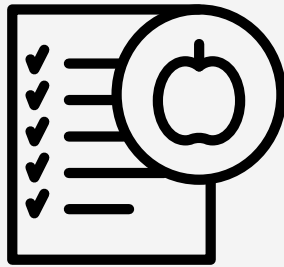


# ainia

## Tortillas:



### European Union Regulatory Framework





# Tortillas:

## European Union Regulatory Framework





The **European tortilla market** is growing fast, gaining importance yearly. In that scenario, TIA held the “**2024 TIA Europe Conference**” in Valencia, with a wide variety of interesting presentations and information.

**The European Union Regulatory Framework** review allows companies to have information about **the most important regulations applicable to tortillas**, with special reference to the **additives allowed in its formulation**, and an **analysis on the most relevant labelling claims.**

# WHO WE ARE

We offer solutions and develop R+D+i projects aligned with the United Nations **SDG 2030**.

Our activity is **international**: with our broad network of collaborators, we develop high- impact technological **transformation projects**.

We contribute to a **healthier, more sustainable and safer society**, promoting a positive change in the future of people.



With more than **35 years of experience**, we are one of the European technology centers with a greater social base: **more than 790 associated companies and 1,700 clients**

# AINIA IN FIGURES

**21 M€** → Income

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**+1,700** → Clients annually

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**+790** → Associated companies

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**+280** → R&D projects





**+110,000** → Analytical tests

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**+2,000** → Training hours

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**265** → Employees

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**+350** → Technological support  
and assistance

# OUR TEAM



**256**

**25**

**65%** women  
**35%** men

professionals  
**(56% women in management)**

disciplines



Who we are



**66%**



graduates  
and PhDs



**34%**



specialised  
technicians



# SPECIALISED LEGAL ADVICE ON R+D+i

**Lawyers with a deep knowledge  
and experience in the Food  
industry.**

**We assist companies from the very  
beginning, supporting them in legal  
matters related to the development,  
production and marketing of their  
products.**

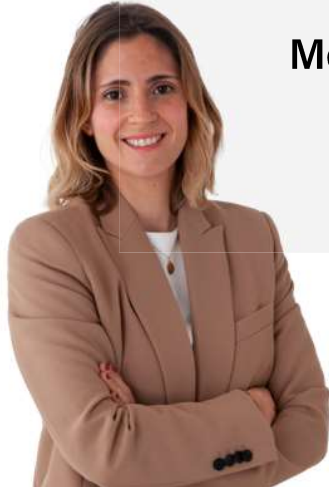


Our clients include leading and international companies in the Food industry.

We work in collaboration with a large multidisciplinary group of specialists.

# SPECIALISED LEGAL ADVICE ON R+D+i

## Meet our legal team



### Fátima Aragonés

Law degree from the Universidad de Castilla-La Mancha and Executive Master in Business Law from the Centro de Estudios Garrigues in collaboration with Harvard Law School. Specialist in Administrative Law, with extensive experience in legal advice to the public and private sectors in matters related to this branch of Law, as well as in legal direction in all types of administrative and contentious-administrative procedures. Specialist in regulatory compliance applied to the food sector as well as in required titles for the exercise of activity in said sector. Registered member N°. 83,061 of the ICAM.



### Laura Herráez

Law degree from the Universitat de Valencia. Specialist in Commercial Law, with extensive and consolidated experience in legal advice to large companies in various sectors. Specialist in regulatory compliance applied to the food sector as well as in food contracts and legal issues related to the food chain, with experience in legal advice to companies in the food industry. Registered member N°. 96,498 of the ICAM.





### **Alfredo Sánchez**

Law degree from the Universidad Cardenal Herrera – CEU and a Master’s in Commercial Law from the Universitat de València. Completed practical legal training at ICAV with a Certificate of Professional Competence from the Consejo General de la Abogacía Española. Specialist in Commercial Law and regulatory compliance applied to the food sector, with experience in providing legal advice to companies in the food industry, covering regulations governing food contact materials. Registered member N° 15.347 of ICAV.

### **Laura López**

Graduated in Law by the Universitat de València and graduated in Criminology by the Universitat Oberta de Catalunya. Master in Criminal Justice System from the Universitat de Lleida. Specialist in Criminal Law and regulatory compliance applied to the Food sector, with broad experience in legal advice to Food companies. Collegiate n° 17,946 ICAV

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Legal  
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regulation



03



# Labelling regulation



# LEGAL FRAMEWORK OVERVIEW

## 01



The European Union **has developed a complex legal framework** applicable to food production and marketing. **Food safety is the idea around which the system is organized.**

In that sense, Regulation (EC) no 178/2002 establishes that "*Food shall not be placed on the market if it is unsafe*" (art. 14.1)



### According to the regulation,

Food shall be deemed to be unsafe if it is considered to be:

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(a) injurious to health;

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(b) unfit for human consumption.

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**We can visualize the legal framework with food safety as a core around which different areas are developed.**

In particular: hygiene, safety, composition, packaging, labelling, new developments aspects (that is, GMO and novel food). Additionally, we shall take into consideration national regulations.

In this figure we've included the most relevant regulations for each area.



**1** General Food Law

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**2** Hygiene

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**3** Safety

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**4** Composition

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**5** Packaging

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**6** Labelling

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**7** GMO

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**8** Novel food

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## 1 General Food Law

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- General Food Law: Regulation (EC) No **178/2002** laying down **the general principles and requirements of food law**



## 2 Hygiene

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- Regulation (EC) No **852/2004** on the **hygiene of foodstuffs**
- Regulation (EC) No **853/2004** laying down **specific hygiene rules** for food of animal origin



## 3 Safety

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- Regulation (EC) No **396/2005** on **maximum residue levels** of pesticides in or on food and feed of plant and animal origin
- Commission Regulation (EC) No **2073/2005** on **microbiological criteria for foodstuffs**
- Commission Regulation (EU) **2017/2158** of 20 November 2017 establishing mitigation measures and benchmark levels for the **reduction of the presence of acrylamide in Food**



## 4 Composition

- Regulation (EC) No **1333/2008** on **food additives**
- Commission Regulation (EU) No **231/2012** laying down specifications for food additives
- Regulation (EC) No **1334/2008** on **flavourings** and certain food ingredients with **flavouring properties**
- Regulation (EC) No **1332/2008** on **food enzymes**
- Regulation (EC) No **1925/2006** on the **addition of vitamins and minerals** and of certain other substances to foods



## 5 Packagwing

- Regulation (EC) No **1935/2004** on **materials and articles intended to come into contact with food**
- Commission Regulation (EC) No **2023/2006** on **good manufacturing practice** for materials and articles intended to come into contact with food



## 6 Labelling

- Regulation (EU) No **1169/2011** on **food information** to consumers
- Regulation (EC) No **1924/2006** on **nutrition and health claims** made on foods
- Commission Regulation (EU) No **432/2012** establishing a list of **permitted health claims** made on foods
- Commission Implementing Regulation (EU) No **828/2014** on the requirements for the provision of information to consumers on the **absence or reduced presence of gluten in foods**
- Regulation (EU) **2018/848** on **organic production and labelling** of organic products
- Commission Delegated Regulation (EU) No **664/2014** with regard to the establishment of the Union symbols for **protected designations of origin, protected geographical indications and traditional specialities guaranteed**





## 7 GMO

- Regulation (EC) No **1829/2003** on **genetically modified food** and feed



## 8 Novel food:

- Regulation (EU) **2015/2283** on **novel foods**
- Commission Implementing Regulation (EU) **2017/2470** establishing the Union **list of novel foods**

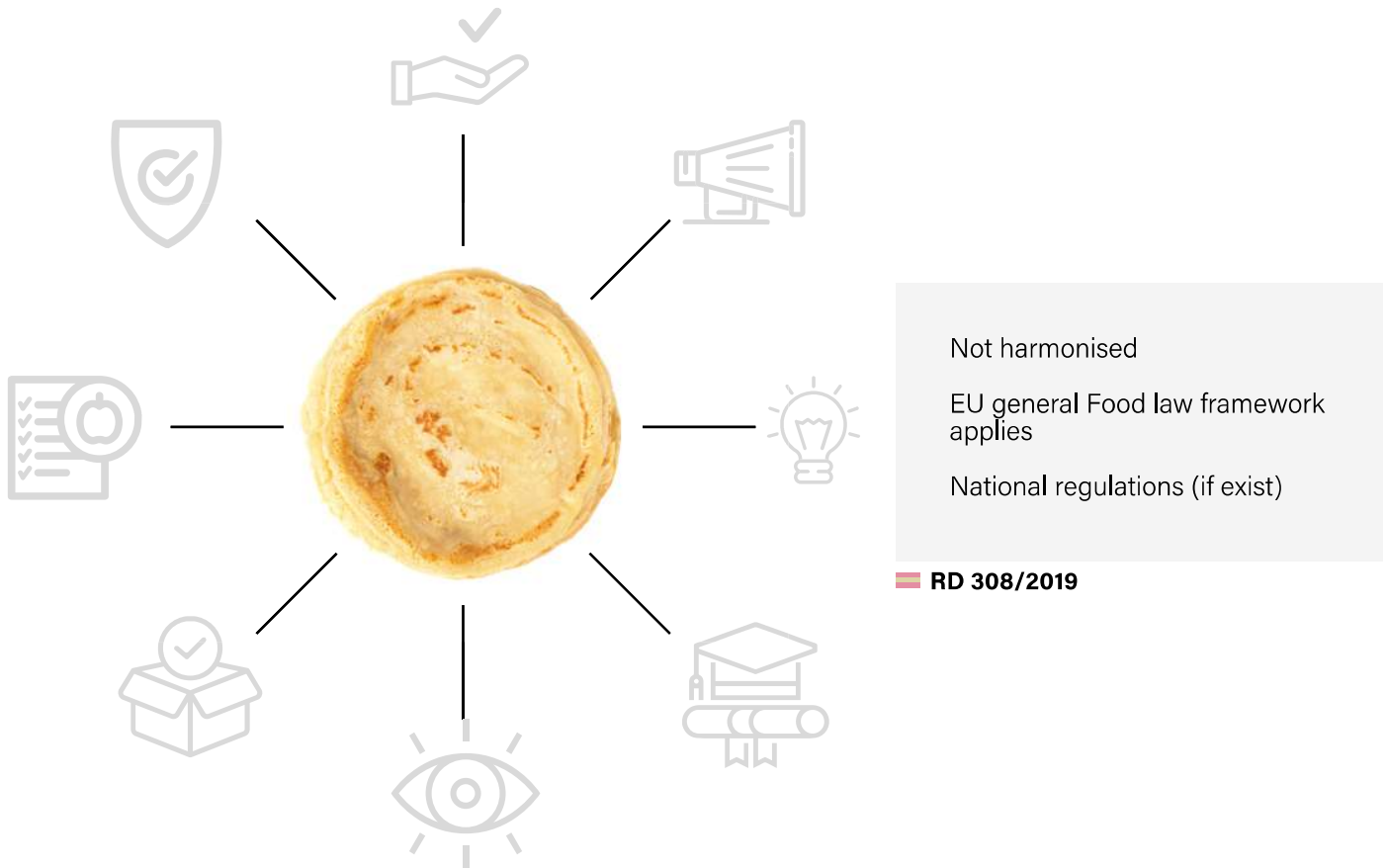




## How are TORTILLAS regulated in EU?

There is **not a legal disposition that regulates** tortillas in the EU framework. Its regulation has not been harmonised. That means that we cannot find a law **that regulates just tortillas, or tortillas and related products.**

In that scenario, all the legal landscape that we've just painted it's applicable.



The last piece of the legal puzzle it's the national regulations. In that sense, it should be **stated that the member States can develop national regulations that can establish additional requirements to tortillas**, such as composition or labelling.

As an example, in Spain a type of tortillas is regulated in the bread regulation (Royal Decree 308/2019).

# FOOD ADDITIVES REGULATION

## 02

What additives can  
be used in tortillas  
production?



The **use of food additives** is ruled by the **Regulation 1333/2008** on food additives. Additionally, the specifications for food additives, that is, the characteristics of the additives, are stated in the **Regulation 231/2012**.



Regulation 1333/2008 is **organized around food categories**, regarding which the food additives are allowed, and their maximum levels of use or restrictions, are established.

Food categories are established in the **Annex II, Part E of the Regulation 1333/2008**. The legal text lists the categories but does not include an explanation of the foodstuffs included in or excluded.



[Regulation 1333/2008 on food additives](#)



[Regulation 231/2012 specifications for food additives](#)



[Guidance document](#)





if you want  
the full document,  
please **click here**



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