

POSITION PAPER

EUROPEAN CONSUMER SAFETY NEEDS SOLID INJURY DATA



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SUMMARY



EVIDENCE-BASED PREVENTION NEEDS INJURY DATA

Targeted prevention needs data about the frequency and severity of injuries, as well as on the concerned population group and circumstances, i.e. products, activities or locations involved in the events.



A COST-EFFECTIVE SOLUTION TO INJURY SURVEILLANCE IS AVAILABLE

The systematic collection of injury data in emergency departments of hospitals, on which the EU-IDB is based, remains the most cost-efficient way to provide solid estimates of the number of patients in Europe and information to inform the standardisation process.

To read more: <https://bit.ly/34X9h4C>



IMPROVING CONSUMER PRODUCT SAFETY NEEDS SPECIFIC INFORMATION

The consumer safety sector has information needs similar to those relating to road and workplace safety.



THE US CONSUMER PRODUCT SAFETY COMMISSION'S SURVEILLANCE SYSTEM (NEISS) PROVIDES AN EXAMPLE

CPSC today provides a comprehensive information gathering system and clearing-house for stakeholders through a user-friendly web-gate open for everybody, unlike the EU-IDB that is in danger of complete collapse.

The way forward

To re-establish a reliable evidence-base for consumer safety, it is necessary for:

01.

DG JUST to take back **the responsibility for the European injury surveillance system on products**. The responsibility for the system dealing with public health indicators can stay with DG SANTE.

02.

Handling of data at EU-level, the operation of the joint database and the provision of a **user friendly access tool to data** for the IDB database to be secured. Queries need to be answered quickly, precisely and without significant costs.

03.

The Parliament, Member States and the European Commission to create a **legal framework** supporting Member States in **collecting and sharing data** to achieve a high quality, representative and up-to-date data sample for the entire Single Market.

01 | BACKGROUND



11 MILLION INJURIES ANNUALLY IN THE EU RELATED TO CONSUMER PRODUCTS

The safety – or the lack of safety – of consumer products plays an important role in the frequency and severity of injuries. In the EU, about 20 million unintentional injuries (“accidents”) occur at home or during leisure time activities annually [1]. These are injuries not related to paid work, traffic or violence. In more than 50% of these injuries (about 11 million injuries annually), products are involved (the rest involve e.g. animals, other persons, plants or natural ground surfaces).



HUGE POTENTIAL FOR SAVINGS THROUGH BETTER PRODUCTS

This does not necessarily mean that the products involved in these accidents are unsafe in terms of the General Product Safety Directive (Directive 2001/95/EC), but it does demonstrate the benefits that could be won from enhancing the safety of products, e.g. through better design, maintenance or use. The prevention of just 10% of consumer product related injuries would save around 1.1 million injury cases. The savings in costs for medical treatment alone has been estimated to be 3 billion Euro [2].



EVIDENCE-BASED PREVENTION NEEDS INJURY DATA

Targeted prevention needs data about the frequency and severity of injuries, as well as on the concerned population group and circumstances, i.e. products, activities or locations involved in the events. It is clear that, without reliable information on risk factors, evidence-based priorities regarding population groups, products or settings cannot be set. A rational risk assessment requires the quantification of the likelihood of an injury, the predictable average severity of an injury and the vulnerability of the average person at risk. Without understanding the interoperation of the characteristics of a product, its use and its typical users, strategies cannot be developed on how to enhance its safety, including new or revised standards [3].



CONSUMER SAFETY HAS SPECIFIC NEEDS FOR INFORMATION

Data on fatalities and medical data on non-fatal events are not enough for this purpose. Only each 170th injury leads to death and medical data do not contain much information on the external causes (the detailed circumstances of the events). The need for specific injury surveillance systems on relevant external risk factors was recognised long ago in the areas of road traffic and safety at work. Due to the specific needs for information, these sectors have developed their own systems to provide meaningful and statistically reliable information for evidence-based prevention policies. The consumer safety sector has similar needs.



THE EUROPEAN SURVEY ON PRODUCT RELATED INJURIES HAS A LONG HISTORY

In the 1980s, this led to the implementation of hospital-based surveillance systems: the National Electronic Injury Surveillance System (NEISS) in the USA, and the European Home and Leisure Accident Surveillance System (EHLASS) in the EU (later renamed to EU-IDB (European Injury Database)). As with NEISS, the EU-IDB is based on a specific data dictionary (coding system) with a strong focus on the consumer products involved [4]. By 2003, a central databank and a web-gate to the EU-IDB were implemented [5].



MANY SUCCESSES IN THE PAST

EU-IDB data shaped many consumer safety initiatives. IDB data have substantially supported the implementation of the General Product Safety Directive; improvements to child care articles and children's furniture; the Toy Safety Directive, the Low Voltage Directive, the Machinery Directive, the Construction Products Regulation, the Personal Protective Equipment Directive, the REACH Regulation on chemicals and the respective subordinate product-specific standards [6].

For example, these helped lead to the reduction of:

- Fractures and brain injuries among children through use of shock-absorbing surfaces in playgrounds, and specific safety requirements for baby-walkers, bunk beds, high chairs and home trampolines;
- Fires and burns caused by children through use of child-resistant cigarette lighters;
- Poisonings and corrosive injuries through use of child-resistant packaging for pharmaceutical products and household chemicals;
- Strangulations through safety regulations on clothing drawstrings and blind cords;
- Brain and spinal cord injuries through use of better bicycle helmets and infant seats for bicycles;
- Amputations of fingers through use of safety installations for wood-splitters and lawn-mowers, and reductions of crush and shear points in garden furniture;
- Scalds and electric shocks through use of mechanisms to store the electric cable of household appliances such as kettles.



THE STRONG FOCUS ON CONSUMER PRODUCT SAFETY WAS LOST FROM THE EUROPEAN INJURY SURVEILLANCE SYSTEM

Owing to such successes, the European injury surveillance system, which was proving to be extremely valuable in setting consumer safety policies, was targeted to support other assignments and functions. In 2003, the political control was transferred from the consumer sector to the public health sector, a sector that pursues priorities other than detecting unsafe products and improving consumer product safety. The scope of the system was expanded from home and leisure accidents to all injuries (including violence). Instead of aiming for one representative data sample for the entire single market, each country was expected to collect a representative national data sample in order to produce comparable national health indicators. A series of projects, co-funded by the EU Health Programme, helped to realise these ambitions, but the new directions neglected the original assignment of providing information for consumer safety.



THE BASIS FOR EVIDENCE-BASED CONSUMER SAFETY HAS ERODED

In 1997, 14 of 15 EU Member States collected and shared data on products, but this number had dropped to seven (of 28 Member States) by 2019. The joint sample of reported cases is no longer representative for the Single Market of now 32 countries (EU-27 plus CH, IS, NO, LI & UK). The European Single Market, the world's largest trading market, lacks a coherent injury surveillance system on consumer products. Today, consumer safety policies in Europe have a random gestation again, based on various information sources, such as consumer complaints, media reports, death certificates and household surveys, so that data are not now comparable between countries or registers, due to the lack of a harmonised methodology and classification. Evidence is drawn from incomplete puzzle with important pieces missing [7].



INEXPENSIVE REVITALISATION IS POSSIBLE

The systematic collection of injury data in emergency departments of hospitals, on which the US-NEISS as well the EU-IDB is based, remains the most cost-efficient way to fill the gaps and provide solid estimates about the number of patients in Europe and detailed information to inform the standardisation process. Valid estimates on frequency and severity are necessary for rational, evidence-based decision making on consumer safety policies as well as their evaluation. This has been recently reconfirmed by a study carried out by the EC's Joint Research Centre, commissioned by DG JUST [8].



THREAT OF ENTIRE LOSS

Now, even the future of the eroded EU-IDB is at stake. DG SANTE has announced that it is ending its hosting of IDB data, and will close the web-gate in 2020, due to budget restrictions. All data collected from 2002 onwards will eventually be lost, and the future EU surveillance system on product related injuries will depend entirely on the goodwill of the countries that presently operate the system.



THE US MODEL

By comparison, since the 1980s, the US government - through the Consumer Product Safety Commission (CPSC) - has continuously improved its system, the quality of coding and sampling, as well as access to the data and their use. CPSC provides today an efficient service centre, a true information clearing-house for producers, traders, standards development organisations, consumers and researchers, e.g. through a user-friendly web-gate, which actually is open for everybody [9].



02 | CALL FOR REVITALISATION OF THE EUROPEAN SURVEY ON PRODUCT RELATED INJURIES

In order to re-establish a reliable evidence-base for consumer safety in the European Single Market, it is necessary for:

1.

the consumer sector, i.e. DG JUST (Justice & Consumers), **to take back the political responsibility** for the weakened but extant European injury surveillance system on products. The political responsibility for the injury surveillance system, dealing with public health indicators, can stay with DG SANTE (Health & Food Safety);

2.

central services for the IDB database to be secured (i.e. handling of data at EU-level, the operation of the joint database and the provision of a user-friendly access tool to data), with help from the new Consumer Programme 2021-2027. Stakeholders (industry, standardisation bodies, consumers & researchers) need to have their queries answered quickly, precisely and without significant costs;

3.

Parliament, Member States and the Commission to strive for a legal framework, which supports Member States in collecting and sharing data on injuries involving products, based on a common methodology, with the aim of achieving a high quality, representative and up-to-date data sample for the entire Single Market.



REFERENCES AND LINKS

- [1] Report “Injuries in the European Union 2013-2015”: https://www.eurosafe.eu.com/uploads/inline-files/IDB%202013-2015_suppl%20to%206th%20edition%20Injuries%20in%20the%20EU.pdf
- [2] Article “Injury data collection: An effective tool for helping to cut the societal costs of injuries”: <https://www.eurosafe.eu.com/uploads/inline-files/IDB%20as%20effective%20tool%20for%20cost%20saving%20measures.pdf>
- [3] Guideline “EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76))”: <https://ec.europa.eu/docsroom/documents/17107?locale=de>
- [4] IDB-Full Data Set (IDB-FDS) Data Dictionary: https://www.eurosafe.eu.com/uploads/inline-files/IDB%20FDS%20Data%20Dictionary%20May%202017_0.pdf
- [5] Web-gate to the EU IDB (public and restricted access): <https://webgate.ec.europa.eu/idb/>
- [6] Web-gate to European standards: https://ec.europa.eu/growth/single-market/european-standards_en
- [7] Joint call “The need for a pan-European accident and injury data system”: https://egmf.org/wp-content/uploads/2016/10/Joint_call_for_a_pan-European_accident_injury_data_system.pdf (annexed)
- [8] Radovnikovic A, Geiss O, Kephelopoulos S, et al: Assessment of the opportunities for increasing the availability of EU data on consumer product-related injuries. Injury Prevention 2020 May 5; doi: 10.1136/injuryprev-2020-043677. <https://injuryprevention.bmj.com/content/early/2020/09/28/injuryprev-2020-043677.long>
- [9] Web-gate to the US National Electronic Injury Surveillance System (NEISS): <https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data>

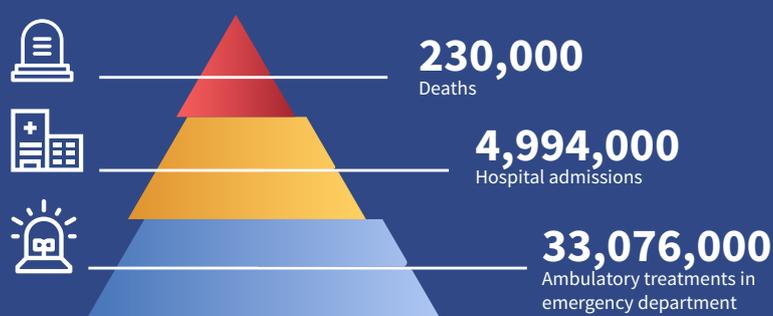


“HOW THE EU-IDB CAN SUPPORT CONSUMER SAFETY”

INJURY: A HUGE HEALTH AND SOCIAL BURDEN

Injuries due to accidents or violence constitute a major public health problem globally and also within the Member States of the European Union. Within the EU-region of 28, each year injuries result in an estimated 230,000 deaths, 5 million hospital admissions and a further 33 million emergency department (ED) attendances, totalling 38 million medical treatments in hospitals [1]. Despite of the magnitude and the severity of the problem, injury surveillance systems in the EU are not yet sufficiently well developed to accurately quantify the burden of injuries on individuals, health services and society in the EU-region.

Figure 1: The injury pyramid for the European Union [1]



Injury prevention policies tend to focus on fatal injuries, as death is the most severe consequence of an injury and statistics about the causes of death are well established and available. Most of the targets of EU and national policies with respect to road traffic safety, safety at work and child safety have been primarily focused on the reduction of deaths. However, deaths are only one aspect of the total injury problem; for every person killed, many more are seriously injured with some being permanently disabled and many more again suffer minor injuries and short-term disabilities. For the entire EU-region the overall direct medical costs are conservatively estimated at 78 billion EUR annually [2].

Not only are the demands on national health budgets immense, but there are also costs in terms of lost economic opportunity and personal suffering. It is increasingly acknowledged that deaths are only one measure of the magnitude of the injury problem. Non-fatal injuries are increasing in importance in terms of both societal and economic costs as well as loss of

productivity. Consequently, there is a growing need for additional targets related to the reduction of non-fatal injuries, in particular those leading to permanent impairments.

Most injuries are unintentional, caused by external risk factors linked to human activities and their physical environment. These external circumstances determine which policy sector bears the main responsibility for prevention policies. Traffic policy provides the framework for traffic injuries, while labour policy is responsible for safety at work. For the huge remaining number of unintentional injuries – frequently summarized as “home and leisure accidents” or “consumer accidents” – it is less clear which policy sector has the lead. More than 52% of all non-fatal injuries (or about 20 million annually) and about 49% of all fatal injuries are consumer accidents (Table 1). In spite of this fact, the biggest shares of national and EU budgets for injury prevention are dedicated to road safety and safety at work, while much less is invested into the safety of consumers.

Table 1: Estimated number of injuries & crude incidence rates in the EU-28 by severity and domain of prevention [1]

Domain	UNINTENTIONAL INJURIES ("ACCIDENTS")			INJURIES DUE TO VIOLENCE		ALL INJURIES
	Home and leisure	Road	Work	Self-harm	Assault	
Deaths	113,861	31,069	4,386	60,017	4,175	232,451
Death rate (per 1000)	0.2239	0.0611	0.0086	0.1180	0.0082	0.4571
%	48.98%	13.37%	1.89%	25.82%	1.80%	100.00%
Admissions	2,649,655	572,881	310,307	209,841	246,792	4,993,847
Admission rate (per 1000)	5.21	1.13	0.61	0.41	0.49	9.82
%	53.06%	11.47%	6.21%	4.20%	4.94%	100.00%
Not admitted	17,148,424	2,793,229	3,275,573	338,049	1,080,045	33,075,571
Rate of not admitted cases (per 1000)	33.72	5.49	6.44	0.66	2.12	65.04
%	51.85%	8.44%	9.90%	1.02%	3.27%	100.00%
All ED attendances	19,798,080	3,366,109	3,585,879	547,890	1,326,837	38,069,418
All ED attendance rate (per 1000)	38.93	6.62	7.05	1.08	2.61	74.87
%	52%	9%	9%	1%	3%	100%

Note: Cases where the domain of prevention is unknown are not displayed separately.

CONSUMER PRODUCTS: SAFETY MATTERS

In most accidents leading to injury, external agents play an important role, and in many cases these agents are manufactured objects (“non-food products”). Products are involved in one or the other way, either through triggering the incidence (e.g. when an unseen step causes stumbling), causing the injury itself (e.g. when razor edge of a radiator causes a cut) or elevating the risk in another way (e.g. when the use of a mobile phones distracts the attention). Some consumer products (in particular safety devices and personal protective equipment) function in the opposite direction and decrease the injury risk. Figure 2 shows the share of

consumer products involved in the start of home and leisure accidents leading to injury (role as so-called underlying objects).

Among home and leisure (consumer) accidents with specified products, 60% involve consumer products in the proper sense; in the remaining 40% involve e.g. other persons, animals or natural ground surfaces. The cases with specified underlying products in the proper sense give a picture of which group of products are mainly involved in causing home and leisure accidents (figure 2) [3].

Figure 2: Objects triggering home and leisure accidents [3]

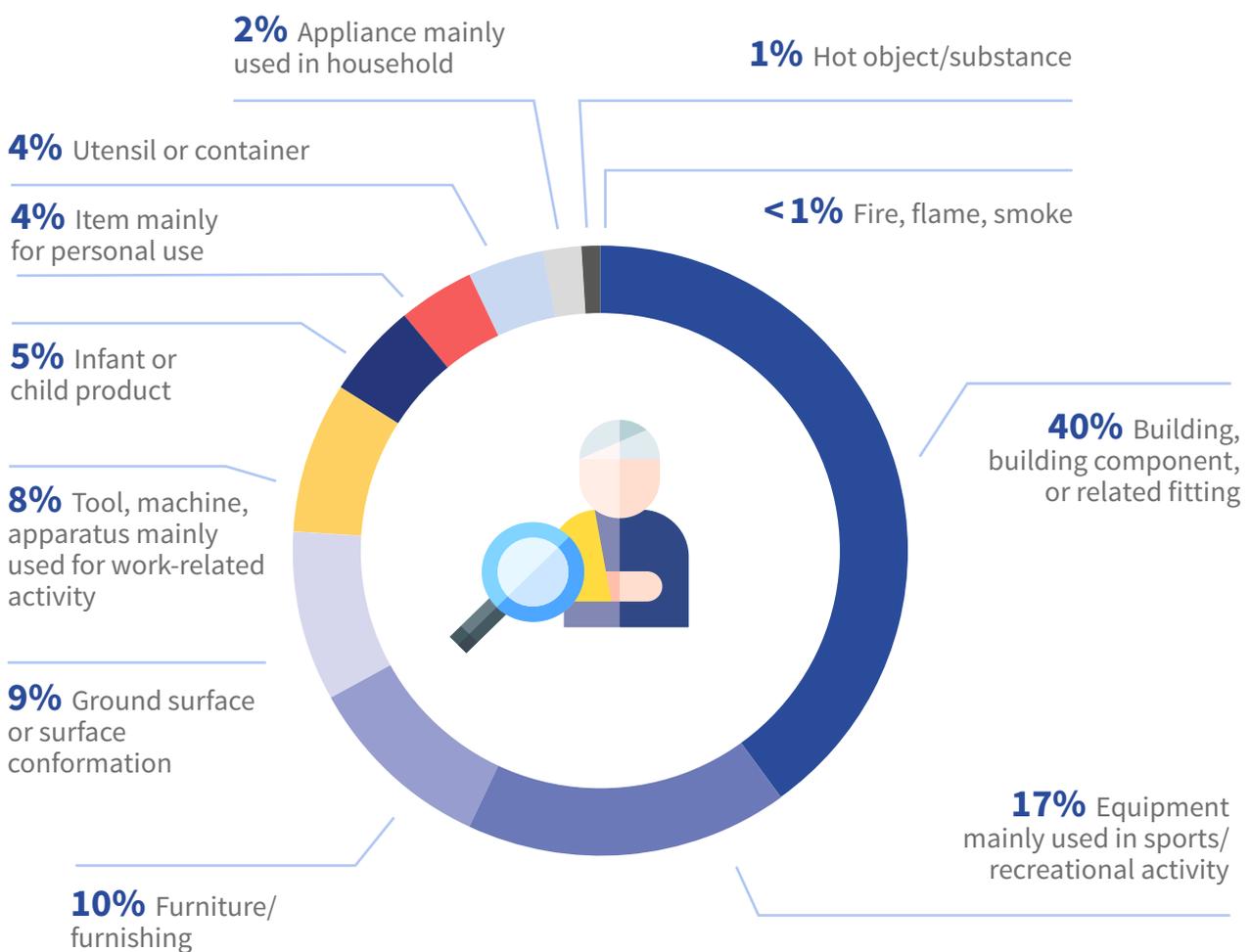


Figure 2 illustrates the importance of product safety. Product involvement does not mean that involved products are unsafe, but the high percentage indicates that enhancing the safety of products can have an important impact on public health. Of course, targeted prevention, e.g. the modification of product design or user instructions, needs much more than just such percentages or counts.

The prevention of just 10% of consumer product related injuries would save 1.1 million injury cases. The savings in costs for medical treatments has been estimated to be 3 billion Euro.

WHAT DATA ARE NEEDED, WHAT ARE AVAILABLE AND WHAT ARE USED?

Most injuries are preventable through better design of products and services and better guidance of consumer behaviour. Reliable and up-to-date accident and injury data are of great importance to a wide range of stakeholders including manufacturers, importers and distributors, enforcement authorities, standards developers, prevention agencies and consumers. The single market requires EU-wide harmonized safety standards and risk assessment procedures.

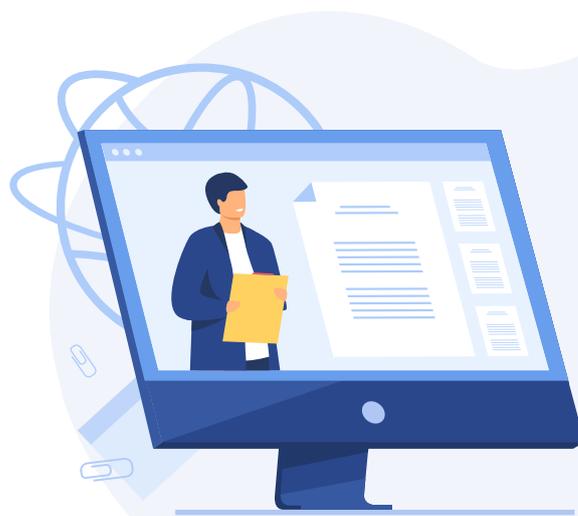
Detailed information on the circumstances of injury events can help to reveal the presence of dangerous products in the market, opportunities for the improvement of widely accepted product design, or help to improve the information and education of consumers. This information is essential for a targeted allocation of resources in market surveillance and consequently to maximize the impact of consumer safety policies in terms of reducing costs of treatment of injuries, hospitalisation or incapacity to work.

Any targeted prevention needs data about the frequency and severity of injuries as well on the concerned population group and circumstances, i.e. products, activities or locations involved in the events. It is perfectly clear that without reliable information on risk factors you cannot set *evidence-based* priorities regarding population groups, products or settings. A rational risk assessment requires the quantification of the likelihood of an injury, the predictable average severity of an injury and the vulnerability of the average person at risk. Without understanding the interoperation of characteristics of a product, its use and its typical users, you cannot develop ideas how to enhance its safety [4].

EU-wide actions against unsafe products are mainly based on notifications from Member States. Core information system is the Rapid Alert System for Dangerous Non-Food-Products (RAPEX), which is based on extremely varying information sources, ranging from consumer complaints, notifications from business competitors, and findings of market surveillance to voluntary product recalls of business operators [5]. This system is well established, but characterized by contingency and subjectivity, it is necessary *but not sufficient*.

Notifications frequently lack information on the potential impact in terms of an evidence-based risk assessment, and hazardous products, which are not notified, do not get identified. The individually perceived chance of a physical damage can differ enormously from the objectively existing chance. Unusual events generate more attention than common situations, even when common situations lead to much more human suffering. Practical politics – also in the area of consumer safety – is challenged by the need to respond to the perceived *as well* as to the real safety needs.

Rational risk assessment requires information on the severity of an average injury event, the expected frequency of such events and the capability of potential users to perceive and handle the risk (vulnerability). The current system of notifications needs to be amended by data, which allow for a rational assessment of the frequency, severity and vulnerability.





In 2015, the Directorate General for Justice and Consumers (DG JUST) invited the Joint Research Centre (JRC), Directorate F-Health and Consumers, to provide scientific and technical support through a study on “Injury and Accident data collection in support of consumer product safety and market surveillance”, which explored opportunities for increasing the availability of information on injuries caused by unsafe consumer products. The study was based on a review of existing data collection practices in EU and opportunities arising from the use of novel IT technologies [6].

Alternative information sources are e.g. poison centres, insurers, firefighters, media reports, social media discussions, search histories of search engines, death certificates and health care services. It is well known that data from poison centres, insurers and firefighters are not standardized, hardly internationally comparable and frequently incomplete. Use of media reports, discussions in social media and search histories in search engines seem to be promising, but are not explored yet. Well explored is the utility of health – mortality and morbidity – data.

Experiences from many countries and more than 40 years show that surveillance systems in primary health care, in particular in accident and emergency departments of hospitals, provide the best opportunity to collect needed information on large numbers of patients with sufficient specificity and quality at the lowest costs. However, existing registration systems need to be amended and enriched in order to gain the needed information [7].

Most available health data tend to focus on the outcome, i.e. diagnoses, treatment and consumed

resources, but much less on causes, risk factors and circumstances, which have caused the injury event and its consequences. The main mission of the health sector is to provide the best possible treatment, and not to investigate and register external circumstances (risk and safety factors) of injury events. Targeted injury prevention such as modifying product design, adapting building regulations or influencing consumer behaviour need this additional information through dedicated surveillance systems. For a long time, traffic and labour safety policies have been based on dedicated complementary injury surveillance systems, also needed for consumer safety policy.

The most important source of information for a rational risk assessment is the analyses of injury events, which have taken place in recent past. This strategy cannot be applied to entirely new products, but real innovative products are rather rare, and most common products are used for many years without substantial changes of construction and design. For most consumer products (toys, child products, furniture, electrical appliances, sport equipment, building components, etc.) the systematic collection and analyses of injury data is the key strategy.

For many years, consumer safety authorities, industry, consumer interest groups, standardisation bodies and public health authorities have called for an injury surveillance system for the European single market, which complements the rapid alert system with solid statistical information on frequency and severity of product related injuries and needed details on specific product related risk factors [8].

PRODUCT RELATED INJURY SURVEILLANCE SYSTEM: STRENGTHS AND LIMITS

Main advantages of the system

- ➔ **Support of product safety enforcement:** The relevance of pop-up issues can be checked quickly: Magnitude of a product related problem, average severity of injury and vulnerability of average victims can be assessed.
- ➔ **Support of new specific safety approaches:** The analysis of circumstances of accidents and injury mechanisms provide insight, what aspects can be improved, even for well-established products, which are not to be considered as unsafe.
- ➔ **Support of targeted injury prevention:** Population at risk, target groups for information can be identified (also national differences); priorities can be set on a rational basis; changes in product related risks can be monitored, e.g. also for the evaluation of EU-level measures.
- ➔ **Rather low costs per case:** Emergency departments see large numbers of injury patients, for a sufficiently large number of cases a sample of 3-10 hospitals is sufficient per country. Survey costs per case are up to ten times higher.

Limits of the system

- ➔ **Limited specificity:** In emergency departments it is hardly possible to identify specific products (e.g. through pictures, producer, brand or product number) and to gain solid information on the exact use, age of the product or where it has been purchased. The system is not suitable to follow up specific cases.
- ➔ **Fatalities are not covered:** Immediately dead victims are not brought to emergency rooms and most severely injured persons can hardly be interviewed. Additional sources for information on fatalities remain needed, e.g. death certificates or systematic analyses of media reports.
- ➔ **Entirely new products:** Detection needs active notification by attentive staff, as the data dictionary is necessarily lagging behind the reality.
- ➔ **Additional costs:** The proper recording of all requested data can hardly be expected as routine task of ordinary emergency department staff. Interviewers (coders) need to be trained and additional labour of hospitals needs remuneration and national budgets.

POLICY BACKGROUND AND LEGAL CONTEXT

The need for a European injury surveillance system has long been recognised by policy makers, but the allocation of the necessary budgets did not follow the ambitions.

Main decisions are:

- ➔ WHO-EURO-Resolution on the Prevention of Injuries 2005 [9]
- ➔ EU Recommendation on the Prevention of Injuries and the Promotion of Safety [10]
- ➔ EU Regulation 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [11]
- ➔ Communication from the Commission on 20 actions for safer products [12]
- ➔ EU Regulation 1338/2008 on Community statistics on public health [13]
- ➔ European Parliament's Resolution on Revision of the General Product Safety Directive and Market Surveillance [14]

Calls for accident data collection and injury surveillance have been recurring at both European and international level. The World Health Organization (WHO) recognised the need for attention and investments in injury surveillance with an important resolution of the WHO Regional Committee for Europe in 2005 (WHO-EUR/RC55/R912) [9].





To tackle the problem of fragmentation and incompleteness of data on injuries, the EU Council in 2007 issued a Recommendation on the prevention of injury and the promotion of safety that invited Member States to improve the usage of the existing data on the national level, and engage in development of additional injury surveillance tools, in order to obtain comparable information. It also invited the European Commission to establish and support the community-wide injury prevention and surveillance activities. The document [10] recommended EU Member States to:

- ➔ Make better use of existing data and develop where appropriate injury surveillance and reporting tools to obtain comparable information, monitor trends and efficacy of preventive measures, assess the need for other actions.
- ➔ Set up national action plans for preventing injuries, initiating interdepartmental and international coordination. Such plans should pay special attention to vulnerable groups, sports and leisure injuries, injuries caused by products and services, violence and self-harm.
- ➔ Engage in activities for promotion of injury prevention and safety in schools, health institutions etc.

An evaluation of the outcomes of the ‘2007 Recommendation’ was carried out in 2011: it highlighted the important role played by the Recommendation in intensifying the availability of data and setting up systems for data collection. However, the report suggested further harmonisation of surveillance and reporting, further investments in EU countries which had not yet developed systematic injury data collection systems, as well as adaptations in the classification of priority areas to improve comparability and reduce

overlaps. This evaluation report has never been published.

A reference to the importance of monitoring accidents and injuries, more widely, can be found in the Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [11]. Under Article 18, the Regulation requires Member States to “establish adequate procedures in order to [...] monitor accidents and harm to health which are suspected to have been caused by those products; [...]”. It was not further specified how this should be done.

A Communication from the Commission to the European Parliament, the Council and the Economic and Social Committee on a multi-annual plan for the surveillance of products in the EU, 20 actions for safer and more compliant products are indicated. In one of the proposed actions, the European Commission commits to examine the costs and benefits of an EU accident/injury database containing a platform for both complaints and injuries. The Communication was adopted by the Commission as part of the proposed legislative package on Product Safety and Market Surveillance in February 2013 [12]. However, an evaluation study has not been carried out yet.

A regulation of the European Parliament and the Council set the legal framework for Community health statistics. One subject, which needs to be covered is “accidents and injuries, including those related to consumer safety, and whenever possible, alcohol- and drug-related harm” [13]. The necessary implementing provision has not been released yet.

The Resolution of the European Parliament on the revision of the General Product Safety Directive and market surveillance [14] states: “The Parliament urges the Commission to establish a public Consumer Product Safety Information Database, including a platform for complaints, if possible based on already existing regional and national systems in the Member States; takes the view that this will raise awareness of dangerous products across borders in the internal market and allow consumers to notify the competent authorities electronically of dangerous products; believes that the database could be formed by developing existing databases such as the European Market Surveillance System (ICSMS) or the Injury Database (IDB); stresses the need for the database to have a legal basis, and for reporting from the Member States to be mandatory; calls for the establishment of an accident statistics system founded on this database, from which mandatory

annual reports will be published; calls for the database to be publicly accessible, while ensuring the necessary confidentiality for businesses”. So far, these requests have only been partly implemented.

On the international scene, the OECD Working Party on Consumer Product Safety has also recognised the importance of improving injury data availability as a tool for protecting consumers and proposed the establishment of a platform for global pooling of injury data (Global Injury Data portal), modelled on the US NEISS system [15].





BRIEF HISTORY AND CURRENT STATE OF IMPLEMENTATION

A sufficiently big number of cases can only be recorded at reasonable costs in the health care facilities. International experiences of the past 45 years show that accident and emergency departments of hospitals (EDs) provide the best way to gain the needed information. Here most of the potentially severe injuries get treated first. Functioning injury surveillance systems, which serve the needs of consumer safety, are based on ED data and complemented by mortality data and data from specific sources such as poisons centres.

World-wide the best example of a functioning injury surveillance system for consumer safety is the National Electronic Injury Surveillance System (NEISS), which is operated by the U.S. Consumer Product Safety Commission (US-CPSC). For more than 40 years, the US-CPSC provides stakeholders in industry and trade, administration and research, as well as media and consumers with evidence-based information, direct access to injury data as well with analytic reports on specific topics [16].

Efforts to establish a similar injury surveillance system with a focus on consumer safety are hardly younger. Already in the 1970s similar systems, also based on data from EDs of hospitals, have been developed in the UK (Home Accident Surveillance System HASS), in the Netherlands (Privé Ongevallen Registratie PORS) or in the Nordic Region (NOMESCO coding system for accident monitoring). Based on these models, a common European coding and sampling system home and leisure accidents was developed in the 1990s under control of the consumer directorate of the Commission, with the name European Home and Leisure Accident Surveillance System (EHLASS). From 1993 onwards, EHLASS data were centrally collected by the Commission, and e.g. in the years 1996-1998 fourteen countries (out of EU-15) delivered data to the joint EHLASS database. At this time there was no web-portal for users and the number of users at EU-level remained very low. The historic data 1993-2001 are not available anymore.

By 2003 the technical, financial and political responsibility shifted from Consumers to Public Health, and the EU subsidizing of national data collection was terminated. In consequence, the number of participating countries dropped from fourteen to six in 2004, while in the same year the number of EU Member States increased from 15 to 25 (EU-25). By means of the Public Health Programmes 2003-2007 and 2008-2013 a series of projects were carried out in order to revitalize the system, however toward a different direction. The scope was expanded from home and leisure accidents to all injuries (including violence), an electronic databank and a web-portal for data users were created. The name of the system changed from EHLASS to European Injury Database (IDB). Until 2008 all IDB data were so-called Full Data Sets (IDB-FDS), which means that all records contained detailed information on involved products as needed for consumer safety.

In addition to the traditional Full Data Set (IDB-FDS) – this is the dataset which contains data on involved products – an additional new Minimum Data Set (IDB-MDS) was introduced in 2008 with a view to facilitate the collection of large numbers of records as needed for valid public health indicators (national incidence rates). The number of participating countries increased substantially to 25 in 2013. Since 2009, there are actually two IDB-systems, one based on IDB-MDS, which mainly serves the public health information needs, and IDB-FDS, which mainly serves the consumer safety needs. IDB-MDS indicators can be retrieved through the so-called public access, but the IDB-FDS data can be accessed only after a somewhat bureaucratic procedure, through the so-called restricted access [17].

By 2014 the EU co-funding for the central operation of the system was substantially reduced and by 2017 completely terminated. The EC Health directorate decided to terminate the support for all thematic health data networks and registers (like IDB). Health statistics shall be concentrated in the statistical office of the EU (Eurostat), and remaining relevant registers

with thematic health data shall be transferred to a future European Research Infrastructure Consortium on Health information, which is planned to be created sometime in the 2020s.

Since 2017, the operation of the IDB data exchange has been entirely dependent on the voluntary contributions of participating countries. Due to the decreased central support and data protection concerns, the number of IDB-FDS-data sharing countries eroded to seven in 2019. Moreover, a survey among users of the “restricted access” app at the EU IDB web-gate revealed that the “restricted access” does not support useful analyses, e.g. cross-tabulations or reading the narratives. As DG SANTE does not have resources for implementing the requested improvements it decided to terminate the hosting of IDB-data and to shut down the IDB-portals by 2020. Fortunately, this has not happened yet, but quick action is needed in order to secure the accessibility and usability of the existing IDB-FDS data-stock for consumer safety purposes.

Since 2003, the Directorate for Health (now DG SANTE) has hosted the data and provided access tools. Capacities were never sufficient to promote the data use efficiently and provide users with clearinghouse services like U.S. CPSC. During all the years the direct use of data suffered from a bureaucratic procedure which requested explicit consent for every query by all data providers. The access tool at the IDB web-gate does not support basic analyses like cross-tabulations or access to case histories. Most queries from researchers, industry, consumer administrations, standardisation bodies or safety agencies were directed to the IDB-network coordinator. The existence of the database and its value remained widely unknown. Private NGOs like EuroSafe tried to compensate but have been too weak to bring the EU-IDB efficiently to market.

Despite of huge investments by Member States and European Commission in past decades, the IDB-FDS has never come into full operation and currently, today its future is rather bleak.



PRODUCT RELATED SURVEILLANCE: DIFFERENCES BETWEEN US AND EU

The comparison between US-NEISS and EU-IDB (table 3) shows similarities and main differences. While the content of the collected information and the ambitions are similar, the existence/lack of central lead makes the difference.

Table 3: Comparison between US NEISS and EU IDB

	NEISS	IDB
Legal basis	Yes: Consumer Product Safety Improvement Act 2008	Not at EU-level, just recommendations
Lead agency	Yes = CPSC	No strong lead agency, EuroSafe acts as Network Coordinator
Leading interest	Support of Product Safety Administration.	Reporting on Health Burden of Injury
Web-gate	https://www.cpsc.gov/ https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data	https://webgate.ec.europa.eu/idb/
Dataset	<ul style="list-style-type: none"> • Date of Treatment • Date of Birth • Age of Patient • Gender of Patient • (Main) diagnosis • Body Part Affected • Disposition of Case (Treatment and follow-up) • Product(s) Mentioned • Whether Intentionally Inflicted • Incident Locale (Place) • Fire Involvement • Whether Work-Related • Race and Ethnicity • Other Race and/or Ethnicity • Comments (Narrative) 	<ul style="list-style-type: none"> • Recording country • Country of residence • Gender of patient • Age of patient • Date of injury • Date of attendance • Treatment and follow-up • Intent • Place of occurrence • Mechanism of injury • Activity when injured • Sports practised when injured • Type of injury (first) • Part of the body injured (first) • Type of injury (second) • Part of the body injured (second) • Product involved in accident • Product causing injury • Product involved in another way • Case description (Narrative)
Data Dictionary	NEISS Coding Manual 2018	IDB-FDS Data Dictionary V1.4 2016
No. of product codes	About 4000 keywords (about 800 codes)	About 1000 codes (20 product groups)
Funding	Sustained funding, including direct funding of data collection and operation of CPSC as federal data clearing house	Data provided by Member States, central services temporarily funded by projects

Resources	Just NEISS: About 10M US\$ annually, about 80 fte (CPSC: About 500 fte)	No resources for central services since 2017, data collection responsibility of national agencies
Sampling	Centrally controlled, direct contracts with hospitals, data collection is centrally paid: High sample quality	Nationally controlled, varying levels of quality control & scope: Varying national implementations
Ambition	One US-wide representative sample	Nationally representative samples
Implementation status	In operation since 1978	Initialized 1990. No. of IDB-FDS countries eroded from 18 (2013) to 7 (2018).
Data owner	Federal agency: CPSC	Various national agencies
No. of hospitals	96	Currently about 90
No. of cases annually	700.000	Currently about 300.000
Scope	All hospital treated injuries (inpatients and ambulatory treatments)	All hospital treated injuries (inpatients and ambulatory treatments)
Costs per record	Well known, about \$6 / case	Less well known, but similar cost dimension
Use of other injury data	Death certificates, media reports, household surveys etc. used, but records not linked	No resources for reporting on other relevant data
User interface	User-friendly public query tool	Less user-friendly tool, bureaucratic access procedure, interface shall be shut down in 2020.
Dissemination of information	CPSC acts as enterprising national clearing house, pro-active promotion of information towards all stakeholders, many studies & data reports & recommendations published.	Very limited activities. No product related recommendations given at EU level.

RECOMMENDATIONS

Shift the political responsibility for the IDB-FDS system (at EU-level) from health (DG SANTE) to consumers (DG JUST).

Work toward a customer-oriented clearinghouse, e.g. with monthly data reports and newsletter to potential customers, and a publicly accessible repository of data reports on important issues.

Secure sufficient and sustained funding for the central services, needed for a sound operation. The data collection itself remains the responsibility of Member States, but central services are essential for the usability of the data provided by Member States and need to be secured:

- ➔ Operation of a joint database for hosting several million injury records
- ➔ Annual call to submit data (including metadata), management of quality check and data upload and assistance for data providers
- ➔ Maintaining the standards of data collection as the Operating Manual, the data dictionary or tools for transcoding data from and into related coding systems
- ➔ Organising regular meetings of data providers and training events for national data administrators.

Secure sufficient and sustained funding for enabling and promoting the use of data for products safety purposes:

- ➔ Provision of user-friendly tools to access and analyse the data in line with data protection regulations and informing stakeholders about the availability of data and benefits of data use.
- ➔ Clear instructions for users of the data
- ➔ Annual routine reports including basic analyses demonstrating the value of data
- ➔ Maintaining a repository of thematic reports as on injury risks related to specific groups of consumer products (certain toys, household appliances, building components, chemical products) or to specific activities (cooking, do-it-yourself activities, certain types of sport)

Enhance the system with a stronger support of consumer safety:

- ➔ Add a variable “Suspected unsafe product” in a new version of the IDB-FDS data dictionary
- ➔ Improve the data quality e.g. by regular validation of the samples of participating hospitals or by validating the samples of cases provided by each hospital; supervise the completeness of records
- ➔ Make use of opportunities of the IT-technology to reduce the burden of data recording hospital staff and patient, e.g. through voice recognition and (semi-)automatic coding of data elements
- ➔ Speed up the data transfer from hospitals to the central services, e.g. through daily direct data transfer.



REFERENCES AND LINKS

- [1] Kisser R, Walters A, Rogmans W, Turner S, Lyons RA: Injuries in the European Union 2013-2015 – supplementary report on trends in IDB data flow, country comparison and ECHI-injury indicators 2013-2015. Amsterdam: Eurosafe (2017). https://www.eurosafe.eu.com/uploads/inline-files/IDB%202013-2015_suppl%20to%206th%20edition%20Injuries%20in%20the%20EU.pdf
- [2] EuroSafe: Injury data collection – an effective tool for helping to cut societal costs of injuries. Amsterdam: Eurosafe (2013). <https://www.eurosafe.eu.com/uploads/inline-files/IDB%20as%20effective%20tool%20for%20cost%20saving%20measures.pdf>
- [3] European Commission: Consumer Markets Scoreboard. 10th Edition – June 2014. https://ec.europa.eu/info/files/consumer-markets-scoreboard-2014-edition_en
- [4] Guideline “EU general risk assessment methodology (Action 5 of Multi-Annual Action Plan for the surveillance of products in the EU (COM(2013)76))”: <https://ec.europa.eu/docsroom/documents/17107?locale=de>
- [5] European Commission: Safety Gate: the rapid alert system for dangerous non-food products. https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm
- [6] Radovnikovic A, Geiss O, Kephelopoulos S, et al: Assessment of the opportunities for increasing the availability of EU data on consumer product-related injuries. Injury Prevention 2020 May 5; doi: 10.1136/injuryprev-2020-043677. <https://injuryprevention.bmj.com/content/early/2020/09/28/injuryprev-2020-043677.long>
- [7] EuroSafe: EU-Injury Database – Operating Manual. Version September 2016. Amsterdam: EuroSafe (2016). https://www.eurosafe.eu.com/uploads/inline-files/IDB_operating_manual_Jan%202017_0.pdf
- [8] ANEC, BEUC, BusinessEurope, CEN, CENELEC, EuroCommerce, EuroSafe, ORGALIME: The need for a pan-European accident and injury data system – joint call. Brussels: ANEC (2013). https://egmf.org/wp-content/uploads/2016/10/Joint_call_for_a_pan-European_accident_injury_data_system.pdf
- [9] WHO – Regional committee for Europe: Resolution Preventing of injuries in the WHO European Region. EUR/RC55/R9 of 15 September 2005. http://www.euro.who.int/__data/assets/pdf_file/0017/88100/RC55_eres09.pdf
- [10] Council Recommendation of 31 May 2007 on the prevention of injuries and the promotion of Safety. OJ C164, p 1-2. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32007H0718%2801%29>
- [11] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. OJ L 218/30. <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF>
- [12] Communication from the Commission to the European Parliament, the Council and the European economic and social committee on 20 actions for safer and compliant products for Europe. (COM/2013/076). <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013DC0076>
- [13] Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health. OJ L 354, p 70-71. https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L_.2008.354.01.0070.01.ENG
- [14] European Parliament resolution of 8 March 2011 on the revision of the General Product Safety Directive and market surveillance. OJ CE 199/1. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52011IP0076>
- [15] OECD Directorate for science, technology and innovation, working party on Consumer Product Safety: Global injury data portal – proposed project roadmap. 22-23 October 2012. DSTI/CP/CPS(2012)14. [www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/CP/CPS\(2014\)13&docLanguage=En](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/CP/CPS(2014)13&docLanguage=En)
- [16] Web-gate to the US National Electronic Injury Surveillance System (NEISS): <https://www.cpsc.gov/Research--Statistics/NEISS-Injury-Data>
- [17] Web-gate to the EU Injury Database (EU-IDB), public and restricted access: <https://webgate.ec.europa.eu/idb/>

“THE NEED FOR A PAN-EUROPEAN ACCIDENT AND INJURY DATA SYSTEM – JOINT CALL”

MARCH 2013

Link to paper: <https://bit.ly/35RXfcd>



THE NEED FOR A PAN-EUROPEAN ACCIDENT AND INJURY DATA SYSTEM

Joint call



ABOUT

ANEC

ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and the use of standards, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

ANEC is funded by the European Union and EFTA, with national consumer organisations contributing in kind. Its Secretariat is based in Brussels.

EUROSAFE

EuroSafe's mission is to promote consumer safety by working in partnership with industry, governments, research institutes and health and safety practitioners to help reduce the greatest risks.

One of the main goals of EuroSafe is to facilitate the sharing of state of art intelligence in injury surveillance and evidence-based practices in prevention; to raise awareness amongst professionals, as well as the general public, of product-related injury risks; and highlight cost effective measures to prevent these injuries.

EuroSafe aims to ensure the highest achievable levels of consumer safety across the entire European region and to decrease current inequalities in injuries between countries by promoting consistent policies, programmes and infrastructures throughout Europe.

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