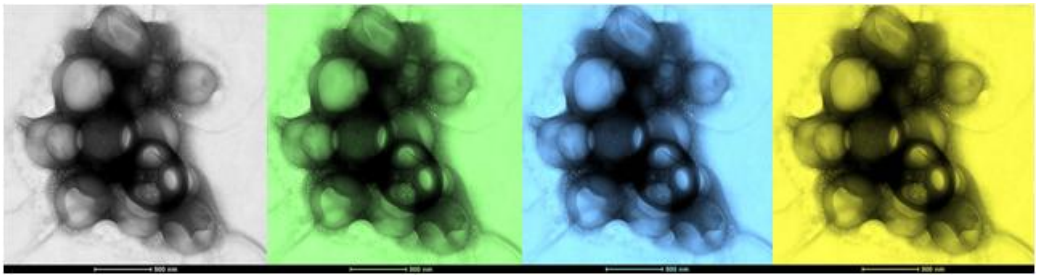
Silver Nanoparticles:

Situation and Perspective for Industrial Application in the Lombardia Region

(an overview*)



(Silver Nanoparticles - CIMAINA)

** Synthesis of the full report, available upon request to the authors.*

Silver nanoparticles: situation and perspective for industrial application in the Lombardia region

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1. Introduction

Final goal of the present study is to understand the relevance and impact (present and potential) of the use of silver in nanoform (nanosilver) on the industry landscape of Lombardia.

Nanotechnologies are still at an early stage of development. Though some nano - related products are already on the (worldwide) market, their number as well as the total quantity of nanomaterials effectively used are limited, apart from very few cases, such as carbon black and synthetic amorphous silica (largely used in the tyre industry).
From an industrial perspective, only in few cases nanomaterials can be considered as *ready to use* material, that end-users can simply buy on t qhe market and implement in their processes and products.
Generally speaking, there is the need of a combination of R&D activities (to develop/improve nanomaterials, scale up, and/or integrate it in the process) as well as a careful evaluation of benefits and risks, related, among others, to technological, economical, regulatory issues that can affect their development.

Therefore the present study looks at the use and application of nanosilver on a global/general perspective, in order to provide benchmark/reference information to industrial players in Lombardia (as well as to stakeholders in general, in particular consumers) both on present and potential application of nanosilver and issues currently at stake for their use and introduction into the market.

Based on information publicly available, the report provides case studies of industry and retailers already using nanosilver for a variety of applications at both international and national level.

In the last chapter, the information collected on a global level is used to evaluate the number of industrial players that could be affected by nanosilver in Lombardia (in terms of deployment/use or competition with other industry). References useful for dissemination of project activities are included in the text.

***Structure of the report**:*

1. General aspects of nanomaterials and nanosilver: definition, characteristics, properties, (available) market figures, regulatory challenges and actions;
2. Information on sectors of application and products currently on the market, case studies on the use of nanosilver: International level and Italy
3. Potential impact of nanosilver on the Lombardia industrial landscape (analysis of the sectors concerned, using ATECO classification, evaluation of number and type of players).

Some specific data in chapter two (claims of companies on nanosilver) and three (number of players for each Ateco category) are included only in the full version of the report.

Methodology:
The report provides a synthesis and assessment of publicly available information collected by international and national sources. In particular:

- International databases on nanotech products;
- Websites of authorities and organization dealing with regulation, monitoring and foresight of nanomaterials and nanotechnology applications;
- Websites of industry and retailers active in the sectors concerned with the application of silver and nanosilver;

- Scientific publication databases (Scopus);
- "Recent Patents on Nanotechnology" Journal (for benchmark data on nanosilver patents).

Italy and Lombardia:

- Website and databases of industry professional association in the sectors of application of nanosilve;
- ISTAT database;
- AIRI/Nanotec IT database of events, publications, contacts about nanotechnology in Italy;
- The Third Italian Nanotechnology Census carried out by AIRI/Nanotec IT.

The search has been performed basing on specific keywords, including silver, nanosilver, antimicrobial, biocidal in combination with the sectors of application and products related to nanosilver. Information and documents collected generally refer to the period 2007 -2013. Websites were visited in the period January-September 2013.

2. Nanotechnologies & Nanomaterials

> *Nanotechnology is the application of scientific knowledge to control and utilize matter in the size range 1 nm to 100 nm, where entirely new physical and chemical, size-related, properties and phenomena can emerge. This often results in new, exciting and different characteristics that can generate a vast array of novel products. [ISO TC 229, 2011]*

Nanotechnologies can play a key role in the value chain of a wide range of products and processes, enabling new components, systems and processes with improved or totally new performances, effectiveness, functionality.

Nanotechnologies – enabled products already on the market generally belong to the so called first and second generation of nanotechnologies (passive and active nanostructures). In short, structural and functional nanomaterials used for technical applications, industrial and consumer products (e.g.; passive nanostructures: materials and surface treatments to provide a variety properties: lightweight, insulation, anti-scratch, anti bacterial, aesthetic, etc; active nanostructures to improve cosmetics, microelectronics components, sensors and other devices, etc).

Despite this kind of use already at hand, nanotechnologies are generally considered at an early stage of maturity, with a medium - long term perspective for a full-fledged market. The global market of nano-related products is estimated at about 200 billion dollars (2009), with a forecasted growth to some 1-3 trillion dollars from 2015[1] and beyond [EC1, 2012].

The number of private enterprises with specific R&D and production activities on nanotechnologies is estimated in the range of 1500 in Europe [ObservatoryNano 1, 2011] and in about 100 in Italy [AIRI Census, 2011]. There are no precise figures about the exact number of enterprises using (as end users) nano-related products, but their number is not negligible and likely to increase with the increase in the production of nanomaterials.

Amongst the plenty nanomaterials (NM) under development, those already on the market are quite few. A recent in depth study from the European Commission [data from SRI consulting, published in EC1, 2012] analysed the most frequently used nanomaterials, in term of the quantity marketed annually.

The global figure provided is around 11,5 million tonnes, with a market value of roughly 20 billion Euro. The large majority (> 95%) of this figure is related to carbon black and synthetic amorphous silica, while aluminium oxide, the next most produced NM, accounts for another 1-2% of the total. NM produced in lower quantity (thousands of tonnes), are barium titanate (BaTiO3), titanium dioxide (TiO2), cerium oxide (CeO2), zinc oxide (ZnO). The figure for carbon nanomaterials (other than carbon black) is in the range of several hundred tonnes. For nanosilver, this reference provides a figure around 20 tonnes/year. Note that figures about NM by different sources can show large differences one with the other (e.g. for nanosilver some sources provide a figure around 300 tonnes/year [Nowack et al, 2011]).

[1]Market fgures for nano-related products refer to the value of products into which nanomaterials are incorporated

Challenges for nanotechnologies and nanomaterials

The peculiar properties of the matter at the nanoscale are the source of novel, advantageous, technological solutions in a large variety of fields, as well as of concerns regarding potential risks for health and the environment.

As for the latter, there are a number of challenges when, developing and using nanomaterials [ObservatoryNano 2, 2012]. In particular:

- The diversity (and complexity) of materials and applications;
- The diversity of properties and characteristics at the nanoscale;
- The limited development of standards and guidance for characterization, risks assessment, management and to support regulation. In particular:
    - limited knowledge on effects on health and the environment of the very different classes of engineered nanomaterials
    - no systematic database on hazards or exposure, or systematic delineation of dose-effects relationship for any given engineered nanomaterials
    - limited quantitative exposure information
- The proprietary nature of information (access to relevant information on type and use of nanomaterials);
- Possibly inadequate statutory authority;
- The stage of maturity and uncertainties on timescale for development;
- The risk benefit balance compared to conventional approaches.

In the last 10 years, there has been a huge effort to tackle these challenges and better understand the potential impact of the different type of nanomaterials and nanotech applications. Though the knowledge has strongly increased, there are still uncertainties, in particular in areas such as terminology, materials characterization, methodologies to evaluate human health and environmental impact.

Several international, regional and national bodies have specific activity to govern nanotechnologies and nanomaterials, providing guidance both on manufacture and use the different type of nanomaterials, and evaluation of risks and benefits.

Regulatory authorities worldwide are deeply involved in evaluating the application of existing regulatory regimes to nanomaterials and nanotechnologies and in considering, whenever necessary, actions to ensure the safety of nano-related products. A clear regulatory framework is fundamental also to help industry in focusing and planning their investment in these technologies.

Europe is at the forefront on nanotechnology regulation, with explicit commitment by the European Commission and several active authorities at the Member States level to investigate these issues. Sectors currently under scrutiny for nanomaterials include [EC1, 2012]:

- **Chemicals and materials (REACH)**
- **Cosmetics**
- **Foods**
- **Biocidal products**
- **Medical devices**
- Pharmaceutical products

- Occupational health and worker safety
- **Environmental safety, waste**

In bold are regulations with the most relevant impact on nanosilver, considering its properties and current use.

Existing regulations apply to materials, articles and products in general, and thus also nanomaterials and nano-related products fall into the scope of these regulation, and manufacturers and producers are requested to ensure their safety. However, uncertainties related to naming, identifying, testing nanomaterials (due to their peculiar properties compared to conventional nanomaterials) are challenging specific assessment and adequate management of their potential risks.

Taking the example of REACH, most of the existing registrations of substances (and related information) does not allow to distinguish whether the substance is in the nanoform or not (as in the case of silver and nanosilver). Amongst the key issues under discussion are thresholds for the registration of substances, currently depending only on the quantity (mass) of the substance produced. Proposals are asking to reduce current thresholds (considering that nanomaterials are generally used in low quantities) and/or consider other parameters, beside mass, that could be relevant in terms of effects of nanomaterials, such as size, size distribution, shape, solubility, surface charge and surface area. These information are considered key to distinguish between the conventional and nanoscale form of the same substance.

Very recently, specific regulatory actions for nanomaterials have been considered regarding cosmetics, foods, biocidal products, while other are under discussion, in particular regarding chemicals. For example in the Cosmetics Directive (in force since July 2013), specific requirements have been included concerning labelling and safety assessment of nanomaterials.

A definition for nanomaterials has been introduced by the European Commission in Oct 2011, in order to be able to identify nanomaterials for regulatory purposes.

Core part of the European Commission definition of nanomaterials is [EC2, 2011]:

> *"Nanomaterial" means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.*
> *In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.*
> *By derogation from point 2, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.*
> *Note: The definition excludes nanostructured materials having an internal or surface structure in the range between 1-100 nm (e.g. electronic components).*

This definition might be integrated with additional information, depending from the needs of the regulation considered. For example, in the case of cosmetics regulation it is specified that requirements for nanomaterials applies only to insoluble or biopersistant manufactured nanomaterials (cosmetics, see ref. [EC3, 2009]) and thus nanosilver is included in this definition.

Despite the official publication of these definitions, there is still an intense debate between regulatory authorities and stakeholders about whether these are sufficient to identify substances that should fall under these regulatory provisions.

The development of standards to better characterize and evaluate Environment Health and Safety issues, and the definition of a clear regulatory regime is fundamental to help industry to better evaluate risks and benefits related to the different type of NM and nanotechnologies applications and to support investments in this field.

Currently, most sources suggest a case by case approach in the evaluation of NM, aiming to assess the risk – benefit of specific type and form of NM in specific condition of use.

Silver and nanosilver

Silver

Silver can be considered a luxury, highly priced good, with a remarkable worldwide market in terms of production and use. Silver properties make it suitable for a range of high added value markets, in particular jewellery/silverware. There has been a large use in photography in the past century, but currently is declining due to digital photography. A relevant market is also that of the electronic industry and, more recently, of the solar energy (mainly organic cells) taking advantage of the conductive properties of silver (and nanosilver as well).

In the last 20 years, there has been an increasing interest for the biocidal properties of silver. According to data from the *Silver Institute*, this type of use accounted in 2009 for about 0,2-0,5% of the global silver consumption. Main applications are filtration (mainly water) and, to a lesser extent, disinfection (pharma and medical devices), textiles, polymers and dispersion and others (data from *Silver Institute in* [DEPA, 2012, Burkhardt et al, 2011]).

Silver is used in different chemical compositions, such as metallic silver, salts or others, and in different physical forms, including particles, suspensions, colloids, coatings. Chemical and physical characteristics strongly influence release of silver ions, that are the main responsible of its biocidal effect. Generally speaking, silver can be considered a broad range biocidal, so suitable for a wide range of applications.

The long history in the use of silver by humans provides a consolidated knowledge about its effects on human health and the environment. As a substance in itself it's considered non toxic for humans. The most remarkable effect is related to the exposure to very high doses, that can cause a disease called argyria (In the past colloidal silver was supposed has a cure for different disease and was ingested in large quantities).
On the other hand, due to its biocidal properties, silver could be classified in certain circumstances as a dangerous substances for the environment. However, hazard for environmental species is strongly influenced by the chemical and physical form as well as transformation of silver particles in the environmental media (speciation) [2].

[2] Extensive description of chemical/physical characteristics and behaviour of silver can be found in references: [Chernousova et al, 2013, EC1, 2012, DEPA, 2012, BUND, 2011, Nowack et al, 2011, PEN, 2008].

As for any other hazardous substance, risk is determined by the combination of hazard and exposure (quantity and way of dispersion into the different environmental media). Several data are available regarding the presence of silver derived from human use in the environment, and specific threshold level are set by environmental regulation. The knowledge and experience on silver, as a substance itself, and on the recent application of silver as a biocidal product, provides a relevant background in the evaluation of risks and benefits of nanosilver.

Nanosilver

There are mainly two aspects that change the behaviour of silver at the nanoscale, compared to conventional silver, and therefore its properties. These are:

- The higher surface to volume ratio. In particular, the larger surface area favours the formation of silver ions and therefore enhance its antibacterial effect.
- The mobility in the human body (and, in principle, in other biological media). Silver nanoparticles could be able to distribute in almost all human organs, as well as to penetrate cell membranes. The increased bioavailability could change the potential impact on human health and the environment, both in terms of hazard and exposure in the different biological media.

The increasing of the surface area is a main reason for enhanced antibacterial effect of nanosilver compared to silver in standard form and because of that, nanosilver is considered for an increasing number of applications.

Silver nanoparticles (close or below 100 nm size) and silver particles (from 100 nm to more than 1µm) are available in different physical and chemical forms, such as silver ion, metallic particles, soluble silver compounds and aggregates that can be found in solution, dispersion, colloidal, suspensions, matrix of different substances (zeolithes, polymers and others).

Size and particle size distribution seems key factors for determining the efficacy of the antibacterial effect. However, the antibacterial properties of silver likely depends also from a number of other chemical and physical characteristics, as well as the condition of use in the product. These properties persist both at the nano and macro scale, though to different extent. Therefore distinguishing how and whether a product is using silver and nanosilver could not be clear cut [Chernousova et al, 2013, Nowack et al, 2011].

Estimates about the production of nanosilver worldwide vary, as anticipated, from 20 tonnes to about 300 tons per year. However, independently from the present estimates, the production of nanosilver will eventually depend from the results of the investigations about its effects on human health and the environment as it will be several times stressed in the following chapters.

3. Products and application sectors of nanosilver

As mentioned above, nanosilver is amongst the most frequently used nanomaterials in consumer products, but in other industrial sectors its use seems limited, at least compared to other NM such as carbon black or silica.

When looking at the products already on the market, it must be considered that so far there hasn't been any obligation (or simple indication) about how and whether to declare the use of nanosilver (and NM in general) in a product. As said in the previous paragraphs, a definition for nanomaterials for regulatory purposes has been introduced only very recently, and is now in force only in few regulations in EU. The definition itself, as well as indication of methods to characterize the type and use of NM in a product, are still under development.

Therefore, identifying and determining the use of nanomaterials/nanosilver in products on the market is a complex and uncertain process. Few data are available (as emphasised by several sources) and even less are publicly available. A source of information is looking at claims for the use of NM (e.g. nanosilver) declared by product manufacturers and retailers. This is the main option used by most existing nanomaterials and nano-related products databases. Another option is the analyses of claims for the use of NM in patents, considering that a relevant patenting activity on a sector is an indicator of the type of products that could be introduced in the market.

As it will be shown by the data in this chapter, the number of consumer products using nanosilver is in the range of few hundreds, a limited figure considering that it refers to the global market. This is also reflected by data on production of nanosilver: though estimates are very broad, quantity seems still limited compared to other substances for industrial and consumer use.

However, in principle, its use could grow very fast and spread worldwide, being related to popular, daily used, products. Several of these products come directly in contact with people, and therefore safety concerns are of particular relevance. Also from the environmental point of view, the use of nanosilver needs appropriate scrutiny, considering that, in specific circumstances, silver in bulk form could be a toxic substance for the environment.

For these reasons there is an increasing attention about the use of nanosilver. Nanosilver is one of the 13 most representative nanomaterials in the OECD WPMN Sponsorship Programme, aiming to evaluate safety dossiers for each of these nanomaterials [OECD WPMN 2010]. Some research bodies authorities in Europe made specific studies to investigate both the impact of nanosilver on health and the environment, and the application of existing regulation (in particular REACH) to nanosilver. Relevant examples are the studies published by RIVM in The Netherlands [RIVM1, 2009] and BUND in Germany [BUND, 2011]. Civil Society Organisation have been also quite active on the matter, examples are the reports from the European Consumers' Organization and European Consumer Voice on Standardization (ANEC) [ANEC/BEUC1, 2010], Friend of the Earth Australia [FoE, 2011], The International Center for Technology Assessment in the USA [CTA, 2007].

Outside Europe, in USA, the Environmental Protection Agency (EPA), within its nanomaterials program, has made specific assessment on the use of nanosilver, looking at this substance for its potential pesticide behaviour in the environment [EPA1, 2010].

All these sources underline that the application of nanosilver in consumer products needs a careful characterization with reference to type and conditions of use and the related potential impacts to human health and the environment. A precautionary approach is considered key both from an industrial and consumer perspective.

This chapter provides an analysis of information gathered by different international databases on nano-related consumer products on the market (few of them specific for nanosilver).

All of these databases used as a search criteria the (public) claim in the use of nanotechnology by the manufacturer, importer, distributor or retailer of the product itself. The methodology of these databases includes search on the Internet and, in limited cases, survey with retailers, shops and producers .

There are different constrains in this approach:

1. Products claims could be imprecise, in terms of type, use, quantity, etc. Whether the products use silver or nanosilver could be unclear;
2. Description of the technology used in a consumer product are generally vague, and in any case written with a market oriented (more than technical) approach.
    - a public statement on the use of nanotechnologies might not be present (it could be considered useless to make it). Rising attention on nanotech safety may discourage companies to use the term for marketing purposes.
    - other general terms could be used (e.g. colloidal silver could be used both for silver and nanosilver).
3. Choice of key words, language (most database use only English) could limit effectiveness of the (internet) search.
4. In the case of survey search, they are time consuming and so generally performed on few contacts, and also response rate are limited.

It's worth noting, regarding point 1), that some studies have performed benchmark analysis of consumer products claiming the use of nanosilver. Various chemical and physical characterizations techniques have been used to investigate type, quantity, and potential release of nanosilver, in some cases also including tests on product use (e.g. washing cycles of a textile product to determine any release of nanosilver during time). In some of these studies, it was not possible to detect the presence of nanosilver (at least in measurable quantities) in the product [DEPA, 2012].

When analysing the data, other critical aspects include:

- Product references changes rapidly: often references and links are no more valid, due to changes in web-links, product descriptions, organisations products portfolio and claims, etc.
- Geographical localisation: generally, databases tends to look at the manufacturer/producer headquarters. However, it's complex (often impossible) to determine whether the product is for the global, regional or local market.
- Comparison between databases: overlaps, classification issues, etc..

There is a limited number of databases listing nano-related products, likely due to the mentioned challenges about the identification of these products on the market[3]. Each of them have some differences in terms of scope, information provided, number of records. Several are the overlaps among them.

Three databases have, in the end, been considered relevant and representative for the aim of the present study, in terms of scope, number and type of records (on nanosilver) included, authority of the organisation. These are[4]:

- **Woodrow Wilson Center (WW - USA):** Nanotechnology consumer products inventory, products available in the US and worldwide market .
- **European Consumers' Organization (BEUC) and European Consumer Voice on Standardization (ANEC) (ANEC/BEUC - Belgium, EU):** inventory of products claiming to contain nano-silver particles available on the EU market (2012 focus study, following 2009 and 2010 inventory of nanomaterials in general).
- **Danish Consumer Council, the Danish Ecological Council and DTU Environment (Nano Taenk , Denmark).** The database is an inventory of products that claims to contains products with nanomaterials or that are marked with world "nano". Products are related to European and worldwide market. All products are readily available to Danish consumers either in stores or via Internet shops.

Considering the uncertainties and approximation just described, the scope of the investigation was not to perform a quantitative analysis, but to identify and prioritise sectors and products relevant for nanosilver, in terms of frequency and type of use, and material characteristics.

The sources mentioned and additional search have been used to gather information on products and organizations active on nanosilver in Italy and Lombardia. Case studies for each sector have been selected and are presented in this chapter.

The information gathered from the databases have been compared with the results of a patent analysis on nanosilver, using a detailed article in the Journal *"Recent Patents on Nanotechnology"*, that has evaluated the use of nanosilver in consumer products looking at patents applications on nanosilver or that can be referred to nanosilver particles [Lem et al, 2012].

The search was made by using a set of key words, including nanoparticles, silver, nanosilver, colloidal silver and others. Using International Patent Classes (IPC) the identified "nanosilver" patents were related to industrial and consumer application sectors.

In the period 1980-2010, the search has identified a total of about 7400 patents, the large majority published since 2000. More than 50% patenting activity is related to the antimicrobial activity of nanosilver, in the area of pharmaceuticals, healthcare, consumer goods, preservatives, sterilization, and water treatment. Focusing

[3] There are, instead, several databases, at regional (EU), national and local level, classifying organizations active in nanotechnologies R&D. However, they do generally provide only organization profiles and indication of research topics, and only few data on products and therefore not useful for the purpose of this study.

[4] The databases are available on: WW: http://www.nanotechproject.org/cpi/ - ANEC/BEUC: http://www.beuc.org/Content/Default.asp?PageID=2142 - NanoTaenk: http://nano.taenk.dk/

only on consumer products, about 1000 patents have been identified by the study. The breakdown in terms of sectors is the following:

- Medical and HealthCare (40%)
- Cosmetics and Personal Care (32%)
- Packaging (7%)
- Electronics (6%)
- Clothing/Textile (4%)
- Food/beverage (4%)
- Filtration (3%)
- Household products (3%)
- Materials (1%)

Top patenting countries include USA, Korea and China (accounting together for more than 80% of total patents), followed by Germany (about 4%) and other countries (RU, EP, JP, GB, TW, UA, IT, IN, FR, DK, ES) [5]. From a qualitative point of view, the data seems to fit well with information retrieved by databases analysis (shown in following paragraph).

Overview of nanosilver-related products

The total number of consumer products using nanosilver is in the range of few hundred (the mentioned databases provided, at the time the website has been visited: 311 products in the WW, 140 in the ANEC/BEUC, 200 in the NanoTaenk). There are a number of overlaps in the US and EU databases, and no remarkable differences in terms of type of products. The reason is likely that most of these products are intended for the worldwide market, considering that:

- products are advertised on the Internet, in English, often by worldwide web retailers;
- some of the most frequent products, in particular in the appliances and cosmetics sectors, are produced by multinational companies or brands.

These companies are often using their nanosilver technology for different products, and these products are counted separately in the databases (e.g. in the ANEC database the 140 products refer to a total of about 70 different companies).

When looking at the countries of origin (producer or retailer country) the majority is from Korea, USA and Germany. They account for more than a half of the products in the two databases. Italy is present with 7 different products (7 products in the WW and 3 in the ANEC/BEUC).

The data are comparable with information from patents, apart from Chinese nanosilver products, that are evidently underestimated by these databases. Reasons could be the language and the fact that many Chinese industries act as suppliers of international manufacturers and retailers, therefore not advertising/selling their products directly on the market.

[5] The article specifies that Chinese patent numbers are over-weighted, due to the limits in patent examinations of the Chinese Utility Model Patents

As shown in figure 1, the use of nanosilver seems to prevail in sectors such as appliances, cosmetics & personal care, clothing and textiles, that overall accounts for about two thirds of the total number of products.

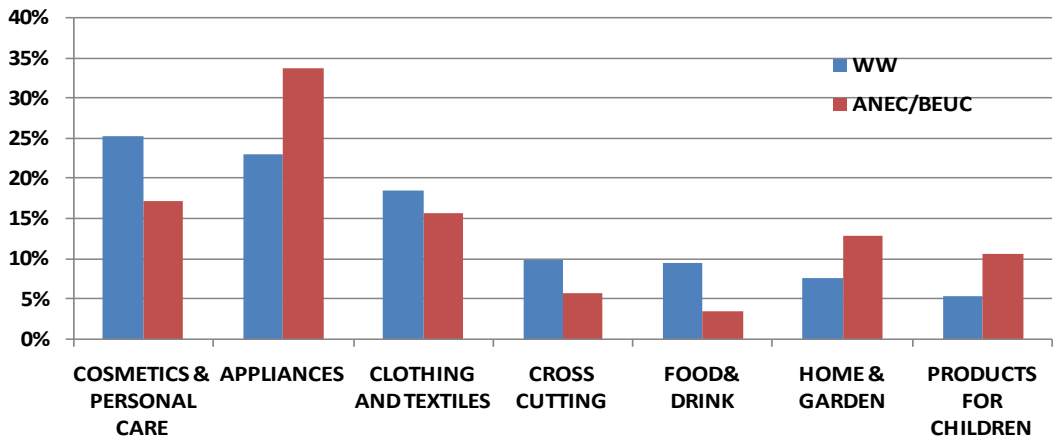

Fig.1: Comparison of the number of products and application sectors of nanosilver in the WW and ANEC/BEUC databases

Figure 2 and the table at the end of the paragraph show a more detailed view, in terms of type of applications and specific products. Amongst the most popular are clothing (underwear and sporting goods in particular), cosmetics (soaps, creams, etc), personal care products (e.g. toothpaste) and appliances (in particular hair dryers), air and water filtration systems, cleaning products (detergents) and basics for babies. Other children products (such as toys) and foods seems to have a minor share (however, their presence is important from the safety and regulatory point of view, considering the type of exposure).

Cross cutting applications, mainly surface treatments for different type of products, in particular in the electronic field, play also an important role.

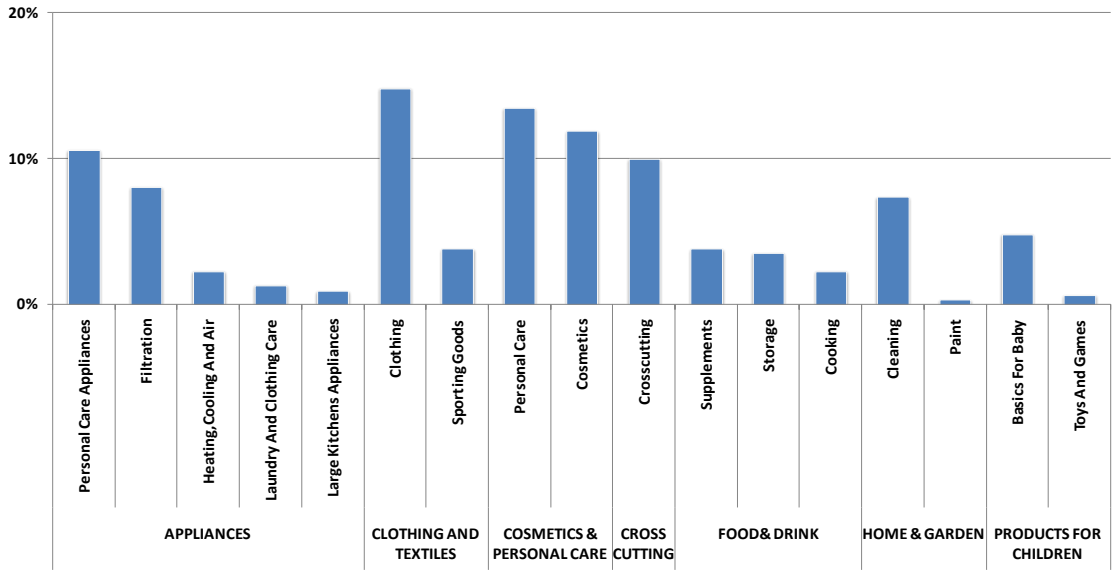

Fig.2: Breakdown of the most frequent category of products included in the WW database

The identified sectors of application fit well with patent analysis [Lem et al, 2012], though with some differences in the shares between sectors.

In particular, the use of nanosilver-related medical textiles (e.g. wound dressing) and medical devices (e.g. catheters) seems largely underestimated by the databases analysis (these type of products may not be classified as consumer product).

Looking at the description of the products given by the manufacturer/retailer, a rough evaluation of the form/type of nanosilver used in the product has been done (data from WW database). This was possible only for some 45% of the identified products using nanosilver. Within them, claimed uses include nanoparticles (5%) and nanoparticles ions (12%), coatings (11%), fibers (6% - where nanosilver might also be used as a coating), nanoparticles in a matrix (6%), colloidal nanosilver (3%) and spray (2%).

Korea and US, followed by Germany and China are the top countries in terms of manufacturers and retailers of nanosilver - related consumer products, as shown in figure 3, and confirmed by the analysis of patents. In the EU, also UK and Poland count on several products. However, it should be pointed out that these data reflect the number of products, not of the companies. Some companies have a portfolio of several products using nanosilver, often based on the same technology, and each of these products could be counted in the database (examples are products from Samsung in Korea, Tenzi, in Poland, Nanotrade in Czech Republic).

Note that figure 4 shows where manufactures or retailers are located, though the market of these products could be broader (often products are available on the internet for the worldwide market).A detailed view of sectors of applications and products using nanosilver is included in the following table.

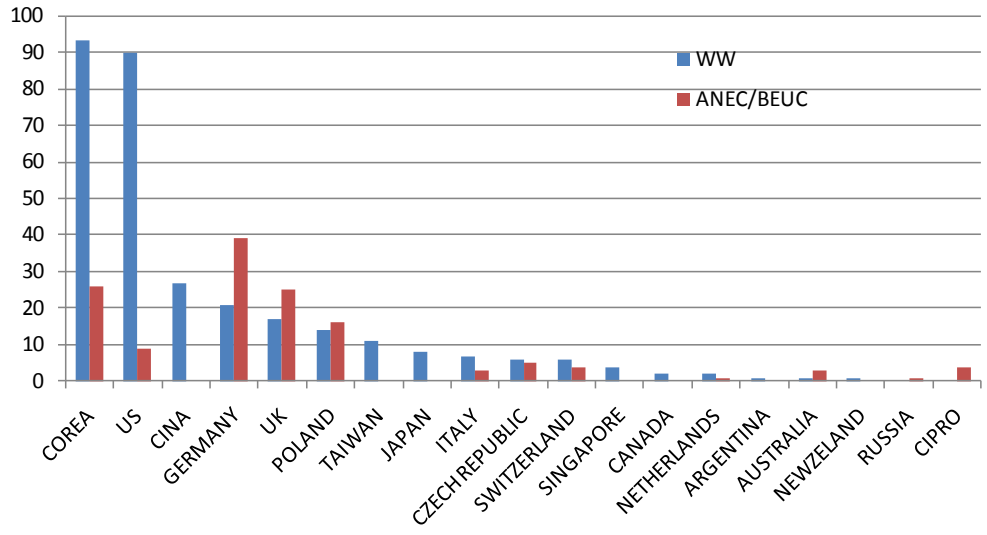

Fig.3: Breakdown of country of origin of the products included in the WW and ANEC/BEUC databases

CATEGORY	SUB- CATEGORY	Products Number (WW/ANEC-BEUC)	KEY PRODUCTS
APPLIANCES			
	**Personal Care Appliances**	**33/26**	**hair dryer, hair straighteners**
	**Filtration**	**25/6**	**air and water filters, vacuum cleaner**
	**Heating, cooling of air**	**7/0**	**air conditioner, air humidifier**
	**Laundry and clothing care**	**4/9**	**washing machines, steam irons**
	**Large kitchens appliances**	**3/5**	**refrigerators**
CLOTHING AND TEXTILES			
	**Clothing**	**46/15**	**underwear, t-shirts, socks, towels, etc**
	**Sporting goods**	**12/7**	**sport clothing**
MEDICAL TEXTILES AND HEALTH RELATED APPLICATIONS			
	**Medical textiles**	**N/A**	**hygiene textile for hospitals settings, bandage and wound dressings**
	**Health related applications**	**N/A**	**implants, catheters, etc.**
COSMETICS & PERSONAL CARE			
	**Personal Care**	**42/6**	**toothpaste, toothbrush, thermal brushes, etc**
	**Cosmetics**	**37/18**	**Skin creams, soaps, deodorants, body lotions**
CROSS CUTTING			
	**Cross-cutting**	**31/8**	**keyboards , mouse, cell phones, cutlery, scissors, sprays**

FOOD & DRINK			
	Supplements	**12/2**	**Dietary supplements**
	**Food storage**	**11/1**	**Food boxes**
	Cooking	**7/2**	**Machines and tools for cooking**
HOME & GARDEN			
	**Cleaning**	**23/16**	**Detergents, sanitizers**
	**Paint**	**1/2**	**antibacterial paints**
PRODUCTS FOR CHILDREN			
	**Basics for baby**	**15/15**	**blankets, cleaning wipes, feeding bottles, detergents, clothing**
	**Toys and games**	**2/0**	**stuffed animals and other toys**
TOTAL		**311/139**	

Nanosilver-related products on the international and national market

The examples of the nanosilver-related products pointed out in the previous paragraph are shortly described hereafter in more detail, including, whenever available, indication also about the industrial players involved[6].

Appliances

That of the household equipment is one of the largest field of application of nanosilver. In products such as refrigerators, hair dryer and steam irons, nanosilver seems to be used as a coating, providing an antibacterial effect by releasing silver ions during use.

In filtration systems, such as in vacuum cleaners and air conditioners, nanosilver seems to be used in the form of both coatings and nanoparticles, somehow embedded in the materials of the product (a vacuum cleaner producer is claiming to have *"particles of antibacterial nano silver in dust bucket").*

One of the most famous nanosilver product is the Samsung washing machine, using a silver plate that is slowly electrolyzed to release silver ions during wash and rinse cycles to "sanitize" clothing. The product was launched in 2003 and started a long debate in the USA, due to the request of the US Environmental Protection Agency (EPA) to consider and regulate it as a pesticide (silver ions might concentrate in waste water treatment plants and kill bacteria used to detoxify the wastewater).

Since then, nanosilver is one of the nanomaterials under scrutiny by EPA[7]. Experimental studies are available evaluating the amount of nanosilver particles released in wastewater by this kind of appliances [Farkas et al, 2011].

Another large (Korean) corporation that made popular the use of nanosilver technology is Daewoo[8], currently using it in particular for refrigerators and air conditioners. Both Samsung and Daewoo are amongst the companies also showing relevant patent activity on nanosilver in the last decades [Lem et al, 2012].

Clothing and Textiles

In clothing and textiles, nanosilver can be used in various forms, incorporating it into the textile during different steps of the manufacturing process, from the processing of the fiber to the textile finishing.

Methods include processing nanoparticles into the fiber, applying a coating or dispersing silver nanoparticles onto the surface of the fiber [DEPA, 2012]. Also non-woven textile can incorporate nanosilver during the production process. Though details on processing methods are generally not explicit in the product declaration, sometime the claim specify the use of a fiber coating.

Products include underwear, socks, fitness T-shirts, towels, mats, mattresses and other daily used textile products. The claim is generally that nanosilver helps to prevent mold, fungal and other infections, kill

[6] The detailed list of products/companies is available in the full version of this report

[7] See EPA webpage on nanomaterials http://www.epa.gov/research/nanoscience/ , and the most recent report on nanosilver Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray (Final Report) http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=241665

[8] Daewoo webpage advertising nanosilver use: http://www.daewooelectronics.com.au/about_dec.asp

bacteria, eliminate odors. Sometime nanosilver content and release is "guaranteed" up to a number of washes.

Clothing and textiles are likely amongst the most promising sectors for the use of nanosilver, as shown by the several and diversified products identified, as well as the many research activities on going in this area [Windler et al , 2013].

Concerns have been raised about the release of nanosilver particles into the environment during washing. Some preliminary studies have been undertaken to assess the release of nanosilver from textiles in a life-cycle perspective[9].

It should be noted that there are different manufacturers, in particular in the USA, producing nanosilver particles and coatings for the textile sector and claiming the safety of their products, and their products are regularly approved by regulatory agencies and fulfilling demanding quality certifications requirements.

Medical Textiles and Health Related Applications

Nano-silver based antimicrobial fabrics can have applications in the medical textiles sector (hygiene textiles) and health-related fields, such for hospital settings (linen, curtains, and other furniture that needs antibacterial properties), or for bandage and wound dressings. In the latter case, both fabric or other type of supports can be used to store silver ions and ensure a time-release mechanism to act against bacteria. Other uses in the medical field includes antibacterial coatings for implants, catheters and others.

Few examples of products using nanosilver have been identified. However, medical and health-related products cannot be considered strictly as consumer products, and might not need to be advertised on the internet. Nanosilver properties are considered very important for bandage and wound dressing to be used in situation of severe burn.

The use of nanosilver in these kind of products needs a careful assessment of the interaction with biological media and more in general the impact on human health. For example, coatings of nanosilver in implants needs both to provide a strong antibacterial action and negligible negative impacts on human cells [Chernousova et al, 2013]. Moreover, most of these products have to address requirement of regulation related to medical devices (generally more stringent that regulations related to consumer products).

Cosmetics & Personal Care

Silver is used since a long time as an active ingredient of a broad range of cosmetics formulations and products for its antimicrobial properties. Its use in the conventional form is allowed in Europe by the EU Cosmetic Directive (the substance is not included in the negative list of non authorized substances).

In the last few years, the nanoscale form of silver seemed to gather increasing interest for cosmetics products such as creams, detergents, deodorants, body lotions, etc. These products claim to have amongst their properties, thanks to nanosilver, antibacterial, disinfection, skin healing and regeneration properties. The

[9] See for example the article "Prospective Environmental Life Cycle Assessment of Nanosilver T-Shirts" [Walser et al, 2011]

form of silver mentioned in cosmetics include silver nanoparticles, colloidal silver, nanosilver formulations and compounds, silver powders, nanostructured silver, etc.

In the personal care sector[10], most popular products seems toothbrushes ,toothpaste, thermal brushes and insoles. Claimed use of nanosilver includes silver nanoparticles, colloidal silver and coatings. For toothbrush, for example, a claim says *"the bristles of the nano silver toothbrush are impregnated with 99,99% pure silver through a novel nanotechnology*".

The cosmetic and personal care sector include an ample range of products that use or could use nanosilver. These products differ in their purposes, markets, end-users, ranging from high end cosmetics produced by large cosmetics companies, to niche products by cosmetic laboratories, as well as formulations sold on by generic web retailers (several of them selling nanosilver colloidal for a range of use and claimed benefits).

The recent introduction of specific requirements for nanomaterials into the EU Cosmetics Directive (in force since July 2013), including labeling of nanomaterials, will likely clarify the overall picture.

The issue of the quantity of silver nanoparticles used/needed to have an antimicrobial effect seems particularly relevant for cosmetic products. From the analysis of patents related to nanosilver, as well as other studies [Lem et al 2012, Chernousova et al, 2013] it seems that, compared to other consumer product, large quantity of the substance are often requested by the application. Some products, foreseeing the release of silver nanoparticles on the skin or other tissues, could be borderline between cosmetics and medical products[11].

It should be noted that, generally speaking, producers of nanosilver formulations often deal explicitly with regulatory and safety issues of their products in the product website, some of them also indicating adoption of specific quality and safety certification procedures.

Cross Cutting

This category refer to coatings, and includes products that might not be easily included in specific application sectors. Nanosilver coatings are generally used to provide antibacterial properties and to disinfect and deodorize surfaces on products such as electronic devices, automobile, textiles, kitchens, bathrooms, children products, etc. These coatings can be applied during product manufacturing (this is generally the case for electronics devices), or during the life of product, using "nanosilver" creams and spray available in the shops.

Food & Drink:

There are two main applications of nanosilver in the food and drink areas: as food contact material for food packaging applications, where nanoparticles can be applied as coatings or bound in the packaging material to provide an antibacterial effect and improve shelf life; as a food additive/supplement, where nanoparticles,

[10] Note that most of the products in the category personal care, such as toothpaste, are classified as cosmetics from the point of view of the EU cosmetic directive.

[11] Specific guidance documents are available to clarify the application of EU Directives to borderline products. See for example http://ec.europa.eu/consumers/sectors/cosmetics/cosmetic-products/borderline-products/

often colloidal, are claimed to provide general health benefits (e.g. dietary supplements based on colloidal silver are present on the market since a long time, and nanoparticles are claimed to further improve properties of these products).

A limited number of products have been identified in this category, in particular in the EU market. This is likely due to the stringent regulatory requirement regarding the food sector in the EU legislation, that limit the introduction of novel substances in these type of products. Moreover, some of these regulations have been recently updated, introducing specific requirements for nanomaterials, including safety evaluation and labeling aspects, that will make even more complex to use them in such products.

However, the interest on this type of applications, in particular packaging, is confirmed by the relevant patent activity on nanosilver in this area [Lem et al, 2012].

Home & Garden:

This category mainly refer to typical chemical industry products, such as surface detergents and other cleaning products, as well as paints intended for consumer and sometime also industrial use. Nanosilver are used in product formulations to provide purification, disinfection, and antibacterial features.

Products for Children

The antibacterial properties of nanosilver could be interesting for a multitude of different type of products related to babies, such as toys, blankets, mats, cups, bottles, cleaning wipe, humidifiers and others.

Thus, though the products using nanosilver is limited compared than in other sectors, its number could, in principle, increase rapidly.

Safety aspects in this area are of particular concern. A recent in depth article has carried out an analysis of several products for babies using nanosilver, to investigate potential release and health effects of silver under real conditions of use [Quadros et al, 2013].

Nanomaterials Producers/Retailers

There are plenty of companies worldwide offering nanomaterials to the market, some of them producing also metal nanoparticles, among which nanosilver. Most of them, in particular in the case of nanosilver, aims to provide materials for a variety of applications and markets. Detailed materials data sheets, whenever publicly available, provide useful information on silver nanoparticles characteristics, applications and safety aspects.

4. Perspectives on the industrial application of nanosilver in Lombardia

As shown by a recent report from Confindustria[12], Lombardia is the most industrialized Italian region, with more than 800,000 companies. About 100,000 of them operate in the manufacturing sector.

Manufacturing firms account for about 20% of the national total, with a similar percentage in terms of employees, and pertains to them almost a third of the value added produced by the domestic manufacturing industry. Exports generated by the region is also about one-third of the national total.

The main characters of the industry in Lombardia are: industrial strength, variety of productions throughout the different product supply chains, innovation capacity, international openness.

A high spending on R&D and a number of patents above the national average indicate the readiness to innovation.

Among the leading sectors are a variety of areas related to the metal and mechanical sectors, that account for about half of the employees and enterprises of the region[13]. Of great importance, in terms of number of enterprises, employees and impact in relation to the national economy, are also textiles and clothing, rubber and plastic materials, food and beverages, furniture and wood (see figure 4). Note that Lombardia, for each of these sectors, represents between 20% and 40% of the national total in terms of businesses and employees.

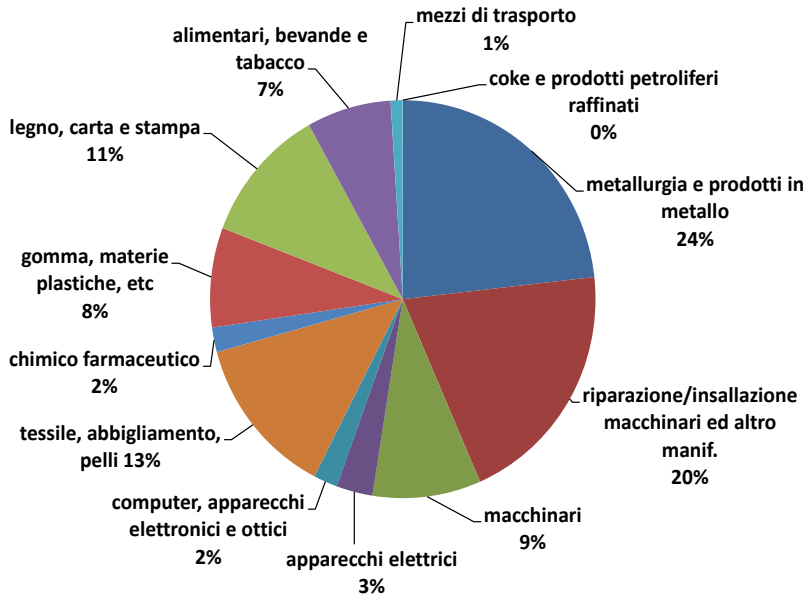

Fig.4: Main manufacturing sectors in Lombardy (number of companies for each manufacturing sector vs. total number - "unita locali" year 2009, ATECO classes, data from [Confindustria, 2012])

In order to evaluate the relevance and the implications of the use of nanosilver in Lombardia, the areas of applications and the key nanosilver–related products identified in the previos section have been correlated with manufacturing sectors, as provided by the ATECO classification (Ateco 2007[14], corresponding to the international classification NACE Rev. 2[15]).

[12] La Lombardia, economia in breve, Confindustria Lombardia, nov 2012 [Confindustria, 2012]

[13] They are (see figure 5): *metallurgia e prodotti in metallo, riparazione/installazione, macchinari ed altre attività manifatturiere, macchinari, apparecchi elettrici computer, apparecchi elettronici e ottici*

It should be noted that only a rough evaluation is possible, considering that most ATECO categories are much broader than the specific products related to nanosilver. Starting from the ATECO classes identified, more detailed figures could be obtained by dedicated, in depth analysis. The correlation is the following[16]:

- Appliances: *included in Ateco 27 and 28[17], in particular 27.51, 28.25, 28.29.9*
- Textile & Clothing: *included in Ateco 13 and 14[18], in particular 13.92.1, 14.12, 14.14, 14.14.29, 14.31*
- Medical textiles and health related applications: *included in Ateco 32 and 21[19], in particular 32.5 and 21.20*
- Cosmetic & Personal Care: *included in Ateco 20[20], in particular 20.42*
- Cross Cutting: *included in Ateco 25 and 26[21], in particular 25.71, 25.99, 26.20, 26.30*
- Food & Drink: *included in Ateco 10, 22 and 28[22], in particular 10.86, 22.22, 28.93*
- Home & Garden: *included in Ateco 20, in particular 20.3, 20.41*
- Products for Children: *included in Ateco 22, 32, 14 and 17[23], in particular 22.19, 32.40, 14.19.29, 17.22*

These sectors can practically all take advantage from the use of nanosilver. Considering the analysis performed, the most interesting areas for the use of nanosilver in Lombardia seems to be textile & clothing, appliances, and some of the activities related to chemicals (e.g. paints, cosmetics, etc). Besides them, healthcare is also a sector where nanosilver could provide a real added value to existing products, and with important industrial national players operating in the region.

[16] Detailed correlation tables are available in the full version of this report

[17] Ateco 27: fabbricazione di apparecchiature elettriche ed apparecchiature per uso domestico non elettriche ("apparecchi elettrici" in fig. 4); Ateco 28: fabbricazione di computer e prodotti di elettronica e ottica; apparecchi elettromedicali, apparecchi di misurazione e di orologi ("computer, apparecchi elettronici ed ottici" in fig. 4)

[18] Ateco 13: industrie tessili and Ateco 14: confezione di articoli di abbigliamento; confezione di articoli in pelle e pelliccia (part of "tessile, abbigliamento, pelli" in fig. 4)

[19] Ateco 32: Altre attività manifatturiere (part of "riparazione/installazione macchinari ed altro manif." In fig. 4); Ateco21: fabbricazione di prodotti farmaceutici di base e di preparati farmaceutici (part of "chimico farmaceutico", fig 4)

[20] Ateco 20: Fabbricazione di prodotti chimici (part of "chimico farmaceutico", fig 4)

[21] Ateco 25: fabbricazione di prodotti in metallo (esclusi macchinari e attrezzature) ("metallurgia e prodotti in metallo" in fig. 4); Ateco 26: fabbricazione di computer e prodotti di elettronica e ottica; apparecchi elettromedicali, apparecchi di misurazione e di orologi ("computer, apparecchi elettronici e ottici" in fig. 4)

[22] Ateco 10: Industrie alimentari (part of "alimentari, bevande e tabacco" in fig. 4), Ateco 22: fabbricazione di articoli in gomma e materie plastiche ("gomma, materie plastiche, ecc" in fig 4); Fabbricaz. di macchinari ed apparecchi ("macchinari" in fig. 4)

[23] Ateco 22: fabbricazione di articoli in gomma e materie plastiche ("gomma, materie plastiche, ecc" in fig 4); Ateco 32: altre industrie manifatturiere and Ateco 17: fabbricazione di carta e di prodotti di carta (part of "legno, carta e stampa" in fig 4); Ateco 14: confezione di articoli di abbigliamento; confezione di articoli in pelle e pelliccia (part of "tessile, abbigliamento, pelli" in fig 4)

5. Conclusions

Nanosilver has been intentionally and explicitly used in a range of products since at least 10 years (the launch of first Daewoo and Samsung appliances). Some authors state that its use goes back to several years before, and refer to products regularly registered and authorized by regulatory bodies since a long time.

Looking only at claims of usage of nanosilver from manufacturers/retailers, the number of products using nanosilver already available in the market looks limited, though they refer to a vast range of sectors of application and types.

Many of them are widely diffused and of daily use and the use of nanosilver could therefore rapidly grow.

Nowadays the largest sectors of application seems appliances, clothing and textiles, personal and health care, coatings. Relevant areas of potential application of nanosilver are also cosmetics, the foods sector and products for children.

Those sectors have a relevant role in the industrial landscape of Lombardia and the eventual use of nanosilver could become an important issue in the innovation pipeline. The survey has highlighted that there are companies active in the above said sectors, present in the Region, that are already employing nanosilver. Their number is presently very limited, but the peculiar properties of nanosilver could make more widespread its use.

For that to happen, however, an answer must be given to a number of challenges which go from the benefits when compared to conventional approaches, to potential risks associated with it and related regulatory requirements, consumer perceptions and acceptability.

These aspects largely change depending upon application, form and type of nanosilver, and condition of use, but the issue cannot be avoided.

There is, particularly in Europe (but also elsewhere), an increasing attention for safety issues related to nanomaterials. This is reflected in the regulatory frameworks, in first place in the sectors of cosmetics, foods and products for children, that will likely delay/hinder commercialization of nano-related products in these areas.

The *"Safety by Design"* concept is gathering increasing attention at European and International level to help addressing these issues. This approach requires to consider all safety issues since the very beginning of the research and innovation process and the design of a new product.

Specific tools and actions are being developed to this end and this approach should be taken into account when willing to develop products using nanosilver.

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