by-products must be managed to meet all environmental regulations.

Waste Management

Any waste materials arising from your operations must be disposed of in line with regulations which are in place to prevent pollution of the air, land and waterways.

Wellbeing

As well as physical health of staff, contractors and visitors to your site, their mental health & wellbeing must be supported and workplace stress & violence must be prevented.



Public Enforcement Authorities in the UK Food & Drink Sector

Indicating their typical responsibilities

Environmental Health Officers

protect the public, they make sure homes and work places are safe, hygienic and healthy, inspecting businesses for health and safety, food hygiene and food standards. They investigate complaints and outbreaks of food poisoning as well as infectious disease and pests, they enforce a range of laws that also cover areas such as pollution , land contamination and domestic water supplies.

Trading Standards Officers

protect the public against unsafe goods, unfair trading and illegal sales practices such as scams. They inspect businesses and investigate complaints and check whether products are safe and labelled correctly. Trading Standards departments enforce a range of laws that include weights & measures, fair trading, product safety, age restricted products, food and animal feed standards and animal health.

Public Health

Seek to **prevent illness** & the **spread of infectious communicable diseases**. Actively **promote healthier lifestyles** aiming to ensure everyone in the population enjoys the best possible health.

Food Standards Agency

Set regulations for food safety and **food hygiene** in Wales, Northern Ireland & England. Work with local authorities to enforce **food safety regulations**. Place staff in meat plants to check the **standards are being met**.

Some Links to Further Information for UK Businesses

[General Food Law](#)

[Food Safety Act](#)

[Food Hygiene Regulations](#)

[Food Information Regulations](#)

[Weights & Measures of Packaged Goods](#)

[Health & Safety At Work](#)

[Consumer Rights](#)

[Producer Responsibility](#)

[Waste Disposal](#)

Welsh business can also access more support and information via [Food Innovation Wales](#)



We hope that you have found this training module a useful and helpful support to your healthy food and drink innovation.

This training module is one of a number of training opportunities, organised into themed training programmes to support SME's (small & medium sized enterprises) in the participating regions of Wales, Northern Ireland, Ireland, Spain, Portugal and France to successfully bring new and reformulated healthy food and drink products to market.

The training was created by the partners within the AHFES project which is a quadruple helix Atlantic area healthy food eco-system for the growth of SME's funded by the European Union under the Interreg Atlantic Area Funding Programme.

This programme promotes transnational cooperation among 36 Atlantic regions of 5 European countries and co-finances cooperation projects in the fields of Innovation & Competitiveness, Resource Efficiency, Territorial Risks Management, Biodiversity and Natural & Cultural Assets.

For more information about other training available [please click here](#).



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