

GUIDELINES FOR THE IMPLEMENTATION OF REGULATION 2023/2006/EC – PRODUCTION OF MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

B2. PAPER AND BOARD: PRODUCTION

B2.1. Characterization of the sector

B2.1.1. Field of application of the guideline

These guidelines are to be applied to companies producing paper and board from virgin fibre or recovered paper until the development of sheet and its setting up in reels or sheets.

B2.1.1. Legislation regulating area of interest (sector)

Regulation (EC) no. 1935/2004 of the European Parliament and of the Council of 27 October 2004, on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Commission Regulation (EC) no. 2023/2006 of 22 December 2006, on good manufacturing practice for materials and articles intended to come into contact with food.

Ministerial Decree 21 March 1973, Hygiene requirements of packages, containers and tools destined to come into contact with food or substances for personal use and following changes and integrations.

Presidential Decree n. 777 of 23 August 1982, Implementation of Directive (EC) 76/893 concerning materials and articles intended to come into contact with food and following updatings.

Legislative Decree no. 108 of 25 January 1992, Implementation of Directive (EC) 89/109 concerning materials and articles intended to come into contact with food.

It may result useful as well:

Ministry for Health Circular 24 January 2006, Materials and articles intended to come into contact with food: companies and food industry responsibilities ⁽³⁾

Joint Research Center-Community Reference Laboratory for Food Contact Materials (CRL-FCM) - Industrial Guidelines on traceability of materials and articles intended to come into contact with food

⁽³⁾ Ministry for Health Circulars are instruments issued as a support to specific legislative aspects

B2.1.1.3. Production process steps: flow pattern and description

Flow pattern of production



LEGENDA

- Everlasting productive phases
 - - - - - Unnecessary or not scheduled productive phases
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Brief description of productive steps

Raw materials warehouse

Raw materials (pulp, selected recovered paper, auxiliary substances, charging and adjuvant substances) getting to the paper mill are checked to verify if corresponding to accompanying documents, do not result damaged even partially and were packed following supplier request.

Once in the mill, raw materials are identified per grade and stored in the raw material warehouse, while quantities data and location of storage site are registered. Unsuitable material is properly identified and stored in a specific area left at this purpose.

Raw material ready for production is then taken out raw material warehouse and sent to the mixing (mixture) division in accordance with quantity and quality required for specific productive grade.

Mixing (Mixture) department

Mixture division fibrous raw materials are duly treated to make them suitable to be used and then mixed amongst themselves and with auxiliary and charging substances on the basis of proportion pointed out in the "formula". Pulps and/or recovered paper is firstly sent to the kneader (or pulper) where pulp fibres are crumbled and suspended into water.

Then, fibres are sent to refiners where, thorough friction, raising of fibrils of pulp surface is obtained, so to allow fibers to increase capacity of binding precisely when forming the sheet.

When using recovered paper, not always refining is necessary but, in this case, the mixture is made one or more cleaning (purge) phases, to remove impurities through proceedings mainly mechanical (filters and centrifugal purgers). Water suspension of fibers is therefore added auxiliary substances in right proportions, such as mass adhesive and colouring agents, retentives and charging substances necessary to mould the mixture ready for forthcoming preparation of paper sheet with required characteristics.

Deinking

For some grades of recycled papers, recovered paper is have one more step, called deinking where, due to the action of surface-actives, a removal of inks is obtained. To the surface-actives action can follow bleaching action of oxidant agents. So managed fiber is ready to be used for the preparation of the mixture.

Paper Machine

The mixture duly diluted is sent to the afflux case, which takes care of spreading it out with homogeneousness on a band continuously moving (wire section) in which fibers lays down and join while water drains in the below area. Then, the sheet is taken to a further and deep dehydration through pressing between calenders in rotation (moist press) just before being dried in the dry end, composed by a number of high temperature calenders in which paper sheet passes by accompanied by two felts. When coming out the dry end, uninterrupted sheet is rolled up on a cylinder (pope), forming the paper reel.

Surface gluing

For some paper grades Paper Machine is equipped with a further phase called "size press", in which already formed sheet undergoes a surface gluing treatment to increase its characteristics of mechanical strength and rigidity.

Patina cooking and coating

Some grades of paper are exposed to a further coating treatment, that can have place in same paper machine (coating on line) or afterwards (coating out of line). Coating is a surface treatment, on the paper sheet (bearing) are laid down, one or both sides, one or more layers of pigments so to allow a better aspect and printability.

Patina is prepared in its specific cooking, a water dispersal of mineral pigments, ligand and auxiliary substances mixed in right proportions.

Finish and setting up

Reels such as come out from paper machine can be directly addressed to the finished products warehouse or undergo to further production.

With calendaring, sheet is to suffer a strong pressure amongst a series of coupling cylinders (iron one is rigid, the other made out of flexible material) so paper can be smoothed and made lighter and homogeneous to the surface.

Embossing, instead, impress a surface deformation to the sheet to make it possible a specific relief drawing.

With the respool, paper ribbon is wrapped up again on board tubes and, in case, cut in small reels (“bobinette”).

Such lower reels can be finally cut in size, it means in sheets for the consignment to customer.

Reels, small reels (bobinette) or sheets, as for customer request, are finally wrapped-up, labeled, sometimes palletized ready to be sent to the finished products warehouse ready to be delivered to customer.

Finished products warehouse

Finished product, duly labeled, is stored in the finished products warehouse. Data on quantity and location of stored material are registered. Material which does not meet is duly identified and stored in a place previously decided.

Delivery

Finished product ready for the delivery is taken out the finished products warehouse as requested in the delivery plan and loaded on means of transport, accompanied by necessary documentation.

B2.2. Fulfilments arising from application of Regulation 2023/2006/EC

In this section are described activities and implementations acted out by paper and board production chain to fulfill with Regulation 2023/2006/EC. As this Regulation was issued when quality assurance systems had become daily work instruments in the majority of manufacturing industries, it is probable paper companies are already producing accordingly with technical rules fixed by themselves.

However, if necessary, Quality Assurance System and Quality Control System will have to be modified and finalized to guarantee:

“ (...omission....) that materials and objects are continuously manufactured and controlled, to assure conformity to the rules and to the qualitative standards suitable for the use they are meant for, without creating risks for human health or modify in an unacceptable way composition of a food product or, yet, produce a deterioration of its organoleptic characteristics”; (art. 3, par. A, Reg. 2023/2006/EC).

This section deals with particular subjects, respecting numerical sequence of articles of Reg. 2023/2006/EC. Each paragraph is therefore the answer of the companies of paper and board production chain at the requests of such article. To make reading easier, paragraphs maintain same title of considered article, while subparagraph indicates specific subjects.

B2.2.1. Quality Assurance Systems (art. 5 Reg. 2023/2006/EC)

Quality Assurance Systems

Paper and board producer (paper mill) is to arrange and maintain a Quality Assurance System capable of guaranteeing managing of Regulation expected targets described by relevant Authorities.

Quality Assurance System has to be substantiated as to make possible controls by relevant Authorities.

Quality Assurance System has to keep into account rules and procedures which regulate company activity, as far as following matters are involved:

- in accordance with laws in force requirements;
- human resources and training;
- raw materials and suppliers, goods and services suppliers included;
- production;
- quality control;
- warehouses, handling and shipment (delivery);
- complaints and corrective and preventive actions.

System has to guarantee that future legislative changes will be adopted within all phases of company process considering also specific and possible contracts with qualified suppliers.

It would be a good idea to arrange a procedure which allowed to get modifications coming from materials and articles intended to come into contact with food law in force updates, for instance through same entrepreneurs associations.

Company size

Whatever is the size of the company, Quality Assurance System implementation is to be guaranteed, as requested by Regulation 2023/2006/EC.

System has to be organized, applied and managed keeping into account real situation of company peculiarity and complexity as well as technical and human resources at disposal.

Within its same structure, company is however to guarantee application and management of the Quality Assurance System to get at the end materials and products corresponding to laws in force on production of materials and articles intended to come into contact with food.

B2.2.1.1 Human resources and training

As for aims of Regulation 1935/2004/EC and 2023/2006/EC, Business operator, will be responsible of resources management and of necessary activities to guarantee that Regulation 2023/2006/EC is enforced at each level of the organization.

Practical aspects of provisions application of Regulation 2023/2003/EC can be given to qualified and properly prepared people which need anyhow to have at their service suitable instruments to have Regulation 2023/2006/EC requirements fulfilled.

Business management has anyhow to guarantee individuation of functions so to allow controls by relevant Authorities.

All the *staff of the firm* potentially interested, even higher managing levels, has to be informed on GMP principles, on duties coming from Regulation 2023/2006/EC, on its aims and its application policies.

Company has to prepare and have applied some procedures to identify necessity of training of all concerned staff and has to have training guaranteed for all personnel on tasks which may affect conformity to this Regulation.

Personnel that will have to work on specific control activities and inspections on GMP will have to be trained on the prepared on the basis of acquired training and experience.

An appropriate registration of training process of all concerned staff will have to be kept.

B2.2.1.1 Production

Production step of a company starts from planning of the formula to get until the storage of finished article (product). This Guideline is referred to the production of paper and board and therefore does not include following transformation processes, such as corrugation, print, punching, coupling with other materials, filming, paraffinizing or bath with acids. If inside paper mills should be realized also transformation works, it will be necessary to make reference to specific guidelines, always realized within the CAST Project.

Manufacturing process gathers all company phases which contributes to guarantee that finished product will be in conformity with legislative, technical and performance requirements arranged since planning phase so to warrant fitness to the final use it was realized for.

Therefore, Assurance Quality System has to count on prescribed procedures of following phases:

- Planning of formula;
- Raw materials and goods and/or services suppliers selection;
- Arrival raw materials and storage;
- Control of raw materials;
- Manufacturing processes;
- Process parameters control;
- Production cycle control;
- Finished product and storage control.

System should provide a risk evaluation in each phase of productive cycle which may have an influence on eligibility of material when coming into contact with food.

Possible causes of contamination of the material when storing, working or moving has to be identified, kept under control, minimized or taken off where possible, through appropriate interventions. In the specific instance, UE Council Resolution includes a list of possible dangers (risks) and relating prevention measures connected with the production of paper and board (for instance, Technical Document no. 4 for wrapping papers and boards).

Planning of formula

Most important concept implied by GMP is of a material thought and realized to be conformed to legislative requirements on materials and articles intended to come into contact with food.

Paper and board produced by mills are to:

- meet with performances request for final utilization;
- meet with laws in force requirements on materials and articles intended to come into contact with food.

At this purpose, they have to be produced in accordance with a formula which considers only raw materials and, through control, guarantee, in any phase of the process, respect for final use and legislative requirements on materials and articles intended to come into contact with food.

In a particular manner raw materials, auxiliary and charging substances such as technological adjuvants must be in conformity with Ministerial Decree 21 march 1973 and following amendments and integrations.

Formula has to be duly proved with documents. When an already existing formula is modified for the production of a new kind of paper and board intended to come into contact with food, new one will have to be checked and verified to prove its conformity.

In the end, paper mill has to show to customers possible changes that could modify suitability to the use of supplied paper and board. It however stands responsibility of same customer to previously inform paper mill what kind of use they have thought for purchased paper.

Raw materials and goods and/or services suppliers selection

Paper mill is to use only agreed raw materials it means the ones they decided, through supplier information and/or inspections and tests of all necessary data to guarantee conformity of paper and board to laws in force requirements, included restrictions due to use conditions. It is particularly important to select correctly virgin fibres and recovered papers as a function of the use of destination of produced papers and boards.

Each supply of raw material has to be kept under adequate control.

It is good practice that raw materials comes from qualified suppliers. For qualification it is meant a pre-arranged process, organized and substantiated that may also suppose supply specifications. Furthermore, it is also suggested to verify, even through questionnaires or periodical inspective visits, the Assurance Quality System for raw materials suppliers.

Conformity of process

Productive process has to be kept under adequate control with the help of Assurance Quality System which has to be thought in a way to guarantee and prove with documents that produced paper and board meet with technical specifications of reference.

Assurance Quality System has to be finalized so to allow enough attention to most critical passages of productive chain which may endanger legislative, technical and qualitative finished product conformity obtainment.

Procedures/Instructions documentation

Each passage of paper and board production which may have influence on eligibility to food contact has to be prescribed with adequate documentation. Examples of such documentation may be: handbooks, procedures, operating instructions, technical standards and registers.

Necessary documentation to comply with activity is to be available for interested personnel, updated and its distribution must be controlled, so that unrevised information can be promptly called in.

B2.2.2. Quality Assessment Systems (art. 6 Reg. 2023/2006/EC)

Paper and board producer (paper mill) is to prepare and maintain a Quality Assessment System capable of guaranteeing respect of conformity with Regulation, as described in general guidelines of this document.

The system has to include procedures that gather all necessary controls, relating registrations and actions to be taken when missing conformity.

All the documentation is to be available for relevant authorities which asked for, in compliance with Regulation 2023/2006/EC and General Policy Regulation 1935/2004/EC.

Rules and procedures are to be covered along productive process, as described in paragraph B2.1.3., also including a part in which management of not conformity and corrective actions are concerned.

B2.2.2.1. Raw materials warehouses management

Approved raw materials coming from qualified suppliers has to be clearly separated from other raw materials not even proved (standardized) or arriving from suppliers which are still to get qualification.

For these materials, it is to be supposed a procedure that authorize use in production only after that function within Quality Assessment System has confirmed material eligibility for use in production.

Possible raw materials under dispute are to be isolated in a given area and clearly identified waiting for the solution of the problem, or downgraded for an unfit use to food contact. Only prefixed function within Quality Assessment System keeps the authority for use in food contact materials.

Local factors, storage or handling inside warehouses are to be a way that guarantee lack of risks of deterioration of necessary materials which allow use for the production of articles intended to come into contact with food.

B2.2.2.2. Production controls

Quality Control System is to be regulated by adequate procedures that guarantee as during the productive process all necessary controls have been carried out, to warrant that product is in conformity with law, technical and quality details set out during project step.

It has to be guaranteed traceability of the product through appropriate registration of machines conditions defined and registered during production and of quality controls made on intermediary and on semi-finished products.

Put in warehouse of finished product and delivery to customer are to be possible only against procedures which allow to show unequivocally that the material has been controlled during all defined step and that latest controls have established conformity with all requirements set out during projecting phase.

Such conformity is to be verified through confrontation between data of control gathered and values and/or tolerances reported in the product technical specifications or in the reference legislation.

Process phases to be kept under control are to be identified on the basis of a risk analysis and with reference to law requirements relating to eligibility at food contact.

B2.2.2.3. Finished product Quality Control

Quality Control System needs appropriate procedures to verify finished products. In the finished products conformity verification, proposed role within the Quality Control System is to use information available on raw materials and process made use of to point out possible limitations or restrictions of use when into contact with food. Proof of controls are to be duly registered.

Analytical determinations should be always carried out with ratified analysis methods. If such methods does not exist, it can be used an analytic method with specific performance characteristics to the specified limit, while waiting for the elaboration of a ratified method.

Measurement and analysis instruments are to be duly set and this operation is to be properly registered.

Aims obtained with controls on finished product are the following:

- compliance of paper and board to the food contact laws in force;
- in those situations in which legislative parameters are not available but, instead, product evaluation elements are, conformity to requirements agreed at contractual step.

B2.2.2.4. Finished product warehouses management

Quality Assurance System is to provide a procedure that authorize put into storage of finished products. Authorization for putting into storage of products and for their delivery to customers is to be given by the in charge role within the Quality Control System after all due controls to verify final fitness to the use finished products were realized for have been made.

Approved finished products are to be plainly separated, or however clearly labeled respect to others which have not been checked yet or that have not been submitted yet to further eligibility controls.

For those products which did not come out to be fit, it is to be arranged a procedure which stops put into storage while waiting definition of matter or their downgrading.

Possible exceptions are to be authorized only by in charge authority within Quality Control System.

Unfit products, clearly identified, are to be stockpiled in a given area, so to make it impossible they may be stored or, anyhow, can be plainly labeled.

As for returned finished products coming back from customers because found not fit, they are to be clearly identified and stored in a given area or, however, be plainly labeled waiting for claim settlement. Only given authority within Quality Control System has the power to authorize use of such materials.

Environmental and stockpiling conditions of storage areas are to be a way to guarantee that no risks of material contamination can be run.

Special attention is to be taken to raw materials handling so to avoid damages which may make material unusable.

B2.2.2.5. Distribution, shipment and delivery

If responsible of shipment and delivery of material until destination, paper mill is to guarantee that this step is regulated by instructions and procedures too, which can make it sure

quality of material protecting it by possible dangers of contamination that may invalidate its eligibility when coming into contact with food.

If means of transport are of customer property, he will be called to assure that vehicles are fit for goods transportation and can maintain unblemished safety and hygiene requirements necessary to guarantee product eligibility.

If delivery is made through external transport companies, it is necessary to follow a procedure that qualifies carrier setting out a technical specification which establishes minimum requirements to be respected to eliminate all possible dangers that may invalidate eligibility to food contact for paper and board carried.

B2.2.2.6. GMP Application conformity and claims management, corrective and precautionary actions

Quality Control System is to dispose of suitable procedures to make it possible monitoring of adequate implementation and full respect of GMP.

Quality Control System is furthermore called to set out procedures to prove with documents identification of faults in conformity, possible corrective measures and monitoring on carrying out of same measures, with special attention to their implementation timing.

Company Quality Assurance System is therefore to be realized to get internal control plans and periodical checks on conformity to laws in act on materials to come into contact with food; in the same way, management procedures of non conformity and corrective actions are to be implemented.

B2.2.3. Documentation (art. 7 Reg. 2023/2006/EC)

All documents relating to Quality Assurance System (handbooks, procedures, operating instructions, formulas etc.) and all activities recording (registration of data process, measurement etc.) are to be organized to constitute an archive, papery or electronic, with immediate access or however easy consultation on possible request by competent authorities.

Such archive will gather also documents that guarantee traceability, as for art. 17 of Regulation 1935/2004/EC, copies of conformity declarations delivered to customers in compliance with art. 16 of Regulation 1935/2004/EC and to national laws in act, and provided support documentation. Such documentation will gather also possible proof conditions, calculations and analysis, carried out by internal or external laboratories, useful to demonstrate conformity.

In case of substantial changes in production capable of modifying basic requirements to get conformity or when laws in act references are modified and/or updated, it is to be verified if documentation to Regulation 2023/2007EC has to be updated.

Encl. B2.1

Technical glossary

Reel: Paper ribbon wrapped up on itself around a tube (core).

Paper and board: Material in reels or sheets made out of fibres, mostly pulp (cellulose), with or without the addition of auxiliary substances and adjuvants, produced starting from a paper mixture for removal of water (rarely instead of water an organic solvent is used) through a chain links and subsequent drying process. It is instead preferred to call of board, usually, when grams of sheet exceed 225 gr. for square metre.

Pulp fibre: One of the main constituents of vegetals, in significant quantities in wood and annual plants. Fiber is constituted of an hollowed tube containing pulp developing while plant is growing. As for paper use, they are mainly divided in long fibres (prevailing in conifers) and short fibres (prevailing in broad-leaved). Other main element for wood is the lignin.

Virgin Fibre: Pulp fibre obtained directly from wood and other seasonal plants with chemical or mechanical processes in which there is a separation of fibres and possible removal of lignin. Such removal take place through chemical disintegration. Presence of lignin is therefore unsteady depending on kind of process used (sulphate chemical pulp, or kraft, sulphite chemical pulp, semi-chemical pulp, chemi- thermomechanical pulp, thermomechanical pulp, mechanical pulp). Fibre can be exposed to a later stage of bleaching to get white quality.

Recovered (paper): First raw material for recovery of cellulose fibre for the production of paper. Paper obtained with recovery fibres is called “recycled paper”. Recovered papers are classified below UNI EN Standard 643/2000 for their same composition and origin. It may be subject to selection treatment or directly selected at the origin.

Pulps (more commonly called “cellulose”): Cellulose fibres, usually in form of rough, pressed and wrapped in bales sheets. In common meaning it is referred only to virgin fibres, even if it gathers also recovery fibres.

Formula: Proportion between different raw materials (pulps, auxiliary and charging substances) which are to be measured out during productive process to give paper requested characteristics.

Auxiliary and adjuvants substances: ensemble of non fibrous chemical substances, mainly of natural origin, used to give specific properties to paper or how technological adjuvants of process.

Charging substances (mineral pigments): mineral substances mainly of natural origin such as carbonates, oxides and silicates, reduced in particles. They are used to regulate opacity, smoothness and capacity of absorbing inks both in paper and patination.

Encl. B2.2

FAQ

Q1 Where is it possible to find mention of classical risks connected with paper process related to food contact?

In Technical Document nr. 4 of EU Council Resolution on wrapping paper “Policy Statement concerning paper and board materials and articles intended to come into contact with foodstuffs”, Version 1 (19.12.2002) is enclosed a list regarding paper and board materials and articles intended to come into contact with food, with risks connected and relating prevention measures for wrapping paper and board production. Such list is approximate and cannot be considered exhaustive, as other dangers may be present as we are talking of specific manufacturing or, vice versa, some other risks presented may not appear. As for tissue papers for food contact, one reference is chapter 8.4 of “Policy Statement concerning tissue paper kitchen towels and napkins”, Version 1 (22.09.2004)

Q2 When can we talk ok “starting material”?

With starting material is intended wood (rounds, chips, sawmill waste etc.), pulp or recovered paper

Q3 Where does GMP start for paper and board intended to come into contact with food?

As for paper, GMP obligation starts with phase of mixture preparation

Q4 Until where has paper and board to come into contact with food traceability to get?

For paper and board traceability has obligatory to get until first reel (bobina madre) as also indicated in the *Industrial Guidelines on traceability of materials and articles for food contact by Joint Research Center – Community Reference Laboratory for Food Contact Materials (CRL-FCM)*

Q5 GMPs are to be applied also to tissue papers?

For tissue papers, GMPs are to applied when such products are realized for food contact and, for that use, identified in conformity with laws in act terms.