

THE SUSY SAFE PROJECT

Final Report 2005-2007

**edited by
The Susy Safe Working Group**

FrancoAngeli

ECONOMIA - *Ricerche*

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Siegfried Klaue, Freie Universität Berlin, Germany.

Robert Nuij, Directorate-General for Health & Consumers, European Commission, Bruxelles.

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Florence Weill, Commission de la Sécurité des Consommateurs (CSC), France.

Acronyms used

CEN: European Committee for Standardization
CENELEC: European Committee for Electrotechnical Standardization
CRF: Case Report Form
CSC: Consumer Safety Commission
DG SANCO: Directorate General for Health and Consumer Affairs
EFTA: The European Free Trade Association
ENT: Ear, Nose and Throat
ESFBI: European Survey on Foreign Bodies Injuries
FB: Foreign Body
FPCI: Food Products Containing Inedibles
FYROM: Former Yugoslav Republic of Macedonia
ICD: International Classification of Diseases
ICD9-CM: International Classification of Diseases, Ninth Revision, Clinical Modification
ICD931 - Foreign body in the ears
ICD932 - Foreign body in the nose
ICD933 - Foreign body in the pharynx and larynx
ICD934 - Foreign body in the trachea, bronchi and lungs
ICD935 - Foreign body in the mouth, oesophagus and stomach
IDB: Injury database
QC: Quality Control
RAPEX: Rapid Alert System for Non-Food Products
WP: Work Plan

1. Participating institutions

The Susy Safe project (SURveillance SYstem on SuffocAtion injuries due to Foreign bodies in European children), aimed at establishing a surveillance registry of control of non-food foreign body injuries, was co-financed by the European Commission (DGSANCO, Direction Consumer Affairs) and by five European Countries (Cyprus, Finland, France, Germany, and Italy); Italy, in particular, was also the coordinating Country of the project.

The project lasted for 2 years, from the 1st of February 2005 to the 30th of April 2007 (thanks to a 60 days deadline extension). During the 27 months of the project various activities were carried out, some of them strictly connected to the project objectives and others, which were secondary (i.e. coordination activities among the project members, economic activities and scientific activities aimed to publicize the project and publish the results together with the analysis techniques).

The bodies participating in the project were:

Italy - Project coordinator Country

Official body:

Ministero dello Sviluppo Economico - Direzione Generale per l'Armonizzazione del Mercato e la Tutela dei Consumatori, Ufficio D1 - Coordinamento delle attività per la sicurezza e la qualità dei prodotti - Antonella D'Alessandro

Technical body:

Università di Torino - Dipartimento di Sanità Pubblica e Microbiologia - Dario Gregori

Università di Torino - Dipartimento di Statistica e Matematica Applicata "Diego de Castro" - Roberto Corradetti

Università di Siena - Dipartimento di Scienze Ortopedico-Riabilitative Radiologiche ed otorinolaringoiatriche, Università di Siena - Desiderio Passali

Cyprus

Competition and Consumer Protection Service - Ministry of Commerce,
Industry and Tourism - Hadjiluca Phroso

Finland

Official body:

Ministry of Trade and Industry - Kristian Tammivuori

Technical body:

Helsinki University Central Hospital - Anne Pntkäranta

France

CSC - Commission de la Sécurité des consommateurs - Florence
Weill

Germany

Charité Universitaetmedizin Berlin - Klaue Siegfried



Table 1-1 Participating centers

<i>Doctor</i>	<i>Hospital</i>	<i>Country</i>
<i>European</i>		
Andreas Melis	Aretaeion Hospital	Cyprus
Olga Kalakouta	Medical and Public Health Services, Ministry of Health	Cyprus
Ivo Slapak	Childrens University Hospital	Czech Republic
Per Caye-Thomasen	Gentofte University Hospital of Copenhagen	Denmark
Anne Pitkäranta	Helsinki University Central Hospital	Finland
Philippe Contencin	Necker - Enfants Malades	France
Stephane Pezzettigotta	Hopital Armand Trousseau	France
Christian Righini	CHU A Michallon	France
Jocelyne Derelle	CHU Nancy	France
Magali Duwelz	Sos Benjamin - Observatoire National d'Etudes des conduites à risques	France
Roehrich Bernhard	St. Joseph-Hospital	Germany
Goktas Onder	Charite Campus Virchow	Germany
Volker Jahnke	Charite Campus Virchow	Germany
Petra Zeriacks	Praxis	Germany
Nikola Simasko	Democritus University School of Medicine	Greece
Domenico Grasso	Burlo - Garofolo	Italy
Nicola Mansi	A.O.R.N. Santobono Pausilipon	Italy
Cesare Cutrone	Azienda di Padova	Italy
Giuseppe Villari	Azienda Ospedaliera G. Rummo	Italy
Italo Sorrentini	Azienda Ospedaliera G. Rummo	Italy
Marilena Trozzi	Ospedale Pediatrico Bambino Ges	Italy
Elisa Gaudini	Policlinico Universitario Le Scotte	Italy
Alessandro Vigo	Azienda Ospedaliera OIRM-Sant'Anna	Italy
Angelo Camaioni	Azienda Ospedaliera Complesso Ospedaliero San Giovanni - Addolorata	Italy
Rico Rinkel	VU Medical Center	the Netherlands
Mieczyslaw Chmielik	The Medical University of Warsaw	Poland
Manuel Pais Clemente	Hopital S. Joao	Portugal
Mihail Dan Cobzeanu	Sf. Spiridon	Romania
Adelaida Iorgulescu	Grigore Alexandrescu	Romania
Miorita Toader	Grigore Alexandrescu	Romania

<i>Doctor</i>	<i>Hospital</i>	<i>Country</i>
Caius-Codrut Sarafoleanu	Sf. Maria Hospital	Romania
Dan Cristian Gheorghe	Maria Sklodowska Curie	Romania
Beata Havelkova	Public health authority of the Slovak republic	Slovak Republic
Janka Jakubikova	Children's University Hospital	Slovak Republic
Miha Zargi	University Medical Centre Ljubljana	Slovenia
Felix Pumarola	Vall DHebron	Spain
Lorenzo Rubio	Hospital Ruber International	Spain
Pontus Stierna	Huddinge University Hospital	Sweden
John Graham	RNTNEH	UK
Sadie Khwaja	Royal Manchester Children's Hospital	UK
<i>Extra-European</i>		
Ranko Mladina	University Hospital Salata - KBC	Croatia
Enas Elsheikh	Suez Canal University	Egypt
Ljiljana Sokolova	Institute for Respiratory Disaeses in Children	FYROM
Jane Buzarov	Institute for Respiratory Disaeses in Children	FYROM
S Muazzam Nasrullah	Service Hospital, Paediatric ward	Pakistan
Sakda Arj-Ong	Ramathibodi Hospital	Thailand
Erdinc Aydin	Baskent University Ankara Hospital	Turkey
Metin Onerci	Hacettepe University	Turkey

2. Foreward

Robert Nuij

Over the last years the focus in the European Commission has moved towards what is sometimes called “science-based policy making” and better regulation; as a consequence, we are under increasing pressure, not necessarily because it is essential to justify decisions, legislations, or activities, but because in order to do so it is extremely important to have a sound knowledge, a sound basis in terms of information for every area that needs to be investigated, in terms of Commission work but naturally also in terms of Consumer Safety. Now that more formal recognition has been given in the new Consumer Policy Strategy for the years 2007-2013, it is important to remark the importance of data collection at an EU level. We would like to see from a Commission perspective data that are representative for all the Member States. So, it will be important to create a harmonized system for collecting such data and this is important to improve the evidence base for risks analysis related to Product and Service Safety.

Therefore, our key objective is to ensure that we have relevant, up-to-date, representative, accurate, systematic information, related to accidents and injuries for consumer products or related to consumer products and any provision of consumer service.

The Injury Database is an European injury service surveillance system based on accidents and Emergency Department data. Currently there are twelve Member States actively involved in it, with seven others undertaking pilot projects to see how they can contribute to this system. So, although it is not an EU-wide system, in the sense that it doesn't cover all Member States, it gives nevertheless a very good representative sample of the situation as regards accidents and injuries in the EU. Such database can give an idea of the products causing problems, as e.g., bicycles, roller skates, swings etc. among products in Play and Leisure Activity or ladders or household ladders among products causing accidents in the domestic work area. However, knowing that a specific product

causes an injury is not enough: it is necessary to know the injury mechanism, the injury mechanism, what consumers are doing with these products and if there is a way to actually address the problem at a European level.

The IDB can not necessarily provide all the needed data, so it would be necessary to look specifically at the areas of interest to find out the required information. The DG SANCO will probably do this in co-operation with State holders, working with people that do have the required data, whether they are Member States, or Universities or Industry Associations. On the one hand, there is the IDB, and we are trying to create additional sources of information by developing new initiatives and networks in specific areas, where we believe we need further work.

As regards these additional sources it has to be said that this is a really very wide area in terms of what is available. One of the things that we hope to do and we are already working on, is to see what kind of Databases already exist in this area and try to improve access to them, to find a way to allow people to have access to those data. We will prioritize what we hope will bring concrete results in short to mid-term. So, we will start looking at priority areas (we know out of studies conducted in the past which those areas are) in terms of services and also of products obtained out of the IDB. We are looking to develop these European networks and systems to collect additional data responding to specific needs and there are different ways to achieve this goal; (i) looking at issues, (ii) specific pilot projects, like the Susy Safe Project, where an issue can be investigated in order to try to find representative data. There are different areas, which can be investigated, areas known for presenting problems. In the area of services, e.g. we have done studies on Playgrounds, Amusement Parks etc., to try and dig a bit deeper into certain areas to understand what the real situation is. Another example is the European Poisons Centres we are in touch with to see whether we can set up a project together in order to get data out of what they receive in their area of work.

The Susy Safe Project, as already mentioned, is one of the projects that came up partly because Member States propose it to us. We now have a large number of cases that have been gathered, making this the largest Database now worldwide in this area. A big success in

itself. In terms of participating countries, the project started off with 5 Member States participating and the institutes that are delivering data into the system are dislocated in 16 different countries. There are also a number of countries even outside the EU, so it has spread quite significantly. In addition, although it is not a success yet, what of course we are looking for would be pointers in terms of injury prevention: this entire data gathering is interesting in itself, but we would like to know what that means for e.g., a manufacturer who is making a certain product, which has small parts attached to it. So it is this kind of area, where we would need to look in terms of what would be of interest for us.

3. Introduction'

Antonella D'Alessandro and Giuseppe Inguì

The General Directorate for Product Safety and Quality of the Italian Ministry for Economic Development was in charge of coordinating the project “Susy Safe”. The General Directorate was created in 1997 with the aim of encouraging actions in three priority areas including product safety with the exception of foodstuffs and drugs.

The idea for the project “Susy Safe” dates back to 2004 and was subsequently developed under the aegis of the European Union with the aim of establishing a surveillance registry for child suffocation due to foreign bodies’ ingestion.

Among the various Italian Ministries involved in product safety issues, the Ministry for Economic Development submitted its candidature to the European Union in 2004 to become Lead Partner in the project “Susy Safe”, since it is the Ministry for Economic Development to be charged of coordinating and to be competent for the products of interest of this project, which do not fall within the legislative and surveillance scope of other Ministry (for example drugs, food, cosmetics, etc.). The group of products that can potentially be harmful to a child due to suffocation is generally indistinct: there is no specific product type that may inevitably generate such risks. Nevertheless, based on the information contained in the database, it appears that an array of products may lead to suffocation: coins, buttons, toys, and so on. Therefore by virtue of its competence and coordinating function the Ministry for Economic Development submitted its candidature to become Lead Partner in the project “Susy Safe”.

The project was set up in 2005 and its first phase ended in the early months of 2007. Several subjects have made this project possible: the University of Torino, that provided scientific and technical assistance, as well as the collection and analysis of data;

¹ All the material in this book is derived from the recordings of the speeches hold at the final Workshop of the Susy Safe Project, on the 27th of March, 2007.

Prof. Dario Gregori, who supported the Ministry also through a dedicated University unit working on project implementation; the General Directorate for Health and Consumer Protection and, specifically, Unit B3 - Product Safety, first in the person of Mr. Delogu and currently of Mr. Soro; Mr. Robert Nuij in charge of project “Susy Safe” for the DG SANCO. Special thanks should also be addressed to Mr. Francesco Piccarreta of the Italian Permanent Representative’s Office in Brussels, who acted as liaison between the offices of the Ministry and the European Commission.

The project was funded partly by the European Commission and partly by the Italian Ministry for Economic Development. The project was also supported by the University of Torino and by the four countries participating in the project: Cyprus, Finland, France and Germany, whose funds have contributed particularly to disseminate information on the project. In France, in particular, the project was effectively implemented at national level through the distribution of project information brochures.

The database was created also thanks to the efforts of all participating countries, who have contributed their cases, thus becoming partners, though without taking part in project funding. These countries are located in various continents, an element that provides a clear definition of the project’ scope.

Special thanks should also be addressed to the internal staff of the General Directorate for Product Safety and Quality of the Italian Ministry for Economic Development, and to all the officials, who have worked for two years on the implementation of the project and have remained constantly in touch with the DG SANCO, the University of Torino and the four participating countries, in order to ensure the best, fastest and most effective solutions to streamline and harmonize procedures among four countries that not only speak different languages, but are the expression of different legal systems. Their task was not always easy particularly in terms of paperwork comprehensiveness and accuracy. Specifically, it was Mr. Inguì, who most often, compared to his colleagues, contacted the various project units and he is probably the most committed to this activity.

Over the past two years the Ministry and the project partners have had several opportunities to meet at various intermediate workshops.

The following chapter will illustrate the results of the project and their significance. Italy, the Lead Partner in this project, is proud of having promoted the establishment of the first surveillance registry in the world that has collected and brought the problem of suffocation due to foreign-bodies to the fore.

Now the partner countries have been invited to participate to what is known as “phase two” of the project that can be regarded as more delicate than the phase one. The first phase of the project consisted on work, based essentially on the good will of the funding Countries and those Countries that voluntarily took on an active role in supplying data for the establishment of the database. The phase two requires the partners to work instead on several fronts. Clearly, it will be necessary to continue supplying data to the database because the surveillance registry consists of a historical set of data but requires a constant inflow of data to remain updated. The current challenge requires the setting of a few objectives: firstly, the data needs to be analyzed in order to become relevant in terms of its impact on production. It appears evident that there are products that may lead to suffocation and death and we are in no position to influence their production. For example, as regards suffocation due to the ingestion of a coin or a button, little can be done on the production front. Indeed, the diameter of a one-cent coin cannot be expected to be changed nor can the production of buttons be halted altogether worldwide. For other product groups, however, a scientific-technical study could significantly contribute to raising awareness in the production stage and, even earlier on, in laying down technical provisions. Therefore the analysis of this data will hopefully enable the European Commission to request that regulatory bodies review, implement, revise, and improve technical specifications that are a support or at least a guideline most serious producers are highly unlikely to brush aside.

Naturally, projects such as this one must also have an impact on the consumer world. The “Susysafe” project website targets two user groups: the consumer, who has access to part of the website, and the subjects intending to supply information, who have access to other parts of the website. The second phase of the project calls for the active participation of consumer associations not only in terms of

their potential supply of data to the surveillance registry but most significantly to disseminate downstream all the information that emerges from this database. In Italy, as it probably was the case in the other countries, consumer associations were informed of the existence of this project, but perhaps they failed to fully understand if and how they can contribute to this database, also due to the fact that consumers experiencing an event as traumatic as the choking of a child due to the ingestion of a foreign body hardly ever contact consumer associations. The reason more likely lies in the fact that the problem is fortunately solved at home or at the hospital and the case is therefore regarded as clinical only. An evident short-circuit occurs between consumers and consumer associations. Indeed the consumer association is the subject of reference for those consumers, who generally turn to it to deal with a number of other issues (e.g. time-sharing or consumer credit or a travel package) but in case of injuries of this nature consumer associations do not come to represent the consumer as a safeguard of his or her interests. It is a fact that consumer associations in all European countries are generally intended to safeguard the consumer's economic interests, while the case in point presents interests that are not economic but related to the health of a child. Therefore PHASE 2 of the project will require a greater effort to make consumer associations aware of their interest in conveying information and also possibly supplying the data they may collect to the database as well as their role in raising awareness among consumers of the objective that consists in enhancing adults' awareness on this issue. Italy has again submitted its candidature as Lead Partner. The Ministry for Economic Development was pleased to learn that the number of Countries that have expressed their interest in participating to the project has increased compared to phase 1.

As previously mentioned the Product Safety and Quality Unit oversaw the project coordination activities acting as an interface between Italy and the other partner Countries and was also in charge of relations with the University of Torino and the European Commission.

The significant results obtained by the Susy Safe project will be presented in detail in the following chapter. 7296 cases of suffocation