

PAPER TECHNOLOGY INTERNATIONAL

THE JOURNAL OF THE BIOFOREST PRODUCTS SECTOR



PITA PAPER *matters!* 2018 Conference & Exhibition at Lancaster University

Introduction to Product Safety Compliance of Paper & Board
Food Contact Materials and Sanitary Tissue Papers
Cristina Lugli (Ecol Studio)

PAPERmatters 2018!

The Presentations

Cristina Lugli Ecol Studio



Cristina is a Key Account Manager and Consultant for the paper and board sector at Ecol Studio, in particular for the European and International market. She is in charge of the Technical and Legislative Support and has 20 years experience in the paper industry. Cristina is involved in National and European Working Groups on paper and board, as (CEN) TC 172 / WG3 – Analytical methods for the assessment of Paper and Board in contact with foodstuffs, Ecolabel (paper products), the Food Contact Materials Working Group of Federchimica (Italian Federation of the Chemical Industry). Cristina is a Chemist, with a PhD in Chemistry and an Italian Food Contact Expert and member of AIBO (Italian Association of Food Contact Experts).



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25-26
September
UK

Cristina Lugli

**INTRODUCTION TO PRODUCT SAFETY COMPLIANCE OF
PAPER & BOARD FOOD CONTACT MATERIALS
AND SANITARY TISSUE PAPERS**

PAPERmatters! 2018
"Paper's coming home!"
Knowledge Partnership 25-26 September

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INTRODUCTION

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**IS IT SAFE TO EAT?
HOW CAN YOU BE CERTAIN OF YOUR **FOOD PACKAGING?****



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WHO WE ARE

Ecol Studio is a company specialised in **consultancy, testing, and training**


CLIENTS NETWORK

- France
- Germany
- Spain
- Poland
- Austria
- Belgium
- Great Britain
- Sweden
- Romania
- Holland
- Greece
- Hungary
- Slovenia
- Finland
- Switzerland
- Serbia
- Denmark

35+
YEARS OF EXPERIENCE

200+
WORLDWIDE CLIENTS

17+
COUNTRIES





Ecol Studio S.p.A (Italy) - 8 sites

ECOL STUDIO CONSULTING AB
Lund, Sweden

ECOL STUDIO UK LIMITED
Kent, UK

Ecol Studio in Spain, France, Germany and Poland by 2021







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WHO WE ARE

ECOL STUDIO FCMs HEADQUARTERS: LUCCA

NEW AND ENLARGED LABORATORY!

- More than 4000 m²
- More than 200 employees
- High-quality equipment and instrumentation
- High level of analytical and technical expertise

LUCCA PAPER DISTRICT OF CAPANNORI

More than 180 companies in the territory
 More than 8000 employees


80% of the national production of tissue paper
 (17% of the European)

40% of the national corrugated cardboard production
 (5% of the European)

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<http://www.ilsole24ore.com>

WHO WE ARE



ECOL STUDIO BUSINESS AREAS
consultancy, testing, and training

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AREA 1

- ENVIRONMENT
- Water, Air
- Emission
- Waste



AREA 2

- SAFETY AT WORK
- OCCUPATIONAL HEALTH SERVICES

AREA 3


- PRODUCT SAFETY
- Food contact materials
- Products for contact with body/skin

- **CUSTOMERS**
PRODUCERS, IMPORTERS, DISTRIBUTORS, RETAILERS, CONSUMERS...
- **TYPE OF MATERIALS**
PLASTICS **PAPER&BOARD** METALS RUBBER GLASS CERAMICS WOOD...
- **PRODUCTS**
RAW MATERIALS, PACKAGING AND CONTAINERS , KITCHENWARE AND TABLEWARE FOOD PROCESSING EQUIPMENTS AND MACHINERY

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DISTINCTIVE SERVICES FOR THE PAPER&BOARD SECTOR

<p>Testing</p>	<p>FCMs GAP analysis – Audit- Management Systems; Reg. (CE) n. 2023/2006</p>
<p>FCMs compliance testing EU and international regulations, standards Chemical –Microbiological –Sensory testing</p>	<ul style="list-style-type: none"> ✓ Implementation/maintenance of the GMP system ✓ Voluntary product certifications (BRC, IFS, etc.) ✓ Support -preparation of qualification - verification audit from large-scale organized distribution
<p>Risk Assessment , NIAS (Non Intentionally Added Substances)</p>	<p>Tailor-made consultancy and Training</p>
<p>Skin safety testing Products -contact with the body</p>	<p>Support in the preparation/issuing of Declaration of compliance</p>
<p>Toy safety - directive 2009/48/EC and EN 71</p>	<p>Legislative updating service: PaperNewsPaper</p>
<p>Ecological quality Testing, assistance - attainment/maintenance ecological quality labels: ECOLABEL, NORDIC SWAN, BLAUER ENGEL</p>	<p>European + Member States legislation on P&B FCMs</p>

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SOMETHING ABOUT ME


Ecol Studio Key Account Manger and Consultant for the P&B sector
Technical and legislative Support for Customers
 20 years experience in the paper industry
 Participation in National and European Working Groups on P&B FCMs


- *Technical Commission UNI/CT 008 – Carta (Paper)*
- *European Technical Committees*
 - *(CEN) TC 172 / WG3 – Analytical methods for the assessment of P&B in contact with foodstuffs*
 - *CEN TC 172 / WG8 - Test methods for tissue papers*
- *Ecolabel (paper products)*
- *Federchimica (Italian Federation of the chemical industry) – FCMs Working Group*

Food Contact Expert nr° 119 (AIBO-Italian Association of Food Contact Experts)
 Chemist - Qualified Chemist (Ordine dei Chimici)
 PhD in Chemistry






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KEY POINTS

<<


1. Product safety: Paper&Board Food Contact Materials and Articles


- Overview: EU Legislative background on Paper&Board Food Contact Materials
- FAQs from the P&B supply chain: how to answer properly and some tips for an efficient testing plan


>>

2. Product safety: Hygiene Paper Products (Sanitary Tissue products)

3. Ecol Studio proposals for the Paper&Board sector






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Food Contact Materials: LEGISLATIVE BACKGROUND

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OVERVIEW - *The legislative background*

- Framework Regulation (EC) No 1935/2004
- GMP Regulation (EC) No 2023/06
- Specific Measures



WHAT DO WE MEAN BY FOOD CONTACT MATERIALS (FCMs)?

Framework Regulation (EC) No 1935/2004 Article 1: *Purpose and subject matter*
Any material or article

- Intended to be brought into contact with food
- Already in contact with food and intended for that purpose
- Can reasonably be expected to be brought into contact with food or to transfer constituents to food under normal or **FORESEEABLE** conditions of use..



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Food Contact Materials: LEGISLATIVE BACKGROUND

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Framework Regulation. Art. 3: General Safety Requirements


1. Materials and articles must be manufactured in **compliance with GMP** so that, under normal or foreseeable conditions of use, they **do not** transfer their constituents to food in quantities which could:

- **endanger human health;**
- **bring about an unacceptable change in the composition of the food;**
- **deteriorate the organoleptic characteristics of food**

2. **Labelling, advertising and presentation must not mislead consumers**




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Food Contact Materials: LEGISLATIVE BACKGROUND



ANNEX I


1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

 Annex I to the Framework Regulation lists **17 food contact materials and articles (FCMs)** which may be covered by specific measures

 **Only 4 materials are subject to specific EU measures**

 For the other 13 materials - **INCLUDING PAPER&BOARD**- the possibility remains for **Member States to adopt national provisions**








LEGISLATIVE BACKGROUND

Framework Regulation: other requirements...

- Article 15: Labelling
 ...FCMs shall be accompanied by **'for food contact'**, or a **specific indication** as to their use (es: coffee machine), or the symbol.
 - instructions for safe and appropriate use (if necessary)...
 - name/address of the responsible for placing on the market
 - **adequate labelling/identification to ensure traceability** (Art. 17)
- Article 16: Declaration of compliance and supporting documentation
 -FCMs and FCAs covered by **specific measures** shall be accompanied by a written declaration stating that they comply with the rules applicable to them...
 - In the **absence of specific measures**, Member States may retain/maintain national provisions
- Article 17: Traceability
 -The traceability of materials and articles shall be ensured at all stages in order to **facilitate control, the recall of defective products, consumer information and the attribution of responsibility**

Food Contact Materials: LEGISLATIVE BACKGROUND


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GMP Regulation (EC) No. 2023/2006

- Materials and articles must be **manufactured in accordance with Good Manufacturing Practices - GMP**

*It is a requirement of the Reg.(EC) No 1935/2004, that **all materials and articles intended for food contact shall be manufactured in accordance with GMP***

- For all FCMs and all stages of production - **except for starting substances** (Article 2 - Scope)
- General requirements for establishing Quality Assurance and Quality Control and documentation
- Provides specific rules for printing inks on non-food contact side (no transfer)





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Food Contact Materials: LEGISLATIVE BACKGROUND

EU NON-HARMONIZED FCMS


WHICH IS THE SCENARIO FOR PAPER&BOARD (P&B)?

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Single MSs (Belgium, the Czech Republic, Germany, France, Greece, Croatia, Italy, the Netherlands and Slovakia) **specific measures on paper and board**

CoE: 2 resolutions- paper and board and tissue paper

Lists of authorised substances: Belgium, the Czech Republic, Italy, the Netherlands and Slovakia, German Recommendations and CoE resolutions




Material	MS with measures	MS with measures and no substances regulated	No substances regulated vs risk assessed*	Substances in common in > 3 MSs
Paper and board	10 MSs +Norden + CoE	BE (81), CZ (217), DE (324), FR (31), HR (35), IT (85), NL (314), SK (35), EL (plastics), [EE]+ CoE (1 110)	1 710 / 565 (33 %)	147 (9 %)



BASELINE STUDY – JRC Final report January 2017

Non-harmonised food contact materials in the EU: Regulatory and market situation



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Food Contact Materials: LEGISLATIVE BACKGROUND

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**WHAT ARE
THE PAPER AND
BOARD PRODUCERS
RESPONSIBLE FOR?**


Be aware of the regulatory framework applicable	
provide a high level of protection of human health	Reg. 1935/04, Art.3
Comply with Good Manufacturing Practices (GMPs)	Reg. 2023/06
Share info along the supply chain (industry)	Traceability. Reg. 1935/04, Art. 17
Clear information- Labelling (consumers)	Labelling. Reg. 1935/04, Art. 15

Goal: Food safety





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Food Contact Materials: LEGISLATIVE BACKGROUND


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**HOW TO
DEMONSTRATE THE
COMPLIANCE
TO THE REGULATIONS?**

Only 4 materials (out of 17) are subject to specific measures	
MS may have their own rules	<ul style="list-style-type: none"> ✓ Different languages ✓ Difficult access to the regulations ✓ Different substances
Mutual recognition does not work	
Uneven quality of: - official controls (authority) - DoC/SD	

BURDENS FOR INDUSTRY

- ✓ Extra costs: consultancy, multiple and different testing





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FOOD CONTACT MATERIALS: LEGISLATIVE BACKGROUND

CASE HISTORY : Paper FCM - recycled fibers

XXXVI. Paper and board for food contact
(01.09.2017)

- Positive list; Tests : OBA and colorants must not migrate, formaldehyde, glyoxal, PAA, heavy metals (Pb, Cd), no preserving effect on the foodstuffs..
- RECYCLED FIBRES: *may be used, provided that the finished articles comply with the requirements...Annex- Preconditions for the use of recycled fibres (BPA, DIPN..)***

Fiche DGCCRF papier et carton
(2016)

- Tests: OBA and colorants must not migrate, heavy metals (Hg, Cd, Cr, Pb), PCP, PCB, no preserving effect on the foodstuffs, formaldehyde, glyoxal, sensory testing...
- RECYCLED FIBRES: requirements of Art. 3 are satisfied**

D.M. 21/03/73 e s.m.i.

- Positive list; Tests: **Purity Requirements:** Lead, Policlorobifenili (PCB), fastness OBA; **Composition Requirements- All. IV Sez. 6** (auxiliary substances: soluble, insoluble; fillers..)
- RECYCLED FIBRES: Recycled P&B NOT ALLOWED FOR GENERAL USE**, only in contact with foods for which migration is prescribed in the EU conventional classification + provided the finished articles comply with some purity requirements (lead and PCB)

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Food Contact Materials: FAQs FROM THE SUPPLY CHAIN

DECLARATION OF COMPLIANCE

WHY HAVE A DOC?

WHAT IS THE PURPOSE OF A DECLARATION OF COMPLIANCE (DOC)?

SHARING INFORMATION ALONG THE SUPPLY CHAIN

- Identification -company issuing DoC
- Helps to identify material
- Legal Compliance (Eu, MSs)
- Intended use (kind of foodstuffs)
- Appropriate use
- General information on compliance testing performed

SATISFY THE NEED OF TRANSPARENCY OF ALL STAKEHOLDERS

WHAT IS THE DIFFERENCE BETWEEN DOC AND SUPPORTING DOCUMENTS?

DECLARATION OF COMPLIANCE


- written statement to prove the downstream user that the described FCM complies
- all the necessary information to establish/verify the compliance

SUPPORTING DOCUMENTS

- compliance work/study from upstream processing stages
- migration tests, calculations, Risk assessments, composition
- Process data/GMP documentation...

-customer-oriented
-product-specific
-accompanying the product

-internal use
-for authorities
(upon request)



Food Contact Materials: FAQs FROM THE SUPPLY CHAIN

DECLARATION OF COMPLIANCE

LEGAL REQUIREMENT?

Member states may retain/adopt national provisions for DoC's **in the absence** of specific legislation at EU level...

Strongly **recommended** as part of good business practice in other states + **INDUSTRIAL GUIDELINES**

Traceability (Art. 17 Reg.1935) should be ensured at all stages of the supply chain to facilitate **monitoring, recall of defective products, consumer information, attribution of responsibility...**


WHICH REGULATION SHOULD BE REPORTED ON THE DOC?


Framework Reg. 1935/2004
Reg. 2023/2006 (GMP)
Other relevant regulations (IT, GER, FR...)...


WHICH FREQUENCY OF TESTING AND DOC?

Raw materials/process variability
Results
Change in the process

GOAL: communication along the supply chain







Food Contact Materials: FAQs FROM THE SUPPLY CHAIN

COMPLIANCE OF P&B FCMS


LOT OF QUESTIONS AND REQUESTS FROM:


- Customers
- Competent Authorities (Local/MS authority)
- Consumers


MAIN TOPICS AND ISSUES

- ✓ How to **fulfil** the EU/MSs regulations
- ✓ **Info flow** along the supply chain – difficulties in obtaining the data
- ✓ Different regulations – different chemicals in the positive lists
- ✓ Mutual recognition ?

- ✓ **NIAS** (*Non-intentionally Added Substances*)
- ✓ **IAS** (*Intentionally Added Substances*)
- ✓ Printing inks and other additives (adhesives...)
- ✓ Mineral oils - MOSH/MOAH







Food Contact Materials: TIPS FOR AN EFFICIENT TESTING PLAN- STEPS

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- A. LIST OF ALL MATERIALS/SUBSTANCES USED IN THE MANUFACTURING PROCESS**
- B. VERIFY RELEVANT/IN FORCE REGULATIONS FOR THE PRODUCT**
- C. CHECK IF THE SUBSTANCES ARE ALLOWED TO BE USED (POSITIVE LISTS, LIMITS, RESTRICTIONS)**
- D. KIND OF FOODSTUFFS - TIME AND TEMPERATURE CONDITIONS**
- E. SET UP A TESTING PLAN: TESTING, SCREENINGS, RISK ASSESSMENTS...**

Risk Management Approach


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HYGIENE PAPER PRODUCTS

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WHAT ARE WE TALKING ABOUT?




which come into direct contact with the human body

tissue paper, paper handkerchiefs, cosmetic tissues, paper towels, toilet paper ...

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HYGIENE PAPER PRODUCTS


EVALUATION AND TESTING

Guidelines for Evaluating Sanitary Papers (BfR)


YES	NO
<p>PAPER FIBRE PRODUCTS SUCH AS: TISSUE PAPER, USED AS PAPER HANDKERCHIEFS, COSMETIC TISSUES PAPER TOWELS, TOILET PAPER AND THE LIKE, WHICH <u>COME INTO DIRECT CONTACT WITH THE HUMAN BODY</u></p>	<ul style="list-style-type: none"> ARTICLES INTENDED TO HAVE MORE THAN JUST TEMPORARY CONTACT WITH THE HUMAN BODY PRE-MOISTENED SANITARY PRODUCTS
<p>Regenerated fibres from recycled paper ?</p>	<p><u>MAY BE USED</u> but not from paper or paperboard from sorting plants for general waste</p>







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HYGIENE PAPER PRODUCTS

EVALUATION AND TESTING

Guidelines for Evaluating Sanitary Papers (BfR)


Formaldehyde
Glyoxal
Polychlorinated biphenyls
transfer of antimicrobial constituents
Slimicides
Fastness of colorants (4)
Fastness of optical brighteners (4)
Azo dyes –must not be used


Chemical evaluation Other tests...

Ecolabel - Product Safety
SVHC
Patch test
VOCs
Phtalates
PAHs
Metals
Allergens

Colorants
EN 71 (Toys)

Goal: Securing the Protection of human health





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ECOL STUDIO PROPOSAL: HOW TO TRACK THE REGULATORY DEVELOPMENTS TO ENSURE REGULATORY COMPLIANCE



Being updated has an impact on **managing**



BUT... Being up to date on legislation may not be enough!



Looking forward has an impact on **making strategies**

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HOW TO TRACK THE REGULATORY DEVELOPMENTS TO ENSURE REGULATORY COMPLIANCE

**PNP IS A TOOL DESIGNED FOR:
BEING UPDATED & LOOKING FORWARD ON P&B**

- **QUARTERLY NEWSLETTER**
- with all the technical + legislative news + updates
- **ONLINE RESERVED AREA**
- **BREAKING NEWS** on the most relevant regulations
- **TAILOR-MADE CONSULTING**
- **ASK an EXPERT**
- **ANNUAL FCMs TRAINING** session

**ECOL STUDIO PROPOSAL
FOR THE P&B SECTOR**



CAN YOU BE CERTAIN OF YOUR FOOD PACKAGING?



**ECOL STUDIO
PAPERNEWS PAPER**
FOCUS ON EUROPEAN LEGISLATION FOR THE PAPER INDUSTRY

WOULD YOU LIKE TO GET MORE INFORMATION?...MEET US AT OUR DESK!




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CONCLUSIONS

THE BACKGROUND

P&B FCMs and FCAs are not yet harmonised
MSs may maintain/adopt **national provisions on FCMs**
The multiple references used by the sector may add **extra burdens and extra costs**



THE WAY FORWARD

EU main ongoing activities:
- **Evaluation** of FCMs legislation
- CEPI - CEN workshop to advance **standardisation needs for Eu P&B value chain (CWA)**



..these events made the boulder of harmonisation process start rolling down the slope...

*Change is the law of life.
And those who look only to the past or present
are certain to miss the future
John F. Kennedy*



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THANK YOU FOR YOUR ATTENTION...

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