

# PAPER BIO PACK

WHAT'S THE FUTURE  
OF PACKAGING IN  
CENTRAL EUROPE?

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 **Legislation**

## Contents:

1. Legislation concerning Food Contact
2. Legislation concerning Packaging and Waste



Part 1

# Legislation concerning Food Contact



In Europe Food safety is regulated by several legislations:

- ❑ **General Food Law 178/2002**
- ❑ **Food Contact Framework Regulation 1035/2004**
- ❑ **Good Manufacturing Practice regulation 2023/2006**
- ❑ **Material specific regulations**
- ❑ **Substances specific regulations**



# FOOD CONTACT PACKAGING COMPLIANCE

GENERAL FOOD LAW LEGISLATION (EC) N° 178-2002

FRAMEWORK REGULATION  
(EC) N° 1935-2004

GMP REGULATION  
(EC) N° 2023-2006

MATERIAL SPECIFIC REGULATION

SUBSTANCE SPECIFIC REGULATION

REGENERATED  
CELLULOSE  
FILM  
EC N° 42-2007

CERAMICS  
84/500/CEE

ACTIVE/INTELLIGENT  
MATERIALS  
EC N° 450-2009

BADGE/NOGE  
EC N° 1895-2005

NITROSAMINES  
93/11/EEC

PLASTIC  
EU N° 10-2011

RECYCLED  
PLASTICS  
EC N° 282-2008

BISPHENOL A  
EU 321-2011  
EU N° 213-2018

EUROPEAN  
COMMISSION

PAPER AND  
PAPERBOARD

METAL AND  
ALLOYS

GLASS

VARNISHES  
AND COATINGS

RUBBER

.....

MEMBER STATES



Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 has established:

- General principles
- European Food Safety Authority (EFSA)
- Procedures in matters of food safety



## GENERAL REQUIREMENTS FOR ALL FOOD CONTACT MATERIALS (FCMs)

- **FCMs shall not release their constituents into food** at levels harmful to human health or change food composition, taste and odor in an unacceptable way;
- **Specific measures for certain groups of materials and articles** (i.e, plastics). When a specific measure is adopted, business operators must provide written **declaration of compliance (DOC)**;
- **Business operators must establish a traceability system** for FCMs from production to distribution;
- **Labelling:** Materials and articles, when they are placed on the market, shall be labelled with the words ‘for food contact’, or a specific indication as to their use or the symbol below:



## GOOD MANUFACTURING PRACTICES (GMP)

### PRODUCERS SHALL:

- Ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:
- premises fit for purpose and staff awareness of critical production stages
- documented quality assurance and quality control systems maintained at the premises, and
- selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles
- **Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.**



Certain FCMs are covered by specific EU regulations

- ✓ CERAMIC MATERIALS
- ✓ REGENERATED CELLULOSE FILM
- ✓ ACTIVE AND INTELLIGENT MATERIALS
- ✓ PLASTICS (including recycled plastic and bioplastics)

**PAPER AND PAPERBOARD ARE NOT YET EU HARMONIZED**  
*see relevant useful documents:*

- ✓ **Industrial guidelines 2019**
  - ✓ [https://www.cepi-eurokraft.org/wpcontent/uploads/2019/04/Food-Contact-Guidelines\\_2019.pdf](https://www.cepi-eurokraft.org/wpcontent/uploads/2019/04/Food-Contact-Guidelines_2019.pdf)
- ✓ **JRC Base line study 2016**
- ✓ **Technical guide on paper and board materials**
  - ✓ [https://www.edqm.eu/sites/default/files/medias/fichiers/Food\\_contact\\_materials/food\\_contact\\_materials\\_technical\\_guide\\_on\\_paper\\_board\\_draft\\_text\\_for\\_consultation.pdf](https://www.edqm.eu/sites/default/files/medias/fichiers/Food_contact_materials/food_contact_materials_technical_guide_on_paper_board_draft_text_for_consultation.pdf)



# PLASTIC EU REGULATION 10/2011 INCLUDES BIOPLASTIC



- ❑ Sets out rules on the **composition of plastic FCMs**
- ❑ **specifies restrictions** on the use of these substances
- ❑ sets out **rules to determine the compliance** of plastic materials and articles.



- It sets out a **Union list of authorised substances** (monomer, starting substances, additives, etc) that can be used in the manufacture of plastic layers of food contact materials.
- It sets **specific migration limits (SML)** and restriction conditions for some substances on the positive list.
- It sets **maximum overall migration limits (OML)** for the plastic food contact materials to be 60mg/kg food.
- It sets out the **compliance testing requirements** (for example, food simulants, test duration & temperature).
- It sets out **requirements for declaration of compliance (DoC)**.



# UNION LIST OF AUTHORISED SUBSTANCES FOR PLASTICS

Annex I to the plastics regulation is a positive list of authorized substances. *The list covers monomers, starting substances, additives, and polymer production aids as well as restriction, specification and specific migration limits are also listed if available.*

*Table 1*

**List of food simulants**

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E



- ❑ **Specific migration limits (SML):** the amount of a specific substance that can migrate from FCM into the food stuff. Usually expressed in mg/kg.
- ❑ **Overall migration limits (OML):** the total amount of all chemical substances that can migrate from FCM into the food stuff. Usually expressed as mg/kg food or per food contact surface area (mg/dm<sup>2</sup>).
- ❑ **Migration testing is usually done by using various food simulants**
  - ❑ Testing temperature and duration also vary depending on food package use conditions.



*Table 1*  
**List of food simulants**

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Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E <div style="display: flex; align-items: center; margin-left: 20px;"> <span style="font-size: 2em; margin-right: 5px;">→</span> <span>Tenax powder: used for dry food contact and as replacement of simulant D2 at high temperature</span> </div>

The choice of food simulants is function of the type of food the material is suppose to come into contact with.



# STANDARD CONDITIONS FOR OVERALL MIGRATION ASSESSMENT

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at contact temperature in [°C] for testing	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{(T-70)/10}$ minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum of $t = 120/2^{(T-70)/10}$ minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.



# STANDARD CONDITIONS FOR OVERALL MIGRATION ASSESSMENT -HIGH TEMPERATURE

## Selection of test time

Contact time in worst foreseeable use	► <u>M7</u> Time to be selected for testing ◀
$t \leq 5 \text{ min}$	5 min
$5 \text{ min} < t \leq 0,5 \text{ hour}$	0,5 hour
$0,5 \text{ hours} < t \leq 1 \text{ hour}$	1 hour
$1 \text{ hour} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ hours} < t \leq 6 \text{ hours}$	6 hours
$6 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$1 \text{ day} < t \leq 3 \text{ days}$	3 days
$3 \text{ days} < t \leq 30 \text{ days}$	10 days
Above 30 days	See specific conditions



# TIME:FORESEABLE TEST CONDITION

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5 \text{ }^{\circ}\text{C}$	5 °C
$5 \text{ }^{\circ}\text{C} < T \leq 20 \text{ }^{\circ}\text{C}$	20 °C
$20 \text{ }^{\circ}\text{C} < T \leq 40 \text{ }^{\circ}\text{C}$	40 °C
$40 \text{ }^{\circ}\text{C} < T \leq 70 \text{ }^{\circ}\text{C}$	70 °C
$70 \text{ }^{\circ}\text{C} < T \leq 100 \text{ }^{\circ}\text{C}$	100 °C or reflux temperature
$100 \text{ }^{\circ}\text{C} < T \leq 121 \text{ }^{\circ}\text{C}$	121 °C (*)
$121 \text{ }^{\circ}\text{C} < T \leq 130 \text{ }^{\circ}\text{C}$	130 °C (*)
$130 \text{ }^{\circ}\text{C} < T \leq 150 \text{ }^{\circ}\text{C}$	150 °C (*)
$150 \text{ }^{\circ}\text{C} < T < 175 \text{ }^{\circ}\text{C}$	175 °C (*)
$175 \text{ }^{\circ}\text{C} < T \leq 200 \text{ }^{\circ}\text{C}$	200 °C (*)
$T > 200 \text{ }^{\circ}\text{C}$	225 °C (*)

The leading concept is the worst possible foreseeable time conditions the material will stay in contact with a specific foodstuff



# TEMPERATURE: FORESEABLE TEST CONDITIONS

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5\text{ }^{\circ}\text{C}$	5 °C
$5\text{ }^{\circ}\text{C} < T \leq 20\text{ }^{\circ}\text{C}$	20 °C
$20\text{ }^{\circ}\text{C} < T \leq 40\text{ }^{\circ}\text{C}$	40 °C
$40\text{ }^{\circ}\text{C} < T \leq 70\text{ }^{\circ}\text{C}$	70 °C
$70\text{ }^{\circ}\text{C} < T \leq 100\text{ }^{\circ}\text{C}$	100 °C or reflux temperature
$100\text{ }^{\circ}\text{C} < T \leq 121\text{ }^{\circ}\text{C}$	121 °C (*)
$121\text{ }^{\circ}\text{C} < T \leq 130\text{ }^{\circ}\text{C}$	130 °C (*)
$130\text{ }^{\circ}\text{C} < T \leq 150\text{ }^{\circ}\text{C}$	150 °C (*)
$150\text{ }^{\circ}\text{C} < T < 175\text{ }^{\circ}\text{C}$	175 °C (*)
$175\text{ }^{\circ}\text{C} < T \leq 200\text{ }^{\circ}\text{C}$	200 °C (*)
$T > 200\text{ }^{\circ}\text{C}$	225 °C (*)

The leading concept is the worst possible foreseeable temperature conditions the material will stay in contact with a specific foodstuff



Use bio-based materials derived from natural sources is likely to extend the range of risk beyond the known components of the packaging materials.

- ✓ **Agri-food by-products used in fermentation processes** may be contaminated with naturally produced contaminants (e.g. mycotoxins due to a range of factors including poor storage or climatic conditions).
- ✓ **Organic compounds**, e.g. dioxins and polychlorinated biphenyls (PCBs); and **inorganic compounds**, e.g. lead and arsenic, as a result of environmental and geological conditions or the after effects of incidents such as fires.
- ✓ **Other compounds** such as nitrates, pesticide and veterinary medicines residues, and plant toxins, e.g. pyrrolizidine alkaloids, can arise due to horticultural or agricultural practices or misuse of agrochemicals or veterinary medicines.



# PAPER: NATIONAL RULES AND LEGISLATIONS IN CE AND OTHER RELEVANT EU COUNTRIES

Italy	DM 21/3/73 and updating.
Germany	LFGB (§§ 30-31) e BfR recommendations BfR serie XXXVI
Poland	National Standard: PN-P-50430
Slovenia	TO BE COMPLETED BY PROJECT PARTNER
Slovakia	Decreto legge 1799:2003 e succ. agg. (sezione 6 - art. 19 e 24; all. 8)
Check Republic	Legge 38/2001 e succ. agg.
Croatia	TO BE COMPLETED BY PROJECT PARTNER
Hungary	TO BE COMPLETED BY PROJECT PARTNER
France	Arrêté du 28 juin 1912; Circulaire No 170 du 2 avril 1955; Brochure No 1227; Note d'information de la DGCCRF No 2004-64 e No 2006-156; Décret No 2008-1469 et No 2007-766 ; DGCCRF Fiches-materiaux-organiques-fibres-vegetales-v02-2019
Netherland	Law Warenwet C:III 55 Hoofdstuk II
Switzerland	Ordinance DFI 817.023.21 (sez. 6)



## Italian legislation

Recycled paper admitted only  
In contact with dry food



**Italian Decree 21/03/73**  
Disciplina igienica degli imballaggi,  
recipienti, utensili, destinati a venire in  
contatto con le sostanze alimentari o con  
sostanze d'uso personale

## French legislation

Recycled paper admitted  
With all food under specific  
conditions



**Fiche MCDA n°4 (V02 - 01/01/2019)**  
Aptitude au contact alimentaire des  
matériaux organiques à base de fibres  
végétales destinés à entrer en contact avec  
des denrées alimentaires

## German legislation

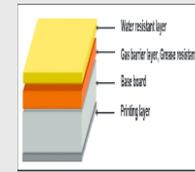
Recycled paper admitted  
With all food under after testing  
Specific contaminants



**Recommendations on  
paper and board (2019)**  
XXXVI, XXXVI/1, and XXXVI/2



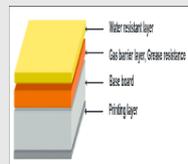
# HOW TO ASSESS COMPLIANCE FOR MULTI-MATERIAL PAPER/BIOPLASTIC



## GENERAL GUIDELINES:

- ✓ **The Food contact layer must be designed in accordance to positive list of the specific material**
  - ✓ EU Harmonized material (Plastic/Bioplastic) see EU 10/2011
  - ✓ Non harmonized material (Paper) see national legislations
  
- ✓ **The testing must be carried out according to national legislation where the material is produced**
  - ✓ **Export ?**
    - ✓ **Theoretically Eu mutual recognition**
    - ✓ **In practice additional testing often required**





- ✓ **The Food contact layer is bioplastic**
  - ✓ Global migration in liquid food simulants
  - ✓ Specific migration in liquid food simulants
  - ✓ Migration must be performed in the worst foreseen contact conditions scenario (time and temperature)
- ✓ **The Food contact layer is paper**
  - ✓ Global/specific migration normally does not apply due to porosity of the material
    - ✓ When assessed is performed with a solid powder (Tenax)
  - ✓ Contaminants are normally assessed after water extraction
  - ✓ Risk assessment must be performed in the worst foreseeable contact conditions scenario (time and temperature)



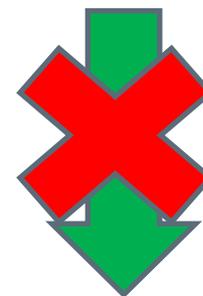
# CASE 1: BIOPLASTIC IS IN CONTACT WITH FOOD

## BIOPLASTIC FCM LAYER



- ✓ Positive list according to EU 10/2011
- ✓ Global migration and specific migration according to national legislation
- ✓ Risk assessment according to 1935/04

## PAPER LAYER



The compliance to positive list is **NOT COMPULSORY**  
The compliance to contaminants limits often suggested unless the barrier property of plastic layer is demonstrated

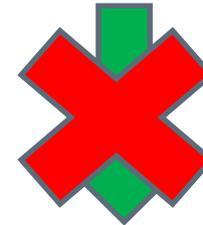


## PAPER FCM LAYER



- ✓ Positive list and testing according to national legislation
- ✓ Risk assessment 1935/04 to verify potential migration from rear layer

## BIOPLASTIC LAYER



NOT COMPULSORY  
THE COMPLIANCE TO  
FCM but... assessment  
of risk assessment is  
performed testing  
the paper layer



## Part 2

# Legislation concerning Packaging and Waste





<https://www.colormark.pl>

- Current **legal bases** for the Circular Economy in EU regulations
- What **changes in the domestic legal order** should be expected in connection with the implementation of the Circular Economy
- **New consumption models and other breakthrough changes** in the economy that the implementation of the Circular Economy may cause



## What is Circular Economy?

- The value of products, materials and resources in the economy is maintained for as long as possible
- Waste generation is kept to a minimum and waste is treated as a resource

## Why Circular Economy?

- Protecting enterprises from resource scarcity and price volatility, increasing resource independence
- Energy savings
- Creating a sustainable, low-carbon, resource-efficient
- and a competitive economy
- Limiting irreversible damage to the environment caused by the use of non-renewable resources



# THE ROAD TO THE CIRCULAR ECONOMY



In 2016, sectors important for the implementation of **circular economy** in the EU employed **4 million people** - **6%** more than in 2012.

## 10%

**Municipal waste** accounts for approximately **7-10%** of all waste generated in the EU.

In 2016, activities related to, among others, recycling, repair and restoration, generated **147 billion euro** in added value and generated **17.5 billion euro** in investment.

## 25%

In 1995, an average of **64%** of **municipal waste** was landfilled in the EU. In 2000, **55%** of them were landfilled, with the recycling rate at **25%**. In 2016, landfilling of municipal waste in the EU decreased to **24%** and the recycling rate increased to **40%**.

## 12%

**Recycling in the EU** is growing, while still meeting **only 12% of raw material needs** - the global economy has a potential of only **9%**.

## 40%

The average level of **municipal waste recycling in the EU** is about **40%**, sometimes reaching **80%** - in Poland it is **27%**, and as much as **42%** of waste is still landfilled (2017).



# THE "WASTE PACKAGE" AS A STEP TOWARDS BUILDING A CIRCULAR ECONOMY

European Commission announcement of 2 December 2015:  
**Closing the loop - An EU action plan for the circular economy**

Revision of six waste and waste management directives



Concerning  
waste  
(2008/98/WE)



Concerning  
packaging  
and  
packaging  
waste  
(94/62/WE)



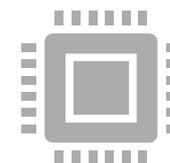
Concerning  
waste  
management  
(1999/31/WE)



Concerning  
end-of-life of  
vehicles  
(2000/53/WE)



Concerning  
batteries and  
accumulators and  
waste batteries  
and accumulators  
(2006/66/WE)



Concerning on  
waste electrical  
and electronic  
equipment  
(2012/19/UE)



# WASTE MANAGEMENT ECONOMY: AMENDMENT TO THE WASTE DIRECTIVE



## Directive (EU) 2018/851 of the European Parliament and the Council of 30 May 2018 amending Directive 2008/98 / EC on waste

- Basic requirements for an extended producer responsibility scheme.
- More ambitious quantitative targets for preparing for re-use and recycling municipal waste.
- Extending the scope of selective waste collection, incl. in the context of hazardous household waste.
- Strengthening the importance of by-product institutions and end-of-waste status.
- Proposed mechanisms to promote products and product ingredients that can be used repeatedly, containing recycled materials, technically durable and easy to repair.
- Efforts to reuse products that are the main sources of critical raw materials.



## Annex IVa to the Waste Directive - incentive mechanisms to apply the waste hierarchy

- Charges for **landfilling and incineration** of waste and restrictions on the use of these processes, encouraging waste prevention and recycling.
- **Waste-proportional fee systems** levied from producers to encourage source separation of recyclable waste and to reduce mixed waste.
- **Tax incentives** to donate products free of charge, especially food.
- **Extended Producer Responsibility** schemes for different types of waste and measures to improve their efficiency and profitability.
- **Deposit refund systems** and other measures to encourage the efficient collection of used products and materials.
- **Sustainable** Public Procurement.
- Applying fiscal measures that support the use of **reusable or recycled products and materials**.
- Use of the best available **waste treatment techniques**.
- Economic incentives for local authorities supporting **waste prevention, separate collection systems**, without supporting landfilling and incineration.
- **Public awareness** raising campaigns.



## The amended art. 9 of the Waste Directive

- Promote and support **sustainable production** and consumption patterns.
- Encourage the design, manufacture and use of products that are **resource efficient, durable, repairable, reusable and upgradable**.
- Encourage the **re-use** of products and the creation of systems that promote repair and re-use, in particular for electrical and electronic equipment, textiles, furniture, packaging and construction materials.
- Support the availability of spare parts, manuals, technical information, or other tools, hardware or software that can be **repaired and reused**.
- **Food waste** reduction.
- Promote the **reduction of hazardous substances** in materials and products.





## Recycling as a pillar of circular economy

- Currently: preparing for the **re-use** and **recycling** of waste materials, such as at least **paper, metal, plastic** and **glass** from households - minimum **50% by 2020**.
- After the changes: higher levels of preparation for re-use and recycling of municipal waste:
  - minimum **55% by 2025**
  - minimum **60% by 2030**
  - minimum **65% by 2035**
- The possibility of postponing the above-mentioned goals of 5 years by countries with more catching up to do
- in terms of **recycling and landfilling reduction**.
- Materials that are used to generate energy, as fuels, burned, fill workings or stored will not be counted towards the achievement of the established goals.



## Separate collection - the key to recycling

- Until now: **separate collection** as a means of facilitating the preparation of waste for **reuse and recycling** with a limited scope of use
- After the changes: **separate collection** is practically the rule in waste management, and its scope is expanding
- By **1 January 2025**, a separate system for the collection of textiles and hazardous waste from households must be established
- By **31 December 2023**, **bio-waste** is to be either **collected separately** or **recycled at source** (e.g. composted at home)



# HIGHER LEVELS OF PACKAGING WASTE RECYCLING

- Separate targets are set for **ferrous metals and aluminum**
- The weight of **recycled packaging waste** is generally measured when the waste enters the **recycling process**
- Recognition of **biodegradation** as a form of recycling
- **BUT oxo-degradable** plastic packaging is not considered biodegradable packaging
- A Member State may postpone by a maximum of five years the deadline for meeting the **recycling targets** while respecting certain minimum levels

Packaging type	31 XII 2025	31 XII 2030
All packaging	65%	70%
Carboard and paper	75%	85%
Plastics	50%	55%
Ferrous metals	70%	80%
Aluminum	50%	60%
Glass	70%	75%
Wood	25%	30%



# SOLUTIONS ACCOMPANYING WASTE PACKAGING IN THE IMPLEMENTATION OF CIRCULAR ECONOMY

**The European Strategy of 16 January 2018 for Plastics in a Circular Economy.**



**Directive (EU) 2019/904** of the European Parliament and of the Council of 5 June 2019 on the reduction of the environmental impact of certain plastic products

- Requirements as to the levels of selective collection of **PET bottles** and the use of recycled material in their production
- Prohibition of the use of certain **single-use** products after July 3, 2021 (straws, cutlery, plates, stirrers, balloon sticks, polystyrene containers)



- **Beverage containers (<3 l)** must have their caps firmly attached after July 3, 2024.

- Limiting the use of **single-use** products until 2026 compared to 2022 (cups, fast food containers, etc.)

- **EPR** implemented by 2023/2024 in the form of participation in the costs of education, waste collection and cleaning, etc.

- Hygiene, **tobacco products and cups** will be appropriately labeled after July 3, 2021.



# THANK YOU!!



## THANK YOU!

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