

CONSUMER PROTECTION AND ELECTRONIC COMMERCE : PROTECTION AGAINST UNSAFE PRODUCTS BOUGHT ONLINE

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Preface

Dear readers,

You are about to learn, in a complete and concrete way, about a phenomenon whose scope and gravity are as massive as the silence that surrounds it in the public debate: the widespread fraud in electronic commerce.

The explosion of e-commerce over the past decade, further increased by the pandemic, has been accompanied by opaque transactions, breaches of product safety and security rules, tax evasion and an unprecedented expansion in the production and smuggling of counterfeit goods.

The figures you are about to see are staggering. Their review and analysis in this study sheds light on an e-commerce jungle. A lucrative jungle for its profiteers, deleterious for its consumers, deadly for thousands of businesses and jobs destroyed by this unfair and savage competition, against which the legal, human and financial means are terribly lacking.

Let's make no mistake: in e-commerce, fraud is not just the shadow or the black sheep of normality. It is a pervasive, invasive, systemic reality. Christine RIEFA has done a thorough job of explaining the mechanisms, drawing lessons and, above all,

proposing solutions capable of curbing and reducing this scourge.

I would like to thank her very much for this work, the precision and seriousness of which will be invaluable to my fellow MEPs and myself in changing the situation and legislating in the right direction: that of protecting consumers, inventors, entrepreneurs and workers.

Europe, because of its size and the intertwining of its flows of electronic transactions and physical goods, is the appropriate framework for action. In this year 2021, it is tackling the issue of e-commerce, which is so sensitive that it has such an impact on our daily lives, in a rather proactive and determined manner. The European Union's legislative projects do not shy away from the problems, demanding in particular that large platforms such as Amazon or AliBaba finally put the means in place to fight against fraudsters and swindlers. But this is only the beginning. So much more needs to be done, such as strengthening customs, securing intellectual property or recovering VAT. Christine RIEFA helps us, helps you to see what is needed to continue this fight.

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Executive Summary

The coronavirus pandemic has accelerated the migration of shoppers online. EU consumers are now frequently buying from online traders established outside of the EU. It is well documented that there is a high incidence of dangerous products sold online both on retailers' websites and online platforms, from domestic and foreign suppliers. BEUC reported that two third of products bought on online marketplaces (including Amazon, AliExpress, eBay and Wish) failed safety tests. Products may be unsafe for a variety of reasons, notably but not exclusively, because they are counterfeit. However, the rise in electronic commerce is not the cause of the sale of unsafe products. It is only an enabler. The sale of unsafe products thrives on a complex and outdated EU legislative framework and inadequate international governance still catching up with global supply chains and new online business models (eg online platforms, drop shipping and fulfilment service providers). The combined increase in small parcels, tax loopholes, deficit in consumer safety enforcement and lack of oversight on the activities of intermediaries have created a fertile ground for unsafe products being sold to EU consumers. In November 2020, the EU Commission adopted a new consumer protection agenda that promises to increase consumer protection through a proposal on digital services (the Digital Services Act) and a revi-

sion of the Consumer Product Safety Directive taking into account the digital transformation the market has experienced. It also commits to focussing on consumer protection in the global context and adopt more suitable enforcement tools. This report suggests changes necessary to improve the safety of consumers who buy online. It recommends and details intervention in 3 key areas:

Plugging EU Regulatory gaps. The many reforms in motion at EU level present a clear opportunity to shape rules that can assist consumers by curtailing access to dangerous good as well as ensuring adequate remedies are in place when consumers are harmed. This includes notably revisions to consumer safety legislation (including the General Product Safety Directive and an extension and adaptation of the scope of Regulation 2019/1020 on market surveillance); revisions to the Product Liability Directive under which consumers can obtain compensation when they have been harmed by defective products; changes to the rules on the liability of online intermediaries (through some improvements to the first draft of the Digital Service Act).

Influencing the adoption of international norms. Protecting EU consumers against unsafe product requires some engagement with standard setting because the nature of electronic commerce and the globalisation of supply chains requires an international response. Efforts in forums such as the WTO, UNCTAD, or the OECD, to promote a high level of protection

and safety, at international level will be essential as well as engaging more bilaterally with countries that are unsafe products geographical hotspots; Conversely, there is a need to support and strengthen the work of Customs as well as international collaboration regarding other forms of enforcement, notably through the development of an international enforcement toolbox and the improvement of the rapid exchange of information on unsafe products.

Removing incentives to buy from traders with poor safety records. This will be done by closing VAT loopholes and other logistical advantages (notably for the delivery of small parcels coming from outside the EU); focussing on building awareness and educating consumers and traders but also acknowledging the needs of 'vulnerable' and low-income consumers who may not be able to make the 'safe' choice due to limited funds and will therefore continue to choose cheap alternatives despite being aware of the risk potential.

Introduction

Consumers buying online face many dangers, some of which were brought to the fore during the Covid19 pandemic¹.²Counterfeit goods, unsafe products and many sub-standards goods and services are sold online to European Consumers. They are notably sold using online platforms (social media and retail platforms) and increasingly through sales concluded with a seller that is not established in the EU or subject to its laws. Unsafe goods are not only dangerous for consumers, they are also undermining competition as they advantage the businesses that do not respect the legislation in place.

The current EU legal framework, while offering a high level of consumer protection, has not quite come to terms with an increase in cross-border e-commerce trade, the development of digital products and new business models, all contributing factors to the sale of unsafe products online.

In November 2020, the EU Commission adopted a new consumer protection agenda that presents a vision for EU consumer policy from 2020 to 2025 and aims to address consum-

¹ See for example, C Riefa, Coronavirus as a catalyst to transform consumer policy and enforcement 43 (2020) *Journal of Consumer Policy* <https://link.springer.com/article/10.1007/s10603-020-09462-0>.

ers' immediate needs in the face of the ongoing COVID-19 pandemic and increase their resilience². The agenda identifies 5 goals and notably includes increasing consumer protection through a proposal on digital services (the Digital Services Act) and a revision of the Consumer Product Safety Directive to take into account the digital transformation the market has experienced. It also commits to focussing on consumer protection in the global context and in particular the Commission plans to fund a project to set up an 'EU e-Lab' as a platform that authorities can use to carry out online investigations and monitor dangerous products sold online.³

While many reforms are underway, questions remain as to how the new reforms need to be shaped to address cross-border issues and plug the gaps in the protection of European consumers against the sale of unsafe products online.

This report presents the key issues associated with the sale of unsafe products online. It explores why e-commerce has become an enabler (section 2). It takes stock of existing legislations and makes recommendation for any changes in forthcoming legislative initiatives notably taking into account the fact that large amounts of unsafe products sold in the EU and comes from parts of the world, where the level of safety and consumer protection is not deemed to be as high as it is in the EU. The

² Communication from the Commission, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery COM (2020) 696 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0696&qid=1605887353618>.

³ *ibid.*

report notably looks into the reforms for the safety of non-food products and product liability (section 3) and the liability of online intermediaries (section 4). This report looks at existing enforcement structures including the role of market surveillance and customs and the impact of a lack of a harmonised international framework to protect consumers (section 5). The report concludes with some recommendations (section 6). Given its topicality, the report also looks at fake Covid19 vaccines and consumer protection (section 7 in Annex 1).



1. Understanding why e-commerce is an enabler for the sale of unsafe products

This part defines unsafe products and looks at statistical data to gauge the size of the problem. It also explains the main factors and causes that have led to electronic commerce becoming an enabler for the sale of unsafe products.

1.1. Scope of the report: defining unsafe products

This report focusses on unsafe products supplied by businesses to consumers online. **An unsafe product is defined in the General Product Safety Directive⁴, as any product that does not meet the definition of a safe product.** Safe products are products that do *not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons*. This is evaluated by reference to a range of factors⁵. **Products may be unsafe for a variety of reasons.** They can be dangerous because of a design flaw or because while the design is sound, the manufacturer uses sub-standard materials. A product can also be unsafe because the instructions accompanying its use are not clear or not communicated to the consumer. Lack of safety may also be the result of the product being fake and thus either not undergoing safety checks or cutting corners in the way those products are put together.

There is therefore a major distinction to draw between fake and unsafe products, although they are often dealt with together. Fake product can in many instances, be innocuous although they may still cause economic harm. Fake products are

⁴ Art 2(c) GPSD.

⁵ specified in Art 2(b) GPSD.

products that infringe on intellectual property rights⁶. A growing number of counterfeit products can pose significant threats to the environment or to consumer health and safety. IP rights are well regulated and, at international level, benefit from a pre-established framework of international conventions. Notably the WTO TRIPS agreement lays down international rules⁷. **In this report we focus on unsafe products. This will include fake, counterfeits and pirated products that have a propensity for being dangerous.** The report does not directly deal with any products that, while infringing on intellectual property rights, do not pose a risk to the health and safety of humans.

1.2. E-commerce as an enabler: size of the problem

Retail e-commerce sales worldwide are estimated to be around \$4 trillion in 2020⁸ and set to continue to grow. The growth rate is projected around 16.5% as estimates are revised down to account for a contraction in retail due to the pandemic⁹. UNCTAD reported that the pandemic had changed internet

⁶ OECD, EUIPO (European Union Intellectual Property Office), *Trends in Trade in Counterfeit and Pirated Goods* (2019) 14. See also TRIPS agreement, Art 61 which states: 'Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale.'

⁷ For more on this aspect, see 5.1.3.

⁸ See both Statista and emarketer, <https://www.statista.com/statistics/379046/worldwide-retail-e-commerce-sales/> and <https://www.emarketer.com/content/global-e-commerce-2020>. It is estimated by Statista that it will account for 6.5 trillion in 2023.

⁹ <https://www.emarketer.com/content/global-e-commerce-2020>.

shopping forever¹⁰ with consumers shopping online more frequently than they used to and consumers in developing economies making the greatest shift¹¹. The most recent figures confirm past trends accelerated by the covid-19 crisis.

1.2.1. Increase in the share of cross-border e-commerce

The increases in cross border e-Commerce revenues as a proportion of total e-commerce are accelerating, predicted to increase from 15% in 2015, to almost 25% in 2021¹². Figures from UNCTAD show that the share of cross-border online shoppers to all online shoppers rose from 17% in 2016 to 23% in 2018.¹³ Eurostat statistics show that **EU consumers are increasingly buying from online traders established outside of the EU**. Indeed, 87% e-shoppers made online purchases from sellers in their own country but an ‘increase could be observed for purchases from sellers in other EU countries (from 29 % in 2014 to 35 % in 2019) and from sellers outside the EU

¹⁰ <https://unctad.org/news/covid-19-has-changed-online-shopping-forever-survey-shows>.

¹¹ https://unctad.org/system/files/official-document/dtstictinf2020d1_en.pdf.

¹² European Commission, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs and WIK Consult., *Development of Cross-Border e-Commerce through Parcel Delivery: Final Report* (2019) ¹⁴ <https://data.europa.eu/doi/10.2873/931558>.

¹³ <https://unctad.org/press-material/global-e-commerce-hits-256-trillion-latest-unctad-estimates>.

(from 17 % in 2014 to 27 % in 2019).¹⁴ However, **consumers do not always realise that they are making purchases from traders established outside of the EU** and can enter the global online marketplace ‘by accident’.¹⁵

1.2.2. High incidence of counterfeit trade

According to the European Commission, almost 27 million articles that infringed on intellectual property rights (IPR) were detained in 2018 with a street value of nearly €740 Million¹⁶. The trade in counterfeit and pirated goods is rising – even as overall trade is stagnating. It is now estimated at 3.3.% of global trade, according to an OECD/ EUIPO report¹⁷. For the European Union, counterfeit trade represents 6.8% of imports from non-EU countries, up from 5% in 2013.¹⁸ These figures do not include domestically produced and consumed fake goods, or pirated products being distributed via the Internet. **It is difficult to find recent estimates for the size of online sales of counterfeits.**

¹⁴ Eurostat, e-commerce statistics for individuals, e-shopping from other EU countries (2019) <https://ec.europa.eu/eurostat/statistics-explained/index.php/E-commerce_statistics_for_individuals#E-shopping_from_other_EU_countries>. Figures for online shopping in the 12 months prior to the survey.

¹⁵ BEUC, vzvb (report by Julie Hunter and Christine Riefa), The challenge of protecting consumers in global online markets (2017) 12.

¹⁶ Marie BOLAND, ‘The Customs Action Plan - Supporting EU Customs to Protect Revenues, Prosperity and Security’ (*Taxation and Customs Union - European Commission*, 24 September 2020) <https://ec.europa.eu/taxation_customs/general-information-customs/customs-action-plan_en> accessed 8 November 2020

¹⁷ OECD, EUIPO (n 7) 45.

¹⁸ OECD, EUIPO (n 7) 60.

However, **‘counterfeiters thrive where there is poor governance’¹⁹** and **‘small parcels sent by post or express courier are a prime and growing conduit for counterfeit goods’²⁰**.

According to the World Customs Organisation,

‘E-commerce contributes to the facilitation of counterfeited products, mainly on the lack of controls operated on online vendors and buyers and the way these products are delivered, i.e. in small parcels. These activities are posing problems in terms of intellectual property rights but also in terms of product safety and can represent a threat to society.’²¹

As a result, it seems logical to **assume that electronic commerce is a key conduit for counterfeit product sales as international governance is fraught and enforcement remains insufficient**. For example, online retail is estimated to account for 60% of sales of electrical goods in the UK and 7% of consumers bought counterfeit electronics via social media alone in 2016.²² Out of this growing number of counterfeit products circulating a proportion will be dangerous and can pose significant threats to the environment or to consumer health

¹⁹ OECD, EUIPO (n 7) 15.

²⁰ OECD, EUIPO (n 7) 19.

²¹ World Customs Organisation, ‘WCO-Annual-Report-2018-2019’ ²² <http://www.wcoomd.org/-/media/wco/public/global/pdf/media/annual-reports/annual-report-2018_2019.pdf> accessed 20 October 2020.

²² CSC Global, The online counterfeit economy: consumer electronics (2020) <https://www.cscglobal.com/cscglobal/pdfs/The-Cost-of-%20Online-Counterfeiting-Consumer-Electronics-EN.pdf>.

and safety. Health and safety risks are often generated by sub-standard counterfeit pharmaceuticals, toys, chemicals (organic and inorganic), food and drink, batteries, etc.²³

Consumers' attitude to fake is somewhat different depending on the product purchased. Concerning luxury goods for example, where risks to consumers are low, the consumers' insatiable desire for cheaper goods arguably inflates the unit value and creates the main market driver for counterfeiting.²⁴ However, concerning make-up, skincare or medication, consumers are generally avoiding fakes and 83% state they would not buy non-genuine consumer products in those categories²⁵. In this area, fake product have a higher propensity to cause consumer harm going way beyond economic harm. Indeed, even harmless/ placebo fake medication can have some devastating consequences if it induces the consumer into believing they are for example vaccinated against covid19 (see section 0) when in fact this is not the case. At worst, fake vaccines may prove toxic to consumers.

In the application of intellectual property laws, it is for right holders to detect infringement and enforce their rights. They are often assisted by customs officers in detecting and stopping

²³ OECD, EUIPO (n 7) 34.

²⁴ David S. Wall, Jo Large, 'Jailhouse frocks: locating the public interest in policing counterfeit luxury fashion goods' (2010) 50(6) *British Journal of Criminology*, 1094, 1095

²⁵ Clarivate, Analytics, 27% of online shoppers have been duped into buying fake make-up, skincare and medicine (2017) <https://clarivate.com/news/counterfeit-consumer-goods-online-pose-risk-shoppers-health/>

goods that may infringe their rights, but much progress is still needed²⁶. It is thus through their efforts that dangerous products that infringe IP rights may be removed from market. However, it is also important to note that too strong IP rights may lead to negative outcomes in the sense IP rights can also be used as a weapon to benefit rights holders to the detriment of others.

1.2.3. High incidence of unsafe products on retail websites and online platforms

An OECD sweep conducted in 2015 found that there was a **high incidence of unsafe products sold online both on retailers' websites and online platforms, both from domestic and foreign suppliers**. Overall, the sweep, which sampled 1709 consumer goods (including toys and games, household electrical items) in 25 countries, found that only 26% of products were compliant with product safety laws. The sweep was testing the incidence of banned/ recalled product, adequate safety information about the goods sold and whether product met safety standards.²⁷ More recently, a number of surveys by

²⁶ European Commission, Commission Staff Working Document, Report on the protection of Intellectual Property Rights in third countries, SWD (2019) 452 final/2, 11 https://trade.ec.europa.eu/doclib/docs/2020/january/tradoc_158561.pdf

²⁷ OECD, "Online Product Safety Sweep Results: Australian Competition and Consumer Commission", OECD Digital Economy Papers, No. 262 (2016), <http://dx.doi.org/10.1787/5f1nb5c64ktd-en>

consumer associations confirm that there is an important proportion of dangerous products sold online and notably on online platforms. **BEUC reported that two third of products bought on online marketplaces** (including Amazon, AliExpress, eBay and Wish) **failed safety tests**.²⁸ The 250 products had been selected based on possible risk and included electrical items, cosmetics, and toys which contributes to such high incidence. The products found to not comply with safety laws included defective smoke and carbon monoxide alarms, children's products with long cords presenting strangulation risks or toys with well above safe levels of chemicals. Other research has shown that there are also a number of documented occurrences of products being sold on marketplaces despite recalls or intervention by enforcement authorities.²⁹

What transpires from the available data on the size of electronic commerce and the sale of unsafe products is that there is a **deep-rooted problem** largely due to the fact electronic commerce, although not the cause, acts as an enabler for the sale of unsafe goods.

²⁸ <https://www.beuc.eu/publications/two-thirds-250-products-bought-online-marketplaces-fail-safety-tests-consumer-groups/html>.

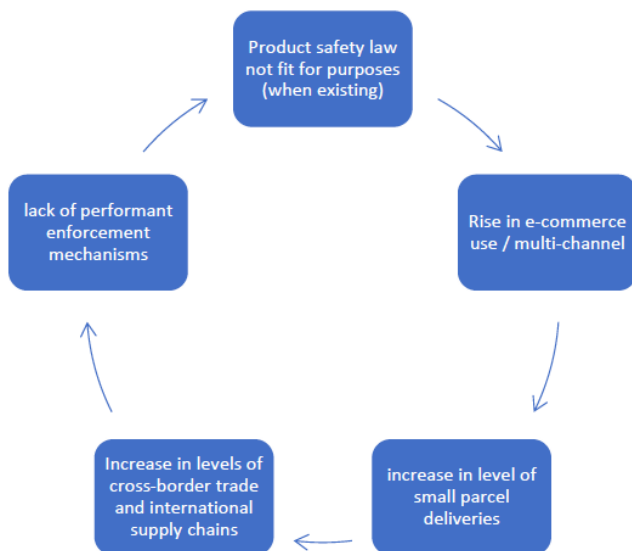
²⁹ BEUC, ANEC, *BEUC and ANEC views for a modern regulatory framework on product safety, Achieving a higher level of consumer safety through a revision of the General Product Safety Directive*, BEUC-X-2020-068 (26/08/2020), ANEC -WP1-2020-G-032 (2020) 4. See for example, work carried out by Which? the consumer association in the UK showing unsafe child car seat being promoted despite them being banned from platforms, <https://www.which.co.uk/news/2019/02/why-are-ebay-and-amazon-still-selling-killer-car-seats/>.

1.3. Factors contributing to e-commerce being an enabler

There are a number of clear factors contributing to electronic commerce having enabled a spike in the volume of dangerous goods available in the EU and across the globe. They are all mutually reinforcing and inter-connected. The starting point and main concern of this report is the fact that product safety laws and their enforcement frameworks are not fit for purpose. **The rise in electronic commerce is not the cause of the sale of unsafe products. It is only an enabler, alongside other factors** such as the fact that online sales rely in large part on:

- the delivery of small parcels rather than large shipment imports;
- supply and distribution chains that are now global and a lot more complex;
- differing levels of consumer safety around the globe and no common international understanding of minimum safety standards;
- enforcement mechanisms devised in the analogue era and for a world governed along geographical frontiers;

- transformation in the e-commerce landscape, including an increase use of marketplaces whose activities are not yet sufficiently regulated (gaps in enforcement of consumer protection online and gaps to hold platforms accountable);³⁰
- New technologies challenging the definition of 'safety' which has traditionally focused on health or physical integrity. Yet security of devices also contributes to their safety;³¹



³⁰ BEUC, ANEC (n 30) 11.

³¹ BEUC, ANEC (n 30) 13.

Fig. 1. Connected factors contributing to the growing number of unsafe products sold online

1.3.1. Complex EU Legislative framework in need of modernisation

The legislation able to assist in controlling the sale of unsafe products online in the EU and further afield is at the confluence of a number of areas of laws. It falls into four main areas: intellectual property law (with regard to fake products), **liability of intermediaries** (eg platforms, which come under the remit of the Electronic Commerce Directive and the proposed Digital Services Act & Digital Markets Act), **consumer law and** what we can describe as **'customs' law**, i.e. the laws that govern the entry of goods and services into a territory and are enforced by customs authorities. Those laws offer some elements of a solution but are **all in need of some modernisation, most of which is underway with a wave of simultaneous reforms** explored in different sections of this report. Most importantly, enforcement of those laws is an important factor in ensuring consumers are protected against dangerous products sold online. Under the remit of consumer law, there are a large number of legal instruments available to tackle the sale of unsafe products. First and foremost, there is legislation

regarding the standards of safety to be expected for products placed on the European Market³² and rules on the liability of producers.³³ It is on those that much of the report focusses. Consumer legislation also spans the way sales occur (notably online) and regulate not only the quality of the goods and services sold, but also the fairness of the practices used. Those laws however are not the best vehicle to tackle the sale of unsafe products.³⁴

1.3.2. Difficulties in monitoring an increase in electronic commerce transactions

While paradoxically e-commerce sales tend to be more documented than sales in a brick-and-mortar shops (consumers need to provide a delivery address for example), the scattered landscape of sellers and the large array of products (including digital content) sold can make this retail channel difficult to monitor.

1.3.2.1. Multi- online sales channels

³² General Product Safety Directive 2001/95/EC (GPSD), OJ L11, 15.01.2002, 4.

³³ Product Liability Directive 85/374/EEC (PLD), OJ L210, 7.8.1985, 29.

³⁴ This includes: Consumer Rights Directive 2011/83/EC regarding distance sales; Directive 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services; Directive 2019/771 on certain aspects concerning contracts for the sale of goods; The Unfair Commercial Practices Directive 2005/29/EC. This last directive could assist in protecting consumers in that it is mostly a public enforcement tool and it would be an unfair practice contrary to professional diligence to sell unsafe products. The other instruments are primarily contractual and enforced mostly privately by consumers

Consumers no longer exclusively buy from brick-and-mortar shops that run an online presence. They increasingly rely on marketplaces as gateway to buy from a multiplicity of traders, many not established in the EU but in countries with less advanced legal safety rules and applying lower technical production standards.³⁵ New intermediary platforms business models, social commerce and novel fulfilment methods add to the complexity.

1.3.2.1.1. A vast array of online intermediary platforms

In B2C relationships, intermediary models need to be distinguished from proprietary retail sites. The use of platforms such as Amazon, Alibaba or eBay in retail is now well established. Platforms have enabled small businesses to sell to consumers without the need for IT infrastructure. However, their nature can be complex and confusing for consumers. The intermediary can accumulate the role of intermediary online platform to introduce buyer and seller and also act as an intermediary, taking payments and for the fulfilment/shipping of the order, while the contract of sale remains with the third-party seller.³⁶ Besides, social media platforms are now entering the retail sphere. While primarily devoted to social interaction, an increasingly large

³⁵ BEUC, ANEC (n 30) 4.

³⁶ For more on the roles taken by Amazon, see Jane K. Winn, The secession of the successful: the rise of Amazon as Private Global Consumer Protection Regulator 58 (2016) *Ariz. L. Rev.* 193-21.

number of people and businesses use social media platforms to sell goods and services. Social commerce is the term used to describe the use of social media tools and interactive technologies in an electronic commerce setting.³⁷ Sales now can take place via messaging apps such as messenger (through Facebook), Whatsapp or Instagram.³⁸ Many challenges are raised by social commerce, not least the fact that scams are often perpetrated via social media and across borders, targeting consumers' vulnerabilities or facilitating the sale of unsafe products that can harm consumers.³⁹ Social media is also associated with the sale of fake goods. Research shows that Instagram accounts selling counterfeit have risen by 171% over 3 years with a number of sales of dangerous cosmetics and social media influencers playing a role in promoting fake products.⁴⁰

1.3.2.1.2. New fulfilment methods and intermediaries

³⁷ Zhao Huang, Morad Benyoucef, The effects of social commerce design on consumer purchase decision-making: an empirical study 25 (2017) *Electronic Commerce Research and Applications* 40. See also, Liang and Turban, An introduction to the special issue on social commerce: a research framework for social commerce 16 (2011) 2 *Int. J. Electron. Commerce*, 5-13, cited in Gibreel, Alotaibi, Altmann, Social Commerce development in emerging markets 27 (2018) *Electronic Commerce Research and Applications*, 152.

³⁸ For more on Social commerce, see Christine Riefa, Beyond e-commerce: some thoughts on regulating the disruptive effect of social (media) commerce, *RDC (Brazil)* 127 (Jan-Feb 2020), 281-304; Christine Riefa, Consumer Protection on Social Media Platforms: Tackling the Challenges of Social Commerce, in Synodinou, Jougleux, Markou, Prastitou (eds.), *EU Internet Law in the Digital Era, Regulation and Enforcement* (Springer 2020) 321-345.

³⁹ For more on those issues, see Consumers International, *Social media scams: understanding the consumer experience to create a safer digital world* (2019) <https://www.consumersinternational.org/media/293343/social-media-scams-final-245.pdf>.

⁴⁰ <https://www.incoproip.com/how-social-media-behavior-influences-counterfeit-purchases/>

There has been an **increase in the use of drop shipping** in which the shop advertises goods it does not store. Instead, when an order is placed, the store orders it from their supplier who then ships it directly to the customer. As a result, the shop never takes possession of the goods in question. It is a fulfilment method that is attractive to traders because it reduced any costs for stocking as well as shipping. It also means that the trader receives a payment from the consumer before they have to pay the supplier.⁴¹ However, drop shipping requires investment in advertising notably on Facebook to be successful and runs on small margins.⁴² Drop shipping means that the delivery time to the consumer tends to be quite high as the order often comes from China, and because quality is not checked, may lead to lots of disgruntled consumers asking for refunds that the trader cannot always afford or be willing to give.

Fulfilment service providers, also referred to as third-party logistics providers or fulfilment houses, have also proliferated with the rise of e-commerce.⁴³ The e-commerce fulfilment services market size estimated at close to \$70 billion in 2019 is growing.⁴⁴ For example, Liege airport in Belgium, is reported to handle 1 million small parcels daily for Alibaba. It has become

⁴¹ <https://www.wired.co.uk/article/dropshipping-instagram-ads>

⁴² *ibid.*

⁴³ Carsten Ullrich, New Approach meets new economy Enforcing EU product safety in e-commerce 26 (2019) 4 *Maastricht Journal of European and Comparative Law* 570.

⁴⁴ <https://www.grandviewresearch.com/industry-analysis/ecommerce-fulfilment-service-market>

its main EU hub and invested in developing infrastructures to assist Alibaba rival Amazon in the region.⁴⁵ The city is also racing ahead and attracting businesses investing in treating large arrivals of goods from China and the USA.⁴⁶ Fulfilment intermediaries are responding to growing demand in tailored B2C shipment, storage and stock management solutions for products ordered online.⁴⁷ One of the advantages for small traders in particular is that they can avoid upfront storage costs (somewhat similar to drop shipping in this respect) and can benefit from economies of scale regarding shipping. Some intermediary platforms also have their own fulfilment centre. Amazon is one such player and it can be confusing for consumers to know if they ordered from Amazon as a seller or if Amazon is simply fulfilling the order. This of course may have an incidence on who to contact and hold liable for any problems with the goods delivered.

1.3.2.2. Digital products and reliance on data

The type of products is also changing. **EU consumer homes are now full of connected products. Those can have secu-**

⁴⁵ <https://www.politico.eu/article/go-back-to-your-cave-alibabas-european-expansion-triggers-anger-in-liege/>

⁴⁶ <https://www.aircargonews.net/cargo-airport/viaeurope-opens-e-hub-in-liege-to-help-process-e-commerce-tsunami/>

⁴⁷ Carsten (n 44).

rity flaws that pose a risk to consumers' safety and a growing number of IoT transactions are to be expected. Safety therefore can no longer be thought of simply in terms of physical products. Besides, Artificial intelligence plays an increasing role in the way products operate. Following the Commission White paper on AI⁴⁸ and the report on liability and safety of new technologies⁴⁹, the Commission is now focussing on a proposal for legislation that will guarantee a high level of protection of consumer interest and fundamental rights as well as rules on civil liability to ensure that victims of damage caused by AI application have the same level of protection in practice as victims of damage caused by other products or services.⁵⁰ The commission is also working on initiatives regarding the safety of new technologies, which includes a revision of the General Product Safety Directive to ensure safety of AI and Internet of Things products.

1.3.3. Difficulties in regulating and monitoring global supply chains

⁴⁸ EU Commission, Artificial Intelligence – a European approach to excellence and trust, COM (2020) 65 final.

⁴⁹ EU Commission, Report on the Safety and liability implications of artificial intelligence, the Internet of Things and robotics COM (2020) 64 final.

⁵⁰ Communication from the Commission, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery COM (2020) 696 final, 11.

Global supply chains suffer from a regulatory deficit. Legal standards and enforcement mechanisms conceived in the analogue era are struggling to adapt. Meanwhile an increase in the international trade of small parcels and some tax loopholes that unfairly advantage traders established outside of the EU are adding to the complexity of protecting consumers buying online.

*1.3.3.1. Lack of harmonised international
legal standards and enforcement me-
chanisms to protect consum-
ers*

While many goods and services are now standardised and sold worldwide, safety laws and their enforcement remain very much national and regional in nature. The increase in globalised supply chains coupled with the development of electronic commerce has enabled manufacturers to use production plants in countries with differing standards, this at the expense of quality and safety⁵¹ in many instances. Indeed, the lower the income of a country, the least likely it is to have a legislation that deals with product safety.⁵² As a result, many manufacturers are not acting against their

⁵¹ Consumers International, The challenge of protecting consumers from unsafe products, a global picture (May 2018) 8.

⁵² Consumers International (n 52) 11.

local law when they produce products that are deemed and/or proven unsafe in the EU. Divergence in standards is problematic, not least because it can unfairly advantage traders who are not subject to stringent safety requirements. When such safety laws exist, they are by and large not fit for purpose. In 2018, Consumers International conducted a survey of 132 organisations in 100 countries. While the study is not considered representative, its findings do give a clear indication that the sale of unsafe goods is flourishing in part because of product safety laws that are no longer fit for purpose in global markets. Indeed, only 13% of respondents thought that their national product safety legislation was operating successfully, and 28% thought that it did not work well at all.⁵³ In any event, the international dimension of transactions and production centres being based in regions where product safety oversight is lacking means that **even the most performant system for national production is only as good as its lowest common denominator.**

Besides enforcement mechanisms are also challenged by online sales notably because of evolving supply chains and the cross-border nature of the Internet. **They often lack the necessary powers and resources for cross-border enforcement.**

⁵³ Consumers International (n 52) 11. The report explains that 84% of survey respondents declared that their country had consumer protection legislation in place in their country, *ibid* 9.

1.3.3.2. Increasing number of small parcels

As a result of changes to supply chains and an increase in the use of electronic commerce, the EU customs union and individual customs authorities are faced with a series of interconnected challenges. Customs authorities are notably tasked with balancing good trade facilitation and efficient movement of goods alongside ensuring compliance with safety legislation, trade policy, and collection of tax revenues. But a vast number of small parcels arrive at the EU borders through postal services making monitoring difficult.

“United Postal Union figures show that about 100 million items were sent from the Asia-Pacific region to Europe in 2015, the second largest postal stream between world regions”.⁵⁴ Under current rules, **low value items sent by postal services are not really scrutinised at all by customs**, due to the way that postal services up until now have been regulated. A report in 2018 by the German Federal Court of Auditors illustrates that the only checks that occur on parcels sent in this way are random checks. Of all the parcels sent less than 1% are controlled at random and of these 22% contained undervalued or counterfeit items or violated import restrictions.”⁵⁵

⁵⁴ European Commission (n 13) 200.

⁵⁵ European Commission (n 13) 231.

In addition, **suppliers based outside the EU** (notably in Asia)⁵⁶ have been able to **benefit from rules that hand an automatic price advantage over EU based businesses in supplying the equivalent products**. Therefore, from an EU consumer's point of view, there is often a price incentive to buy a product supplied by a trader based outside the EU rather than choose an EU based trader. This is the case **because** there is an exemption on import VAT for low value goods coming into the EU (see below section 2.3.3.1) and **the rate of postage which is charged to a non-EU based supplier** as payment for an EU postal service undertaking the delivery from the border to the customer. This postage cost is often lower than both the actual costs involved and the cost that a consumer would pay an EU based supplier.⁵⁷

1.3.3.1. Tax loopholes favouring 'out-of-the EU' establishment

There are also clear loopholes notably in the tax system that, although not directly linked to the sale of dangerous goods

⁵⁶ European Commission (n 13) 231.

⁵⁷ European Commission (n 13) 20. This is because postal services around the world are historically organised around 'terminal dues', ie an apportionment of costs. The rate of remuneration is arbitrary in nature and countries are grouped into 4 rate bands with the industrialised countries paying 100% of the rate and each band below that paying incrementally less. The remuneration each country receives takes no account of the costs (which can vary significantly) incurred each time a mail item is delivered. The changes in trade flows as a result of e-commerce mean that millions of small parcels are now being sent by postal service. For countries that have a high volume of small parcel imports from countries in one of the lower rate bands and have high delivery costs the terminal dues are insufficient to cover the costs. This leaves a considerable deficit burden on the universal service provider. For those countries (mostly in Asia) that produce and export large quantities of low value goods and are in one of the lower rate bands for terminal dues the opposite is true. They benefit from cheaper deliveries

online may play a part in creating an environment that does not incentivise, reward or support behaviours that assist in the sale of dangerous goods.

The tax regime in the EU does not impose a tax where there is no establishment. This has allowed big companies established abroad to flourish without having to pay the same taxes than brick and mortar shops. The EU is currently trying to make changes in order to **create ‘taxable digital presence’ rules under which businesses with a significant digital presence will have to pay tax where they realise profit, regardless of where they are in fact based.**⁵⁸

Another interim reform, is looking to tax activities that are currently not taxed.⁵⁹ Under the proposal, **tax would be applied to revenues created from:**

- selling of user data
- selling online advertising space;
- **digital intermediary activities** that allow users to interact with others and facilitates the sale of goods and services between them (eg online retail platforms, sharing economy platforms).⁶⁰

⁵⁸ Proposal for a Council Directive laying down rules relating to the corporate taxation of a significant digital presence COM (2018) 147 final.

⁵⁹ Proposal for a Council Directive on the common system of a digital services tax on revenues resulting from the provision of certain digital services COM (2018) 148 final.

⁶⁰ Art 3 Proposal COM (2018) 148 final.

Those activities would be taxed at 3% of revenues (at the place the users are located). It would apply to businesses with annual worldwide revenues of €750 millions and €50 in the EU.

A parallel initiative was developed by an OECD proposal along the same vein. Some countries have also moved unilaterally and imposed a tax or are in the process of imposing such tax.⁶¹

As most of the large internet companies are US based, the taxes imposed are being investigated by the USA amidst tariff threats in the context of international trade and tax law.⁶² Nevertheless, the OECD renewed commitment to address tax challenges and the work continues towards an agreement by mid-2021 and agreed work under two pillars.⁶³

Regarding VAT, the challenges relate to the collection of VAT and tax on goods and services sold online by non-resident suppliers particularly in B2C trade and imports of low-value items. There is currently an exemption on VAT on imported low value items (below €22), although it should be abolished in 2021. There is a lower level of scrutiny applied to low value items. Unsurprisingly, **there is evidence of problems such as undervaluation of goods to avoid customs duties and VAT**

⁶¹ This includes for eg France, Austria, Poland, Italy, Spain, the UK who have implemented a digital services tax. With other countries in the process of doing so. For more details, see <https://taxfoundation.org/digital-tax-europe-2020/>.

⁶² <https://taxfoundation.org/us-trade-representative-ustr-digital-services-tax-investigations/>.

⁶³ OECD, Tax challenges arising from digitalisation – Report on Pillar One Blueprint, Inclusive framework on BEPS (2020) <http://www.oecd.org/tax/beps/tax-challenges-arising-from-digitalisation-report-on-pillar-one-blueprint-beba0634-en.htm> and OECD, Tax challenges arising from digitalisation – Report on Pillar Two Blueprint, Inclusive framework on BEPS (2020) <http://www.oecd.org/tax/beps/tax-challenges-arising-from-digitalisation-report-on-pillar-two-blueprint-abb4c3d1-en.htm>.

and of smuggling of illicit or unsafe goods’.⁶⁴ VAT collection is an issue identified by the OECD/G20 as part of the base erosion and profit shifting (BEPS) project.⁶⁵ The opportunity for fraud undervaluation at the €22 threshold is estimated by the EU at 4 billion in lost VAT revenue. The number of parcels that are not undervalued and are below the threshold are estimated at 1 billion.⁶⁶ Lost revenue is an issue that will exacerbate over-time leading to possible deficits on budgets and an impact on customs to carry out its duties.⁶⁷ The absence of VAT collected on digital content sold online also means that competition is altered because traders based outside the jurisdiction often escape VAT where those established in the Jurisdiction have to pay it. Their products are thus more expensive for consumers to buy or their margins are lower than traders established outside of the jurisdiction.

⁶⁴ EU Customs Union Plan (2020) ‘Customs-Action-Plan-2020_en.Pdf’ 1 <https://ec.europa.eu/taxation_customs/sites/taxation/files/customs-action-plan-2020_en.pdf> accessed 8 November 2020.

⁶⁵ OECD, Addressing the Tax Challenges of the Digital Economy, Action 1 (2015) final report, OECD/G20 Erosion and Profit Shifting Project, <https://www.oecd.org/tax/beps/addressing-the-tax-challenges-of-the-digital-economy-action-1-2015-final-report-9789264241046-en.htm>

⁶⁶ European Commission (n 13) 231

⁶⁷ *ibid*



2. Consumer safety and liability for non-food products

In the EU, consumer safety is split broadly speaking between public enforcement through what is known as 'consumer safety' and private enforcement via 'product liability'. Private enforcement relies on the individual(s) harmed to take action in court or via alternative dispute resolution. Public enforcement relies on national enforcement authorities to take action against traders.

2.1. Consumer Safety

Consumer safety in the EU is governed by separate legislation and enforcement structures spanning three main areas: food, non-food products and pharmaceuticals and medical devices. Pharmaceuticals, medical devices and food are outside the scope of this study but some details about the protection of consumers against fake covid-19 vaccine sold online has been included given its topicality (section 0, Annex 1).

This report focusses on the sale of non-food products. Consumer Safety for non-food products is an area that is regulated by a mix of horizontal as well as vertical legislation. This report focusses mostly on the General Product Safety Directive (GPSD) and its operation⁶⁸ (the horizontal legislation). The legislation acts as a safety net because it covers any loopholes in sector-specific legislation and is the legislation of reference where no specific legislation has been adopted. It applies to products irrespective of the selling techniques, including distance and electronic selling.⁶⁹ The legislative framework rests on the principle of precaution and is organised

⁶⁸ For details, on the other aspects of vertical regulation, see: https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/standards-and-risks-specific-products_en

⁶⁹ Recital 7 GPSD.

around legislation complemented by voluntary standards. Regulation 765/2008/EC on market surveillance⁷⁰ complements the GPSD.⁷¹ It provides detailed definition of the market actors that are caught by liability rules under the GPSD. It lays down rules for accreditation of conformity assessment bodies performing conformity assessment activities.⁷² It lays down the general principles of CE marking.⁷³ However from July 2021, it will no longer contain provisions regarding market surveillance following reform and the adoption of Reg 2019/1020 (detailed in section 3.1.5.4).⁷⁴

The GPSD is now outdated having been adopted in 2001 and attempts at modernising it, in the past, have failed. However, the Commission is due to present a new proposal in 2021. In this report we lay out the operation of the current legislation and point out where **revisions would be welcomed to ensure the GPSD is able to protect consumers in a digital age**. The report also deals with extra-territorial elements because the control of dangerous products sold online is essentially a problem that cannot be solved at a national or regional level only and necessitates international cooperation (section 0).

⁷⁰ Regulation 765/2008/EC of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, OJ 13.08.2008, L218/30.

⁷¹ Recital 6 and 7 of Regulation 765/2008/EC.

⁷² Art 1(1) Reg 765/2008.

⁷³ Art 1(4) Reg 765/2008.

⁷⁴ Regulation 2019/1020 of 20 June 2019 on market surveillance and compliance of products and amending (...), OJ 25.6.2019, L169/1.

Fig 2. horizontal and vertical consumer safety legislation

2.1.1. Safe products

The main principle of the GPSD is that **only safe products can be placed on the market.**⁷⁵

2.1.1.1. Legal definition in need of clarification

The way in which the term ‘safe’ product is defined can have huge influence on the scope and effectiveness of legislation.⁷⁶ Yet, a definition of what is a safe product does not always exist in national legislation.⁷⁷ Even where a definition exists there is some variation as to the scope of what it may cover. For example, most countries with legislation would expect a safe product to comply with safety regulations or not harm consumers’ health and physical safety. However, a much lower proportion expect that the product must specifically cover

⁷⁵ Art 3 GPSD.

⁷⁶ Consumers International, the challenge of protecting consumers from unsafe products, a global picture (May 2018) 11.

⁷⁷ 15% of respondents indicated that there is no legal definition of what constitutes a safe product in their country. See Consumers International (n 78) 12.

foreseeable misuse or be suitable for all consumers to use including particularly vulnerable groups⁷⁸, such as elderly or children as the GPSD does.⁷⁹ **In an international context, this would prove problematic as the level of expected safety will vary from country to country and may be placed lower than it is in the EU.**

In the EU, Art 2(b) GPSD states:

Safe product shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

- (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;*
- (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;*
- (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;*

⁷⁸ Ibid (n 78). The next potential obstacle is the absence of a general safety provision such as the one used on the EU in a number of product safety regulations.

⁷⁹ Art 2(b)(iv) GPSD.

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be dangerous.

2.1.1.2. Safe digital products

The concept of ‘safe products’ was developed at a time where risks were mechanical and not digital. It was also developed in the context of primary liability for risks having an impact on consumers’ health and physical integrity. It does not however take into account risks that may derive from secondary liability. This is problematic when digital products’ failures may cause injury such as an autonomous car losing connectivity and injuring the driver or when a product’s composition contains toxic chemicals.⁸⁰ **The GPSD also lacks an acknowledgment that cybersecurity should form an integral part of safety.** Security flaws to digital products enabling them to be hacked may prove dangerous to consumers. The definition of products does not include software specifically. This may prove problematic as consumers no longer tend to buy bundled products and can select separate hardware and software.

⁸⁰ This report does not look into chemical but there is a clear need to improve protection in this area also. 23% of products that are notified as dangerous to the EU Safety gate display chemical-related risks. For more on those issues, see BEUC, ANEC (n 30) 8-9.

2.1.1.3. Placing safe products on the market

The safety of products is assessed at the time they are placed on the market, failing to recognise that some products may require some ‘continued conformity’⁸¹, ie remain safe for their lifetime rather than just the precise moment they are first placed on the market.⁸² This is particularly pressing for products that will require software update and/or when products are using self-learning artificial intelligence and resulting in harmful outcomes for consumers.⁸³ Ensuring safety may require to also interpret ‘maintenance’ as meaning that software must be updated on a regular basis (which is something some producers have little incentive to do, preferring obsolescence of the product as a business model). The action of placing on the market also depends on how the goods reach the marketplace, for example, whether they are placed on the market by operators also based in the EU or based outside and whether the online seller targets the EU or not.⁸⁴

⁸¹ The concept is not defined in the GPSD. Instead, a definition is found in Art 2 of Regulation 765/2008 as the first making available as the supply in the course of a commercial activity.

⁸² BEUC, ANEC (n 30) 8.

⁸³ However, it will also be useful as we seek to ensure second-hand goods have a longer lifespan in the circular economy. Currently some second-hand goods are excluded from the scope of the GPSD. Note also issues regarding EU exports being designed down for developing countries’ markets or even within the EU (dual quality standards) – to fit lower safety requirements. This issue is not talked about much but should be addressed as some of those product dumping practices are also dangerous for consumers. Through e-commerce, those products could also find a way back to the EU market.

⁸⁴ Commission Notice on the market surveillance of products sold online (2017/C 250/01) OJ 1.08.2017, C250/1, 5.

2.1.2. Precautionary principle

One of the **key features of the GPSD is the precautionary principle**. According to this principle, **when scientific evidence about health hazard is uncertain, but the stakes are high⁸⁵, products should not be allowed on the market**. This principle is in stark contrast with other approaches, notably that adopted in the USA where what is not proven to be harmful can be placed on the market.⁸⁶ **In order to tackle the challenges of increased online shopping and globalized supply chain, the precautionary principle should be maintained**. While the exact contours of the principle are often disputed⁸⁷, it is nevertheless a sound principle in that it ensures caution is applied and gives national authorities a basis to withdraw product from the market that present a risk. Use of principles such as this one is important because product risks are in constant evolution and adopting prescriptive legislation would quickly become obsolete. The precautionary principle, as a guiding beacon, ensures longevity and flexibility. It also can ensure that the legislation can adapt to control new risks as they occur. The principle should thus continue to be a cornerstone of the product safety regime in the EU and further afield.⁸⁸

⁸⁵ European Parliament (Didier Bourguignon), The Precautionary Principle, Definitions, applications and governance PE 573.876 (Dec 2015) 4.

⁸⁶ Wiener, Rogers, Comparing precaution in the United States and Europe 5 (2002) 4 *Journal of Risk Research* 317-349, https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1985&context=faculty_scholarship.

⁸⁷ European Parliament (n 88) 4.

⁸⁸ This position is supported by BEUC. See BEUC, ANEC (n 30) 10.

2.1.3. Safety by Design and use of voluntary standards

Technology has transformed the way in which products are designed, manufactured and sold. The level of complexity in products can also contribute to their propensity for being dangerous. Intervention therefore cannot simply be focussed on the sale of dangerous products, but needs to target the entire supply



chain, from conception and design, to consumption.

Fig. 3. safety by design

Article 3(2) GPSD states that a product conforming to certain technical standards will be deemed safe. **The GPSD is complemented by the application of standards but not all legislation around the world bundles standards as part of the manufacturer's obligations.**⁸⁹ A number of standards exist notably at international level.⁹⁰ In the EU, those are issued by a European Standards Organisation such as CEN or

⁸⁹ Consumers International, the challenge of protecting consumers from unsafe products, a global picture (May 2018) 14.

⁹⁰ They include ISO 10377 Consumer product safety; ISO 20245 Cross-border trade of second-hand goods; and ISO 10393 (2013) Consumer product recalls.

CENELEC. Those standards can assist in demonstrating that products are safe and a number of standards that are referenced in the European Union Official Journal and are presumed safe.⁹¹ **It may be necessary to revisit this set up in the EU and ensure legislators can decide on detailed safety requirements for certain products and Member States can oppose standards in case they are not sufficiently protective**⁹² or not widely respected. Indeed, there is often a lack of knowledge and consistent guidance for businesses to organise testing procedures. In developing countries notably there appears to be a need for independent testing centres and government funding to spot check imports of new and second-hand goods.⁹³

Information and labelling of products is also an issue, in particular when it comes to the sale of consumer goods across borders, where the OECD highlighted that some important information is in fact displayed in a language that consumers do not understand.⁹⁴ Some products are dangerous only when not used properly and thus being able to read the notice is extremely important. But in any event, it is **often**

⁹¹ For a list concerning standards pertaining to the application of the General Product Safety Directive, see: <https://ec.europa.eu/docsroom/documents/37941>

⁹² BEUC, Factsheet, Sewing up the holes in Europe's product safety net (2020).

⁹³ Consumers International, the challenge of protecting consumers from unsafe products, a global picture (May 2018) 15.

⁹⁴ OECD, Online product safety: trends and challenges, OECD Digital Economy Papers No.261 (OECD 2016).

the case that the safety labelling on product is not completely clear to consumers, leading to some misuse of product and detriment as a result. Aside from the clear need for transparency and better tailored notices, some consumer education programmes may be required to ensure consumers are aware of risks and act accordingly.

2.1.4. Who is liable for lack of safety?

The GPSD provides that **‘producers’ are primarily liable for any lack of safety. Some liability however does also fall on ‘distributors’** (those whose activities do not affect the safety properties of a product)⁹⁵ who need to act with due care to help ensure compliance and refrain from supplying any product suspected to be dangerous.⁹⁶

A producer is defined in Art 2(e) GPSD:

- the manufacturer when he is established in the EU, or any person presenting themselves as the producer by affixing their mark or name, or the person who reconditions the product;
- a representative in the EU, if the manufacturer is not established in the EU;

⁹⁵ Art 2(f) GPSD.

⁹⁶ Art 5(2) GPSD.

- or in any other case, the importer of the product into the EU, from a state that is not a member state.
- Other professionals in the supply chain can also be deemed producer if their activities may affect the safety of a product.

Regulation 765/2008 further defines the categories of producers contained in Art 2(e) GPSD.⁹⁷ However, not all legislations around the world dealing with consumer safety will have the same list of professionals meaning that there can be some uncertainty as to what liability may be available and against whom to act.⁹⁸ This seriously hampers the identification of who can be held liable for any violations. In the EU, a key issue is to determine **if and how other actors in the online supply chain need to be included** in the list already established in Art 2(e) GPSD and future revisions. For example, this could **include new protagonists such as fulfilment centres and online platforms**.

2.1.4.1. Fulfilment service providers

⁹⁷ Note that Regulation 765/2008 is also amended in some respect by Reg 2019/1020, although this latter regulation does not apply to all consumer products.

⁹⁸ Consumers International (n 52) 12.

Under the GPSD and Regulation 765/2008, **the role of fulfilment service providers is not clear and they do not have any specific liability**. However, they could be deemed:

- 'manufacturers' if they affix their own names or trade-marks to the products.
- 'producers' if their activities may affect the safety of the product.
- 'authorised representatives' if they have been mandated by the manufacturer established in a third country.
- 'importers' according to the Commission, if the products they store, label, package etc, come from outside the EU and they place them on the Union market.⁹⁹

They could also be deemed distributors where activities go beyond those of parcel providers but they do not affect the safety of the product. In this case, they cannot be directly liable for the sale of dangerous products, but will have a role in ensuring they use due care¹⁰⁰ and verify that products have CE marking if legally required, that necessary information accompanies the product (eg safety instructions or declaration of conformity), that language requirements are complied with and that tracea-

⁹⁹ Commission Notice on the market surveillance of products sold online (2017/C 250/01) OJ 1.08.2017, C250/1, 5.

¹⁰⁰ Art 5(2) GPSD.

bility requirements regarding manufacturer and importer are fulfilled.¹⁰¹ In addition, they would have an obligation to cooperate with Market Surveillance authorities. **To ensure that there is no ambiguity and fulfilment centre can be held accountable to combat the sale of dangerous product, it would be advisable to clarify their liability**, by extending the application of Regulation 2019/1020 on market surveillance (see section 3.1.5.4).

2.1.4.2. Online platforms

Online platforms are not strictly speaking caught by the GPSD. They could be considered distributors in that they do not affect the safety of the product they distribute but currently their operation and liability falls under the ecommerce Directive (see section 0) which offers an exemption of liability if, on acquiring knowledge they remove the dangerous items expeditiously. BEUC advises that the **marketplaces ought to be considered as importers for all products sold via their interfaces (website or apps) as well as those goods passing through their fulfilment centres.**¹⁰² This should be complemented with

¹⁰¹ For more details on their obligations, see the Blue Guide, Commission Notice C (2016) 1958, section 3.4, [https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52016XC0726\(02\)](https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52016XC0726(02)).

¹⁰² BEUC, ANEC (n 30) 11.

an extension of their obligations under the both the Product Liability directive and the Digital Service Act that are currently being revised.¹⁰³ Market places could be conceptualised as operators in the supply chain according to BEUC and thus could be held ultimately liable if products sold through their platforms are dangerous and if the responsible producer cannot be held accountable.¹⁰⁴ Market surveillance authorities should be enabled to address their enforcement actions to the platform. This could be done by an extension of the application of Regulation 2019/1020.

2.1.5. Market Surveillance

Market surveillance is a preventative as well as a corrective activity. It is the sum of activities carried out and measures taken by market surveillance authorities to ensure that products do comply with legislation. It requires large infrastructures and an ability to identify and report unsafe products to facilitate their removal from the market before they can harm consumers or as quickly as possible thereafter. **Market surveillance is an area where many countries have now put in place some form of infrastructure. Yet, appraisal of those system reveals that they are rarely able to tackle unsafe products**

¹⁰³ BEUC, ANEC (n 30) 11.

¹⁰⁴ BEUC, ANEC (n 30) 11-12.

effectively.¹⁰⁵ Lack of enforcement is partly explained by the way enforcement is structured. It often falls to local authorities that do not have adequate capacity. It is also explained by a lack of adequate sanctions for violations. When a product is found to be unsafe, a series of corrective actions including recalls and withdrawal from the market, are normally available. However, corrective actions are not always mandatory, and rest of the voluntary actions of businesses, meaning that some products identified as dangerous may not be withdrawn from the market. According to Consumers International, this is the case in 17% of cases.¹⁰⁶ **Low levels of enforcement abroad has an incidence on how much monitoring needs to take place in the EU as products are not stopped at source.**

2.1.5.1. Monitoring and flagging unsafe products: the EU Safety Gate (RAPEX)

In the EU, the application, monitoring and enforcement of the GPSD takes place at national level. There is no centralised enforcement authority. However, coordinated action is a hallmark of the application of the GPSD. Monitoring of

¹⁰⁵ Consumers International (n 52) 18 shows high levels of dissatisfaction with the enforcement of existing rules.

¹⁰⁶ Consumers International (n 52) 19.

unsafe products takes place via the Safety Gate¹⁰⁷ which is the centralised database from the European Commission where all national enforcement authorities can report on unsafe products they have detected on their markets and alert others.¹⁰⁸ But the system needs improving with a need for more information and a quicker turnaround time for the publication of alerts.¹⁰⁹

In addition, there are clear concerns relating to the way in which data about unsafe product is collected and reported. Notably, aside from the limitations of the systems already in place, there does not appear to be much by way of consumers being able to communicate on their experience of dangerous products and/ or claim if they made a purchase and used the product. This is only one aspect of a **missed feedback loop. Accident and injury data is not always tallied up and available to public authorities that can use it to identify areas of risk.**¹¹⁰

2.1.5.2. Improving consumer awareness

¹⁰⁷ Safety gate, the rapid alert system for non-food product: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications&lng=en.

¹⁰⁸ The GPSD established this alert system. In the GPSD, it is referred to as RAPEX.

¹⁰⁹ BEUC, ANEC (n 30) 16.

¹¹⁰ Consumers International (n 52) 17. 49% of respondents indicated that their country was not collecting this type of information and noted a strong correlation between a country's income and the likelihood of collecting the data. According to BEUC, ANEC (n 30) 16 there is a need to revitalise the European Injury Database.

Consumer awareness goes hand in hand with also raising awareness of businesses as some small businesses in particular may not be clear on their obligations. **Consumers tend to be unaware of the existence of unsafe products¹¹¹ and where recalls are not happening or are too slow, this exposes many consumers to potential harm.** Yet, public information systems that consumers could consult to gain information themselves are lacking in many cases.¹¹² Where such systems exist, the sources of information are dis-jointed and consumers would often need to consult several sources. According to the Commission, market surveillance authorities have a role to play in raising awareness among consumers.¹¹³ This includes providing information that will be useful to consumers in making their choices, such as:

- checking if traceability information and warnings are disclosed;
- checking RAPEX and OECD's portal on product recalls before purchase;
- double checking information of the seller with manufacturer's information;

¹¹¹ Commission Notice on the market surveillance of products sold online (2017/C 250/01) OJ 1.08.2017, C250/1, 2.

¹¹² 'more than two third of respondents (69%) do not have a publicly accessible system' according to Consumers International, the challenge of protecting consumers from unsafe products, a global picture (May 2018) 19.

¹¹³ Commission Notice (n 112) 16-17.

- ascertain with seller if product complies with EU requirements
- use complaint tools regarding safety issues encountered.¹¹⁴

In any event, a number of tools need to be used to ensure consumers will seek this information. Thus, **market surveillance authority may want to use their website or media campaigns to educate consumers, as well as host consumer complaints systems that could also be used to monitor unsafe products.**¹¹⁵

2.1.5.3. Online market surveillance needs

The Commission notice on the market surveillance of products sold online stresses the importance of a strategy and the planning of surveillance online.¹¹⁶ Notably the notice also puts forward some general principles, such as the principle of proportionality, the precautionary principle and targeting the most relevant actors in the supply chain and requesting corrective action from those responsible for placing the goods on the

¹¹⁴ Commission Notice (n 112) 16-17.

¹¹⁵ Commission Notice (n 112) 17.

¹¹⁶ Commission Notice (n 112) 11-12.

market, as well as a principle of cooperation, which is especially relevant considering the cross-border nature of e-commerce.¹¹⁷

Market Surveillance Authorities (MSAs) will have to prioritise enforcement as it is unlikely that they can have unlimited resources, in spite of wide calls for those resources to be increased.¹¹⁸ This may require developing databases that can give precise information on which to act in order to target operators and possibly also jurisdictions where foreign operators that are causing most harm may be established. **Enforcement should include reactive as well as proactive surveillance and actions.** For example, the Commission suggest checking if any of the goods contained in RAPEX are also sold online.¹¹⁹

Online controls do require some adaptation from normal offline processes. For example, this may include creating dedicated units to monitor online activity and build expertise. This may require the creation of specific procedures or guidelines.¹²⁰ The Commission plans to fund a project to set up an 'EU e-Lab' as a platform that will provide a common toolbox that authorities can use to carry out online investigations and monitor dangerous products sold online by deploying advanced

¹¹⁷ Commission Notice (n 112) 12.

¹¹⁸ BEUC, ANEC (n 30) 16.

¹¹⁹ Commission Notice (n 112) 12.

¹²⁰ See notably, Study on good practice in market surveillance activities related to non-food consumer product sold online, Annex: Good practice cases, <https://op.europa.eu/en/publication-detail/-/publication/e50a1e6d-78ab-49a0-82b4-896e62f7b655>

IT solutions, using AI, data mining techniques and webcrawlers.¹²¹

Investigating may prove more difficult as some member states in the EU do not enable mystery shopping, and enforcers may face challenges also in identifying the economic operator that may be responsible. Corrective actions may also be challenging as operator may disappear and it may not be possible to seize stocks of goods that are sold in small packages especially when the operator is located outside the EU. Within the EU, it will be possible to use RAPEX to alert other authorities and require assistance. It will be possible to block webpages containing unsafe products under art 8(1) GPSD and Art 16(2) Reg 756/2008. However, there is no notice and action procedure in operation, although the e-commerce directive and now the DSA can serve as its basis (see section 4.3.4.2).¹²²

With regards to Chinese products sold in the EU, the authorities can take advantage of the already existing RAPEX-China system established between the EU Commission and the Chinese General Administration of Quality Supervision and Quarantine (AQSIQ).¹²³ This system does however need further improvements and continued collaboration (section 5.3.2).

¹²¹ Communication from the Commission, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery COM (2020) 696 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0696&qid=1605887353618>

¹²² Commission Notice (n 112) 15.

¹²³ Commission Notice (n 112) 15.

2.1.5.4. Expanding the scope of Regulation 2019/1020 on market surveillance and product compliance to all consumer products

In the EU, Regulation 765/2008 setting out the requirements for accreditation and market surveillance¹²⁴ which complemented the GPSD as a horizontal instrument¹²⁵ was amended by Regulation 2019/1020. All references to market surveillance are stripped from this Directive as of July 2021 (and from January 2021 regarding international enforcement) and will be featured in Reg 2019/1020. Regulation 765/2008 therefore becomes simply a Directive on accreditation from July 2021, date at which Regulation 2019/1020 will enter into force.

However, the **scope of Regulation 2019/1020 is restricted to products that fall under specific legislation and does not apply with regards to enforcement of the GPSD. This leaves unacceptable gaps for many consumer products in the EU.** Notably, BEUC noted that the way the legislation is currently devised means that a bed for a child is subject to less stringent market surveillance than a bed for a doll.¹²⁶ The measures contained in the Regulation aim at improving product traceability and help market surveillance authority in their work.

¹²⁴ Regulation 765/2008/EC of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, OJ 13.08.2008, L218/30.

¹²⁵ Recitals 4, 5, 6 and 7 of Regulation 765/2008/EC.

¹²⁶ BEUC, ANEC (n.30) 6.

Because **a revision of the GPSD could easily extend those market controls to all consumer goods**, we detail the content of the Regulation below.

The new **Regulation (EU) 2019/1020 on market surveillance and compliance of products** could already hold some elements of a solution because it requires authorities to **intensify controls of products including those that are sold online**. **Recital 13 recognises that there is a need for strengthening enforcement measures amidst global market challenges, increasingly complex supply chains and the increase of products that are offered for sale online to end users within the Union**. It provides a framework for controls on products entering the Union market¹²⁷ and notably some coordination with customs. The Regulation recognises a principle of equivalence in that Member States should ensure their market surveillance is organised with the same effectiveness for products made available online as it is for products made available offline.¹²⁸ It however acknowledges that ‘while performing market surveillance of products offered for sale online, MSAs are facing numerous difficulties, such as tracing products offered for sale online, identifying the responsible economic operators or con-

¹²⁷ Art 1(3) Reg 2019/1020.

¹²⁸ Recital 28 Reg 2019/1020.

ducting risk-assessments or tests due to lack of physical access to products.¹²⁹ Recital 30 also explains that special attention should be given to emerging technologies taking into account that consumers are increasingly using connected devices in their daily lives, new risks that should be addressed by the EU regulatory framework.

- New categories of economic operators

There are 4 types of economic operators subject to the Regulation: manufacturers, importers and **two new categories, namely authorised representatives and fulfilment service providers. Information society services providers can also be called upon to contribute to enforcement efforts notably to restrict access to an online interface.**¹³⁰

Art 4(1) Reg 2019/1020 introduces the requirement that only manufacturers with **authorised representatives** in the EU (mandated by the manufacturer) can put products on the market. This, in theory, would mean that it is no longer possible to put products on the market without having an entity answerable to market surveillance authorities in the EU. This representative is the contact for the national enforcement authority, acting on behalf of the manufacturer. This person however does not have

¹²⁹ Recital 29 Reg 2019/1020.

¹³⁰ Art 14(4)(k) Reg 2019/1020.

to take possession of the products or be a part of the manufacturer's company. This tool may have limited effect because, it is not certain that all sellers targeting the EU market will have such representative, many being unaware of their duties under EU law or trying to avoid the rules and escape liability. Policing the existence of a representative will be time and resource consuming and there is a high possibility that it will not be enforced. In turn this will incentivise the use of letterbox companies.¹³¹

Fulfilment service providers can be held accountable with respect to the products they handle if there is no manufacturer, importer or representative established in the Union.¹³² Fulfilment service providers are defined by Art 3(11) Reg 2019/1020 (which does not apply to products governed by GPSD, see below) as: *any natural or legal person, offering in the course of a commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved (excluding postal services, parcel delivery services and any other postal services or freight transport services).*

- Obligations of economic operators

¹³¹ For more on the issues and potential problems with the use of authorised representatives, see BEUC, ANEC (n 30) 11.

¹³² Art 4(2)(d) Reg 2019/1020.

Art 4(3) Reg 2019/1020 requires operators to perform tasks such as the preparation of documentation that assist MSAs in their tasks. This includes the preparation/ verification of declaration of conformity and other technical documentation and inform authorities if they have reasons to believe that the products in question present a risk. They are also required to cooperate with MSAs. The regulation makes provisions for information requirements concerning name and contact details of the economic operator, to be disclosed on the product or packaging.¹³³ Those obligations only apply for a number of selected pieces of specific legislation, listed in Art 4(5) which includes notably personal protective equipment and toys. Economic operators are also under a duty to cooperate with market surveillance authorities regarding actions which could eliminate or mitigate risks presented by products made available by the operators.¹³⁴

Information society service providers¹³⁵ are also subject to a duty to cooperate to facilitate any action to eliminate or, if not possible, mitigate risks presented by a product that is or was offered for sales through their services.¹³⁶

¹³³ Art 4(4) Reg 2019/1020.

¹³⁴ Art 7(1) Reg 2019/1020.

¹³⁵ ie providers of services normally provided for remuneration, at a distance, by electronic means and at the individual request of the recipient of services as defined in Art 1(1)(b) of Directive 2015/1535 of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society Services (codification) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015L1535>

¹³⁶ Art 7(2) Reg 2019/1020

- Distance sales

Art 6 deals with distances sales. It states: Products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at end users in the Union. An offer for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State. The Commission considers that an online operator that delivers to addresses in the EU, accepts currencies used in the EU as a payment from consumers and uses an EU language, directs its activities to the EU and as a result would be subject to the application of EU safety laws.¹³⁷

- Powers for Market Surveillance Authorities

Art 14 lists 11 **powers that every market surveillance authority should have as a minimum**. Those powers include:

- Power to require information from economic operators on compliance (including access to embedded software if necessary to assess compliance); and information about the supply chain, distribution networks, quantities of products;

¹³⁷ Commission Notice on the market surveillance of products sold online (2017/C 250/01) OJ 1.08.2017, C250/1, 5.

- Power to require economic operators to provide information required to ascertain the ownership of websites, where relevant;
- Power to carry out unannounced on-site inspection and physical checks of products;
- Power to enter any premises, land or means of transport that the economic operator uses in connection to its trade to obtain evidence and identify non-compliance;
- Power to start investigations on the MSA's own initiative to identify non-compliance and bring it to an end;
- Power to require economic operators to take appropriate action to bring non-compliance to an end or eliminate the risk;
- Power to take appropriate measures where an economic operator fails to take appropriate corrective action or in case of persistent risk. This can include the power to prohibit or restricting the making available of the product, or ordering that the product is withdrawn or recalled;
- Power to impose penalties
- Power to carrying out mystery shopping exercises;
- Power to reverse engineer to discover non-compliance;
- In order to eliminate serious risk, where no other effective means are available, the power to require removal of content referring to the related products from an online interface or require display of warnings on access to the online interface; if this is not done, the power to

require the information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement the measure.

This therefore enables market surveillance authority officers to enter fulfilment centres to take samples for testing or require online platforms to restrict access to listings where there is a risk of serious and irreparable harm to end user due to non-compliance. Those powers however have to be balanced out with the operation of Articles 12 to 15 of Directive 2000/31/EC (e-commerce directive) which limits the liability of information society services. Note that this Directive is being currently revised under the guise of the Digital Services Act (see section 4.2).

In cases of non-compliance, the MSA can recover the totality of the costs of enforcement from the relevant economic operator.¹³⁸ MSAs can require economic operators to require that they take appropriate and proportionate corrective action to bring non-compliance to an end or eliminate the risk within a specified period.¹³⁹ Appropriate actions may include bringing the product into compliance, preventing

¹³⁸ Art 15 Reg 2019/1020.

¹³⁹ Art 16 Reg 2019/1020.

the product from being made available, withdrawing or recalling the product and alerting the public, destroying the product or ensuring it is inoperable, affixing warnings, etc.¹⁴⁰ **MSAs can proceed with withdrawal and recall themselves if the operator is not acting.**¹⁴¹

2.1.6. Improving traceability and product recall mechanisms

Product traceability is an important step in tracking unsafe products. Technology can assist on this front although it of course needs to comply and respect any privacy concerns.¹⁴² Electronic product codes can assist in traceability efforts. Different technologies exist, all able to assist in following items through the supply chain and warn consumers when a product in their possession is causing a risk of injury.¹⁴³ For example, there is an increase use of radiofrequency identification (RFID) notably on food products. QR codes are also performing similar roles although relying on different technology. The GS1

¹⁴⁰ Art 16(3) Reg 2019/1020.

¹⁴¹ Art 16(5) Reg 2019/1020.

¹⁴² On privacy concerns concerning RFID, see Article 29 Data Protection Working Party, *Working Document on Data Protection Issues Related to RFID Technology* (2005) 10107/05/EC WP105.

¹⁴³ see J Luzak, A Broken Notion: Impact of Modern Technologies on Product Liability (2020) 11 *European Journal of Risk Regulation* 6630-649.

Standard¹⁴⁴ enables the identification of location, product, machine and even assets in the supply chain. The coding can also be applied to components of a products, although at this stage it is not possible to have all components marked. Those QR codes can assist with fighting illicit trade.¹⁴⁵ They can also assist in case there is a need to recall products.¹⁴⁶

Product recalls are found in a large majority of countries. However, their roll out varies and is **often met with disappointing levels of success even in the EU**.¹⁴⁷ According to a Commission study, ‘a quarter of EU consumers (24.5%) are either unaware or do not believe that manufacturers are obliged to recall dangerous products. While 13.1% admit they do not know if such obligation exists, 11.4% believe that this is not the case. Furthermore, over a third of the EU population is not aware that all products are potentially subject to recalls (36.0%)’.¹⁴⁸ National recalls may not happen because they are not mandatory in all cases. The Consumers International survey identified a

¹⁴⁴ <https://www.gs1.org/standards>.

¹⁴⁵ Currently it is being rolled out regarding tobacco products, <https://www.gs1.org/standards/fighting-illicit-trade>.

¹⁴⁶ For more on this aspect and the challenges linked with traceability (including second hand products and small items), see https://ec.europa.eu/info/events/international-product-safety-week-2020-2020-nov-09_en.

¹⁴⁷ European Commission (IPSOS), Survey on Consumer Behaviour and Product Recall Effectiveness (2019) 6 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

¹⁴⁸ European Commission (IPSOS), Survey on Consumer Behaviour and Product Recall Effectiveness (2019) 8 https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

correlation here with regularity of recalls and income. The higher the income of a country the more likely recalls happened with regularity.¹⁴⁹ This is concerning because countries with low income are suffer from dumping of low-quality goods and services and a high occurrence of dangerous products.

In developed countries, recall can be challenging even if they are required by law (as is the case in the EU), because traceability may be limited. ISO 10393 on international product recalls, intended for suppliers can also be used by government agencies to help develop or improve recall policies and guidelines.¹⁵⁰ The OECD Recommendation on Consumer Product Safety also notes the importance of product recalls in detailing measures to ensure that businesses play their role and government bodies collaborate to develop guidelines and standards. BEUC notes that there is a need to continue work in this area, to improve recall. One solution includes product registrations where appropriate but warns that the responsibility for recall should not be shifted to consumers with the primary obligation of safe products staying with economic operators.¹⁵¹ **Improving the framework for recall should be something that is dealt with the modernisation of the GPSD with minimum**

¹⁴⁹ Consumers International (n 52) 20.

¹⁵⁰ <https://www.iso.org/obp/ui/#iso:std:iso:10393:ed-1:v1:en>

¹⁵¹ BEUC, ANEC (n 30) 16.

requirements for recall notices and processes and technology could be used as a tool to assist as part of a package of solutions.

2.1.7. The Union Product Compliance Network

Chapter VI of Reg 2019/1020 is devoted to cross-border mutual assistance within the EU. This can include requests for information, investigatory assistance and enforcement measures. Chapter VIII on coordinated enforcement and international cooperation **establishes a Union Product Compliance Network** to serve as a platform for structured coordination and cooperation between enforcement authorities and the Commission and streamline the practices of market surveillance within the Union.¹⁵² In addition, Art 35 set out cooperation between the Commission, the national MSA and regulatory authorities in third countries or international organisations to improve the efficiency of market surveillance in the Union. All agreements with third countries or international organisations are to be based on reciprocity and includes provision on confidentiality.

2.2. Product Liability

¹⁵² Art 29 Reg 2019/1020.

The Product Liability Directive 85/374/EEC¹⁵³ (PLD) establishes a strict liability regime for the sale of defective products. Consumers can obtain compensation if they have bought a defective product that caused them damage. The directive dates back from 1985 and thus predates much of the new technology that has now entered consumers' homes and daily lives.¹⁵⁴

2.2.1. Tangible v intangible products

'Product' means all moveable products and does include electricity.¹⁵⁵ The PLD does not make any reference to intangible products, ie digital content. It is accepted that digital content that is embedded in a tangible good (smart watch for example) is included in the scope of the Directive.¹⁵⁶ The Commission also confirmed that software is a product covered by the PLD, but there is still hesitation as to the legal classification of stand-alone software in member states and in academic circles.¹⁵⁷ **Therefore, a clarification of the scope of the term product to include Internet of Things products and other digital**

¹⁵³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31985L0374&from=EN>

¹⁵⁴ Although it does refer to an age of increasing technicalities and risks inherent in modern technological production in Recital 2 PLD.

¹⁵⁵ Art 2 PLD.

¹⁵⁶ BEUC, Product Liability 2.0, how to make EU rules fit for consumers in the digital age (2020) 12.

¹⁵⁷ BEUC, Product Liability 2.0 (n 157) 12.

contents and products would we welcome to ensure a uniform application of liability rules.

2.2.2. Defective products and damage suffered by the consumer

The PLD worked to eradicate physical risks for consumers. However, in the context of digital goods, a defect may not cause direct physical damage. As a result, consumers may have to use national tort laws, that are normally fault based to seek remedies. For liability to be engaged under the PLD, the consumer only has to prove the damage, the defect and the causal link between them. The threshold is thus normally considered to be lower under strict liability than under tort law mechanisms. However, **proving damage, defect and causality may remain an obstacle for many consumers and inhibit their ability to seek compensation.**

At international level, better cooperation is essential but often sorely lacking. As supply chains are international, unsafe products often find their ways into several countries and better cooperation could help stop products deemed unsafe before they reach market. There is however no international sharing of rapid alert data save for the OECD system (section 5.3.2).

2.2.2.1. Defective product

A product is defective when it does not provide the safety which a person is entitled to expect, taking into account all circumstances, which includes the presentation of the product, the use that can reasonably be expected, the time when the product is put into circulation.¹⁵⁸ Products however are not defective simply because a better product is subsequently made available on the market.¹⁵⁹ As consumers are now surrounded by smart products, which defects may cause damage, it seems important to update the PLD to include those products that because of a loss of connectivity may cause accidents or cause economic harm. **BEUC is also calling for the PLD to adopt an extended notion of ‘defect’ which would no longer be based on expectations of safety but rather on expectations the users may have of their products.**¹⁶⁰ This would include for example, harm that would be caused by non-compliance with the General Data Protection Regulation (GDPR) suggesting that deviation from privacy-by-design and privacy-by-default rules ought to render a product defective.¹⁶¹ Liability could also be engaged if a smart product did not provide the safety expected and could be hacked, or the underlying AI decisions

¹⁵⁸ Art 6(1) PLD.

¹⁵⁹ Art 6(2) PLD.

¹⁶⁰ BEUC, Product Liability 2.0 (n 157) 14.

¹⁶¹ BEUC, Product Liability 2.0 (n 157) 13.

led to harm. **The concept of defect also needs to be understood not simply at the time they are put on the market, but over their life cycles** as is already the case under Directive 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services¹⁶² or Directive 2019/771 on certain aspects concerning contracts for the sale of goods.¹⁶³

2.2.2.2. Damage suffered

The damage suffered is limited by Art 9 PLD, to damage caused by death or by personal injuries, damage to or destruction of property (but not the defective product itself) valued at over €500 and intended for private use and used by the injured person for his private use or consumption. Member States could also elect to place a ceiling of €70 million on the overall liability of a producer for damages resulting from a death or personal injury caused by identical items with the same defect.¹⁶⁴ This is problematic as **many products sold online may not qualify for the current lower threshold meaning that obtaining redress will be more difficult for consumers.** The

¹⁶² Art 8(2)(b) which provides that the trader needs to ensure availability of updates, including security updates necessary to keep the content in conformity, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32019L0770>

¹⁶³ Art 7(3) which provides that a seller is liable for digital elements being in conformity including updates, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uris-ery:OJ.L_2019.136.01.0028.01.ENG&toc=OJ.L:2019:136:TOC

¹⁶⁴ Art 16 PLD.

overall cap also acts as a bar to collective actions in particular and provides little incentives for manufacturers to take care in releasing safe products, if their overall liability is capped. Besides damages to data which can harm consumers greatly, are not caught by the PLD at present. There is thus a **need to re-think those limitations on the damage suffered by consumers**. In addition, it may be beneficial to think of enabling consumers to recover the cost of the defective products directly from producers rather than having to recoup it from retailers, as this requires two separate legal actions for consumers. In effect, this could also act as a sanction for producers of unsafe products.

2.2.2.3. Burden of proof

Currently, the consumer needs to prove damage, defect and causal link.¹⁶⁵ Proving damage is normally straight forward. However, the complexity of products may act as an obstacle to consumers claiming compensation. Conversely, the **Expert Group on Liability and New Technologies**¹⁶⁶ **suggested a reversal of this burden of proof because it may be significantly easier for the producer to prove relevant facts.**

¹⁶⁵ Art 4 PLD.

¹⁶⁶ Expert Group on Liability and New Technologies – New Technologies Formation, Liability for Artificial Intelligence (November 2019) 44.

2.2.3. Who is liable for the damage caused by defective products?

Under the Directive, **the producer is liable for the damage caused by a defect in his product.**¹⁶⁷ A producer is a manufacturer of a finished product or of any raw material or the manufacturer of a component part, and any person who will put its name, trademark or any other distinguishing feature on the product and presents himself as the producer.¹⁶⁸ Other persons can also be liable. This includes the person who imports the product in the EU, the supplier where the producer or importer cannot be identified or where the supplier does not inform the injured person of the identity of the producer.

When two or more persons are liable for the same damage, they can be jointly and severally liable under the Directive, although they can, under national law, have a right to recourse against others in the supply chain.

The PLD does not deal with software developers' liability or the liability of platforms and the role they play in the online purchase ecosystem, nor does it address the role played by other intermediaries such as fulfilment centres. **When a producer cannot be identified, or refuses to remedy the harm, it**

¹⁶⁷ Art 1 PLD.

¹⁶⁸ Art 3(1) PLD.

would be desirable to hold online platforms or fulfilment centres accountable and seek to engage the liability of others involved in the production and supply chain. Joint liability could be envisaged as is already the case in the PLD (albeit on a much more restricted list of producers).

According to BEUC, it would be possible to consider online marketplaces as suppliers and thus hold them liable if the producer cannot be identified or the marketplace fails to give timely information on the seller and enable communication with the seller of defective products. The platform also ought to be liable if the producer is identified but fails to take measures to remedy the harm, or if the marketplace has received clear evidence of non-compliant products or has significant influence or control in the transaction chain.¹⁶⁹

From a consumer protection perspective, it may be important to mirror the solutions made to reform the GPSD as well as the electronic commerce directive. It would be confusing otherwise not only for consumers but also businesses if the liability lines fell in different places for public and private enforcement matters. Indeed, the sale of a harmful electrical item on Amazon marketplace, should not lead to Amazon being liable to remove ad and the products from posts (under the new DSA) and stop the product from reaching consumers and other consumers (under GPSD), but not for any

¹⁶⁹ BEUC, Product Liability 2.0 (n 157) 19.

damages that may be due to the consumer due to injuries suffered (Product Liability Directive).

The Directive offers a number of defences to producers notably the development risk defence and the regulatory compliance defence, both of **which should be abolished according to BEUC**.¹⁷⁰ Similarly the limitation period of 10 years post first-circulation of a product¹⁷¹ ought to be extended with a view to stimulate more sustainable consumption and longer lifespans for products.¹⁷²

¹⁷⁰ BEUC, Product Liability 2.0 (n 157) 20-21.

¹⁷¹ Art 10 PLD.

¹⁷² BEUC, Product Liability 2.0 (n 157) 20-22.



3. Liability of online intermediaries for the sale of unsafe products

Liability is in a state of flux. It varies across the world. Within the EU, **the liability regime applicable to online intermediaries has evolved and is undergoing reform. This can be harnessed as an opportunity to ensure adequate protection against the sale of dangerous products to consumers**

3.1. Convergence in liability regimes in different regions of the world?

How much liability should online intermediaries shoulder when transactions occurring or originating on their platforms cause harm to consumers?¹⁷³ Should intermediaries become gatekeepers and in effect become a private enforcement mechanism? The response to these questions and the **liability regimes vary across the world** and in many respects is still in development. There are different positions adopted across the world and liability may also vary by sectors. **However, there seems to be some timid convergence towards raising liability levels with regards to the sale of dangerous products.**

On the one hand, Chinese law is, puts pressure on intermediaries that have knowledge of infringing activities without necessarily having much control over them.¹⁷⁴ **Business operators (which would include online retail platforms and social media platforms) are under a duty to compensate consumers that are victim of a fraud¹⁷⁵** and consumers can recover more

¹⁷³ See for example concerning the liability of online auction sites and touching on search engines, C Riefa, Consumer Protection and Online Auction Platforms: Towards a safer legal framework (Routledge 2016) 175.

¹⁷⁴ Christine Riefa, Jojo Y.C. Mo, Mind the Gap: Modelling the Liability of Online Auction Intermediaries and Market places in Hong Kong on the EU Regime (2016) Chinese Journal of Comparative Law 1-26.

¹⁷⁵ BEUC Vzbv, report by Julie Hunter and Christine Riefa, The Challenge of Protecting EU Consumers in Global Online Markets (2017).

than they have actually lost because punitive damages can be imposed. Laws in ASEAN, Cambodia and Indonesia also make online platforms gatekeepers pushing some, if not all, liability on them.

In the USA, the liability regime for intermediaries offers protection under ‘safe harbour rules’¹⁷⁶ meaning that under certain circumstances, **intermediaries are not held liable for the misconduct of their users**. There is in the USA a **palpable reluctance to impose liability on intermediaries in certain areas of law, intellectual property in particular**¹⁷⁷ where the many cases trying to engage a platform’s liability for sale of fake goods by a third party have failed.¹⁷⁸ **However, the California Court of Appeal has recently reversed this trend in the area of product liability**, declaring Amazon liable for the sale of a laptop battery that combusted and caused third degree burns.¹⁷⁹ In this case, Amazon charged the buyer for the **purchase, retrieved the laptop battery from its warehouse,**

¹⁷⁶ Michael W. Carroll, Safe harbours from intermediary liability and social media, in John A. Rothchild (ed), *Research Handbook on Electronic Commerce Law* (Edward Elgar 2016) 168-184.

¹⁷⁷ For a discussion of how this status quo ought to be changed in the USA, see Irene Calboli, Contributory trademark infringement on the internet: Shouldn’t intermediaries finally know what they need to know and control?, in John A. Rothchild (ed), *Research Handbook on Electronic Commerce Law* (Edward Elgar 2016) 211-231

¹⁷⁸ See for example, *Tiffany (NJ) Inc. and Tiffany and Company v eBay Inc.* (United States District Court Southern District of New York, Case No. 04 Civ 4607 (RJS), 14 July 2008), where the court ruled that eBay’s use of jewellery company Tiffany’s trademarks was protected under nominative fair use. It rejected claims that eBay should be liable because the site knew or had reason to know of the infringement at issue and should have done more to stop it from occurring.

¹⁷⁹ *Angela Bolger v Amazon.com* (13 August 2020) Super. Ct. No. 37-2017-00003009-CU-PL-CTL D075738, <https://www.courthousenews.com/wp-content/uploads/2020/08/D075738.pdf>. Note that other cases are ongoing in other American States on similar issues. See, <https://www.natlawreview.com/article/crack-dam-shields-online-retail-platforms-liability-defective-products-third-parties>.

prepared the battery for shipment in Amazon-branded packaging and sent it to Bolger. The court found that Amazon was pivotal in bringing the product to the consumer. This coincided with the introduction of a new bill in California to hold platforms *'strictly liable (subject to certain exceptions) for all damages caused by defective products placed into the stream of commerce to the same extent as a retailer'*.¹⁸⁰ The rationale offered is that not addressing the issue risks pushing manufacturers, distributors and sellers to favour online platforms where their liability is ambiguous compared to sale in brick-and-mortar shops. If this were the case, consumers, public health systems, and private and public insurers, would have to unjustly pay for the cost of treating and healing injuries without contributions from those that actually caused the harm or profited from the manufacture, sale or distribution of a defective product.¹⁸¹ However, some critics of the Bill argue that the blanket liability would favour big platform players that are better poised to shoulder liability for the sale of defective products, and hurt the prospects of small and medium sized intermediaries.¹⁸² The bill also explains that strict liability of marketplaces

¹⁸⁰ AB 3262 Product liability: electronic retail marketplaces (2019-2020), draft last amended 24 August 2020, https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB3262. The bill has not completed its passage through the legislative houses at the time of writing.

¹⁸¹ AB 3262 (n 181) Section 1(f).

¹⁸² <https://uk.reuters.com/article/legal-us-otc-amazon/amazon-backs-proposed-calif-product-liability-law-for-online-sellers-idUKKBN25L2JS>

acts as an incentive to safety and the lack of such liability creates an increased risk of defective products being sold to consumers. However, the bill makes a series of exception for:

- online advertising of defective products if there is no facilitation of the placement of products 'into the stream of commerce' because newspapers, magazines and broadcasters are not subject to strict liability rules;¹⁸³
- pre-owned or used and described as such and hand-made;
- sales where the platform did not receive a direct or indirect financial benefit from the sale of the defective product that caused the injury;
- sales at auctions;¹⁸⁴

There is nevertheless a possibility to disapply the exception if the application of strict liability to the electronic retail marketplace is consistent with the policy considerations underlying strict liability.¹⁸⁵

In the EU, the liability regime is currently set out by the E-commerce Directive (ECD)¹⁸⁶ that offers some protection to platforms. However, this regime has long been criticised and is

¹⁸³ AB 3262 (n 181) Section 1(g).

¹⁸⁴ AB 3262 (n 181) Section 2(b).

¹⁸⁵ AB 3262 (n 181) Section 2(c).

¹⁸⁶ Council Directive (EC) 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce, in the internal market [2000] OJ L178/1.

now **being reformed under the guise of the Digital Services Act**.¹⁸⁷ This reform will capture some of the issues regarding liability for the sale of dangerous products online, but it is, on its own, insufficient and would need to be complemented by a reform of products safety and liability laws.

3.2. Liability of intermediaries in the EU under the E-commerce directive

In order to encourage the development of the Internet, laws were first adopted offering a shield against liability. The reason is that it was feared that if providers were overly burdened with liability for the third-party content they carried, development would be hampered.¹⁸⁸ An immunity regime was deemed in the public interest. As a result, the e-commerce Directive was designed to offer protection to mere conduits¹⁸⁹, caching activities¹⁹⁰ and hosts.¹⁹¹ However some 20 years later, the way the Internet has developed requires some changes to this ecosystem.

¹⁸⁷ Proposal for a Regulation on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC, COM (2020) 825 final.

¹⁸⁸ C Riefa, *Consumer Protection and Online Auction Platforms, Towards a Safer Legal Framework* (Routledge 2016) 176.

¹⁸⁹ Art 12 e-commerce Directive.

¹⁹⁰ Art 13 e-commerce Directive

¹⁹¹ Art 14 e-commerce Directive.

Articles 12, 13 and 14 ECD provides an exemption from liability for illegal content and activities. Hosts do not have control or knowledge over, and upon obtaining such knowledge acts expeditiously to disable access¹⁹² are exempt from liability. The discourse on liability shifted alongside a growing appetite for increasing the liability that should befall intermediaries, at least when it comes to secondary liability.¹⁹³

The European Court of Justice restricted the scope of the exemption to neutral 'hosts' that behave like diligent economic operators in their discovery and removal of any litigious materials.¹⁹⁴ The influence the online platform exercises over the way a service is provided can bar the intermediary from benefiting from the legal classification of information society services altogether (and not just the immunity of article 14) despite meeting all of its criteria.¹⁹⁵ Although is not possible to impose general monitoring obligation on online platforms under article 15 ECD¹⁹⁶ national legislation can impose specific obligations.

¹⁹² Article 14 e-commerce Directive.

¹⁹³ For a full round up of case law in the area of intellectual property, see EU IPO, *The Liability and Obligations of Intermediary Service Providers in the European Union (IPR Enforcement Case Law Collection*, August 2019). See also, Giancarlo F. Frosio, 'Reforming Intermediary Liability in the Platform Economy: A European Digital Single Market Strategy 112 (2017) Northwest. U. L. Rev 19; P. Van Eecke, 'Online Service Providers and Liability: A Plea for a Balanced Approach' 48 (2011) C.M.L.R 1455.

¹⁹⁴ See Joined Cases Google France SARL, Google Inc v Louis Vuitton Malletier SA (C-236/08) v Viaticum SA, Luteciel SARL (C-237/08) and Google France SARL v Centre National de Recherche en relations humaines (CNRHH) SARL, Pierre Alexis Thonet, Bruno Raboin, Tiger SARL (C-238/08) [2010] I-02417; See also Case C324/09 L'Oréal SA and Others v eBay International AG and Others [2011] I-06011.

¹⁹⁵ Case C- 434/15 Asociación Profesional Élite Taxi v Uber Systems Spain SL.

¹⁹⁶ In *J20 v Facebook Ireland Ltd* [2016] NIQB 98, Facebook was fined for failing to remove information that it had knowledge of. The Court of Appeal disagreed with the argument that the platform knew or

Article 1(3) of the e-Commerce Directive 'makes it clear that the e-Commerce Directive "complements Community law applicable to information society services without prejudice to the level of protection for, in particular, public health and consumer interests, as established by Community acts and national legislation implementing them in so far as this does not restrict the freedom to provide information society services". This means that the e-Commerce Directive and relevant EU consumer acquis apply in principle in a complementary manner'.¹⁹⁷

Under the E-commerce directive, the memorandum of understanding on the sale of counterfeit goods on the internet and the product safety pledge were developed as voluntary commitments to tackle the sale of counterfeits and unsafe products.

4.2.1. The MoU on the sale of counterfeit goods on the internet

The Memorandum of Understanding (MoU)¹⁹⁸ is facilitated by the European Commission. It aims at preventing offers of counterfeit goods from appearing on online marketplaces. It was first adopted in 2011 and revised in 2016 to include performance indicator and track its effectiveness. The most recent report on

ought to have known about the content without the need to be notified simply because it was similar to content previously found to be unlawful.

¹⁹⁷ See Commission Staff Working Document, Guidance on the implementation/ application of Directive 2005/29/EC on Unfair Commercial Practices SWD (2016) 163 final, 126.

¹⁹⁸ Memorandum of Understanding on the sale of counterfeit goods on the internet (21 June 2016) <https://ec.europa.eu/docsroom/documents/34122/attachments/2/translations/en/renditions/native>

the functioning of the MoU in 2020 shows that cooperation on the removal of counterfeit goods from marketplaces has been beneficial although its impact remains somewhat limited. First, it is not widely adopted by stakeholders, although it counts the major marketplaces in its ranks.¹⁹⁹ The MoU offers a moratorium on new litigation and rules on the use of notice and take down procedures including a commitment from platforms to facilitate swift removal and the adoption of deterrent measures. Parties also commit to work on pro-active prevention measures including monitoring of offers by IP owners and verification of identity of sellers by the platforms, alongside other preventive measures. The parties also agreed to share information and agreed to enable consumers to report offer of counterfeit goods and rogue sellers. Platforms committed to assist consumers who unintentionally purchase counterfeit goods on their website and endorsed the principle that counterfeit goods should not be returned to sellers.²⁰⁰ Platforms and right owners committed to cooperate in the detection of repeat infringers, especially, but not limited to, those selling high volumes, dangerous, pre-release or obvious counterfeit goods.²⁰¹

¹⁹⁹ See list of signatories, including Alibaba, Amazon, eBay, Facebook Marketplace, Allegro, OXL and Price minister <https://ec.europa.eu/docsroom/documents/34122/attachments/1/translations/en/renditions/native>.

²⁰⁰ MoU (n 199) para 33.

²⁰¹ *Ibid* 34.

3.2.2. The Product Safety Pledge

In 2017, the European Commission issued a notice on the market surveillance of products sold online that was quickly followed by the adoption of a product safety pledge.²⁰² **The pledge is a voluntary commitment that goes beyond the current legal obligations of online platforms.** The pledge was originally signed by Amazon, eBay, Alibaba and Rakuten. They were since joined by Allegro, Cdiscount, Wish.com, Bol.com and eMAG. The pledge aims to ensure faster removal of dangerous non-food consumer products offered for sale online and sets out actions by online marketplaces to strengthen product safety, such as providing a clear way for customers to notify dangerous product listings.

The experience however is that **there is a significant shortfall between the spirit of the safety pledge and the reality of the handling of safety complaints on the platforms.**²⁰³ Platforms signatory to the pledge have made some progress in identifying, monitoring and removing harmful products notably those linked to Covid-19. However, there is little progress concerning: cooperation with market surveillance authorities; identifying the supply chains of dangerous product; the treatment of

²⁰² Commission notice (n 112) and Product Safety Pledge (updated 09.10.2020) https://ec.europa.eu/info/sites/info/files/voluntary_commitment_document_2020_2signatures_v4.pdf.

²⁰³ Hannah Walsh, Shopping Sites ignore reports of unsafe products Which? Magazine (Dec 2020) 34.

customer notices; training sellers using the platforms; avoiding repeat offences; and using new tech to improve detection of unsafe products²⁰⁴, despite some initial developments (reported in the second progress report).²⁰⁵

While no obligations can come from being a signatory to the pledge²⁰⁶, **it may act as a moral obligation carrying with it a reputational risk if it is not followed.** As a result, the issue remains unsolved as not only are many platforms and social media where unsafe goods are sold not participating, they also are not held to account should they miss to engage with the pledge.

From a practical point of view, there is a lack of a strong reporting process to ensure that products can be removed quickly from available purchase and that they stay removed. Even products listed on RAPEX (EU shared database for reporting faulty items and product recalls) were available months after they ought to have been removed from sale. A study from Which? putting to the test the reporting processes on found that platforms may have reporting tools but it is not always clear how

²⁰⁴ Note that not all signatories are included in the figures and data used for the Third progress report on the implementation of the product safety pledge (November 2020).

²⁰⁵ Second progress report on the implementation of the product safety pledge (January 2020).

²⁰⁶ The small print of the pledge states: 'This voluntary commitment is not legally binding and does not now nor in the future create any contractual or precontractual obligations under any law or legal system. Nothing in this voluntary commitment shall be construed as creating any liability, rights, waiver of any rights or obligations for any parties or as releasing any parties from their legal obligations. This voluntary commitment shall not be construed in any way as replacing, extending or interpreting the existing legal framework. This voluntary commitment is not to be used as, or form part of, evidence in any legal proceedings.'

to report a safety issue. Besides, the platforms tested did not respond in an appropriate timeframe. It took a minimum of 2 weeks where the product advert remained up on the site for Amazon & E Bay to 1 month for Wish and the survey team chasing. This is vastly different from the 5 working days turnaround time included in the pledge.²⁰⁷ Delays could have been avoided with a simple and clear reporting category concerning unsafe products. However, it seems the main issue rests squarely in the platforms' lack of commitment to safety as the products reported stayed for sale on the platforms with little action taken to alert consumers or force traders to recall.

A soft law approach has not paid dividends. In this regards the changes being discussed within the scope of the Digital Services Act may come to assist but it would also be useful to tackle the issue not just from an intermediary liability point of view, but also by legislating specifically in the revised version of the General Product Safety Directive and the Product Liability Directive.

3.3 Reforming the liability of intermediaries in the EU: The Digital Services Act

²⁰⁷ Hannah Walsh, Shopping Sites ignore reports of unsafe products Which? Magazine (Dec 2020).

The Digital Services Act comes as part of a package that is composed of two legislative elements: The Digital Services Act²⁰⁸ (DSA) and the Digital Market Act²⁰⁹ (DMA) both of which are currently only proposals. Many changes may thus come to change the overall shape of the proposed Regulations and this report points out where some changes may be necessary to protect consumers against the sale of dangerous products.

The proposed DSA is a horizontal instrument. It comes to complement already existing sectoral legislation. It covers all content, including goods and services. Its adoption **will not replace rules that may already be contained or will be contained in other sector specific legislation on product safety**.²¹⁰ The DSA is also not a replacement for the e-commerce directive²¹¹, but instead, it builds on its provisions and provides for a cooperation and coordination mechanism for the

²⁰⁸ Proposal for a Regulation on a Single Market for Digital Services (Digital Services Act) and amending Directive 2000/31/EC (15.12.2020) COM (2020) 825 final.

²⁰⁹ Proposal for a Regulation on contestable and fair markets in the digital sector (Digital Markets Act) (15.12.2020) COM (2020) 842 final. The DMA focusses on the regulation of 'gatekeepers', ie large platforms that are enjoying an entrenched and durable position often as a result of conglomerate ecosystems around their core platform services, reinforcing existing barriers. It essentially caters for competition concerns although a regulation of digital markets may benefit consumers who would in future have more opportunities to switch providers if they wish to. This may in turn lead to fairer prices. Operators that qualify as gatekeepers are subject to new obligations, notably concerning inter-operability, access to data, and on advertising practices. To enforce this new framework, the EU opted for the adoption of market investigations. Non-compliance will lead to fines up to 10% of total worldwide annual turnover and periodic penalties of up to 5% of the average daily turnover. Additional remedies are available in case of systemic infringements following a market investigation. Those remedies can include non-financial behavioural and structural remedies.

²¹⁰ Art 1(5)(h) DSA. Note that the DSA does not list the product safety laws it may be referring to. It only specifically mentions the CPC Regulation 2017/2394.

²¹¹ Although it deletes art 12 to 15 from the e-commerce directive, to incorporate them into the DSA. See Recital 16 DSA.

supervision of the obligations it imposes.²¹² **The DSA will control online platforms, including social media and marketplaces. The DSA applies to providers irrespective of their place of establishment or residence**, in so far as they provide services in the Union, evidenced by a substantial connection to the Union.²¹³ **The proposed DSA adopts a number of provisions that could assist in tackling the sale of unsafe products on platforms** although they do not seem to go far enough. However, it is important to note that in the scope of the DSA, the sale of dangerous product is not a main objective.

3.3.1. Scope of the DSA

The DSA is able to capture the sale dangerous products sold via the use of intermediary platforms. Indeed, it deals with illegal content. Illegal content is broadly defined, and it includes the sale of non-compliant or counterfeit products. It will also cover activities involving infringements of consumer law.²¹⁴ Article 2(f) defines ‘online platform’ as *‘a provider of a hosting service which, at the request of a recipient of the service, stores and disseminates to the public information, unless that activity is a minor and purely ancillary feature of another service and, for objective and technical reasons cannot be used without that*

²¹² Digital Services Act COM (2020) 825 final, 4.

²¹³ Recital 7 DSA. Recital 8 defines what a substantial connection may be.

²¹⁴ Recital 12 DSA and Art 2(g) DSA.

other service, and the integration of the feature into the other service is not a means to circumvent the applicability of this Regulation'. This will therefore include online retail platforms and social media platforms who may facilitate the sale of dangerous products.

3.3.2. Hosting liability

Article 5 DSA provides (as art 14 of the electronic commerce directive did) that no liability is imposed on providers that do *'not have actual knowledge of illegal activities or illegal content and, as regards claims for damages, is not aware of facts or circumstances from which the illegal activity or illegal content is apparent; or upon obtaining such knowledge of awareness, acts expeditiously to remove or disable access to the illegal content'*. Whereas the e-commerce directive effectively discouraged own-investigations by platforms as they risked losing their passive roles, the DSA enables hosts to monitor, if they wish to, without losing the protection of *the exemption*.²¹⁵ *However, as the e-commerce directive did, there can be no general monitoring obligations or fact-finding obligations imposed on platforms.*²¹⁶

BEUC recommended creating a special liability regime for platforms which allow the conclusion of distance contracts. This

²¹⁵ Recital 22 DSA and Art 6.

²¹⁶ Recital 28 and Art 7 DSA.

would require that platforms are liable for damages where they do not take adequate measures for the protection of platform users, upon obtaining credible evidence of an activity causing physical injury.²¹⁷ BEUC also floated the idea that market-places should be liable for damages, contract performance and or guarantees and consumers ought to be able to exercise the same rights and remedies that are available against supplier and producer in accordance with existing legislations relating to sales.²¹⁸

Under article 5(3) DSA online platforms that allow consumers to conclude distance contracts with traders, should not be able to benefit from the exemption from liability for hosting service providers if the consumer may be misled into thinking they were transacting with the platform and not with a third party hosted on the platforms.²¹⁹ As such it does not place an obligation on platforms to be liable for the sale of dangerous. The obligation is in fact one of transparency. Indeed, the provision applies regarding to liability under consumer laws and the exemption cannot be used only if the ‘average and reasonably well-informed consumer’ believes the product is provided by the platform itself or by a third party under its authority or control. It therefore seems all

²¹⁷ BEUC, Making the Digital Services Act Work for Consumers (2020) BEUC-X-2020-031, 30.04.2020, 15.

²¹⁸ BEUC, Digital Services Act (n 217) 15. BEUC cites notably obligations to inform about the supplier of the goods and services under the Omnibus Directive and following C-149/15 *Whatelet v Bietheres* under which an intermediary can be regarded as a seller.

²¹⁹ Recital 28 DSA.

platforms have to do is to include prominent disclaimers to continue to benefit from the exemption. However, Article 5(4) DSA explains that courts and administrative authorities can require the service provider to terminate or prevent an infringement.

3.3.3. Tracking down sellers of unsafe products

The proposed DSA introduces rules on the traceability of business users.²²⁰ This means that online platforms are required to identify their business users and clarify the identity of the seller. This may assist in tracking down scammers and rogue traders selling illegal products (including counterfeit and dangerous products).

Trader should be required to provide certain essential information to the online platform, including for promoting messages or offering products.²²¹ This information includes:

- (a) Name, address, telephone number and email address of the trader;
- (b) A copy of the identification document of the trader or any other electronic identification;
- (c) The bank account details of the trader, where the trader is a natural person;

²²⁰ Article 22 DSA. This does respond to BEUC's recommendations, requiring robust business user authentication. See BEUC, Digital Services Act (n 217) 11.

²²¹ Recital 49 and art 22(a) DSA.

- (d) The name, address, telephone number and electronic mail address of the economic operator within the meaning of article 3(13) and article 4 of Regulation (EU) 2019/1020 (on market surveillance) or any relevant act of Union law;
- (e) Where the trader is registered in a trade register or similar public register, the trade register in which the trader is registered and identification number or equivalent means of identification;
- (f) A self-certification by the trader committing to only offer products and services that comply with the applicable rules of Union Law.

The information in para (a), (d), (e) and (f) is made public and available to the recipient of the service in a clear, easily accessible and comprehensible manner.²²² The online platform shall also design and organise its online interface in a way that enables traders to comply with their obligations regarding pre-contractual information and product safety information under applicable Union Law.²²³

Platforms should make reasonable efforts to verify the reliability of the information provided. However, the DSA stops at efforts that would be excessive or costly online fact-finding exercises

²²² Art 22(6) DSA.

²²³ Art 22(7) DSA.

or carry out verifications on the spot. Platforms are also not to be understood as guaranteeing the reliability of the information towards consumers and other interested parties.²²⁴ In the case of fraudulent traders established abroad, it seems all the platform may have to do is ask for documentation and store it. It will not have to necessarily verify its veracity. The platform is only required to make reasonable efforts to assess the reliability of the information concerning name, address, telephone number and email, and same for the economic operator and registration in a trade register. But this is only through freely accessible official online databases or online interface made available by a Member states or the Union or through request to the trader to provide information. If the information is suspected to be inaccurate, and the trader does not correct it, the platform can suspend the account until compliance.²²⁵

This therefore does not seem to be going far enough and is unlikely, on its own, to be sufficient to protect consumers against the sale of dangerous products. This **merely amounts to a transparency obligation and simple checks that may not be sufficiently sophisticated to capture the large volume of dangerous product sold on platforms.** It also **falls short of BEUC's recommendations, requiring robust product verification obligation.**²²⁶

²²⁴ Recital 50 DSA.

²²⁵ Art 22(6) DSA.

²²⁶ BEUC, Digital Services Act (n 217) 11.

3.3.4. Removal of unsafe products

A number of measures contained in the proposed DSA contribute to the removal of products that are dangerous for consumers.

3.3.4.1. Orders from national judicial or administrative authorities to act against illegal content and provide information

Articles 8 requires that platforms shall, upon request of an order to act against a specific item of illegal content, issued by a relevant national judicial or administrative authority, must inform the said authority of the effect given to their order. This needs to be done without undue delay and specifying the action taken and the moment when the action was taken. Orders however need to contain some specific elements including reasons for illegality, exact URLs and/or information enabling the identification of the illegal content and some information about redress available, the scope of the order. The order needs to be strictly necessary to achieve its objective and drafted in the language declared by the provider. The order is received by the Digital Services Coordinator and sent and circulated to others in other

Member States. Providers can also be asked to provide information via orders.²²⁷

Under Art 21, where an online platform becomes aware of any information giving rise to a suspicion that a serious criminal offence involving a threat to life or safety of persons has taken place, or is likely to take place, it shall promptly inform the law enforcement or judicial authority of the Member State or Member States concerned and provide all relevant information. Where identifying the member states concerned is not possible, Europol can be advised.

3.3.4.2. Notice and action procedures

The large share of respondents to the Commission's open public consultation who have notified illegal content or goods to digital service providers expressed their dissatisfaction with the response and the ineffectiveness of reporting mechanisms after the exposure took place and noted the need for simple, standardised and transparent notice and action obligations.²²⁸

BEUC also called for further harmonisation of processes.²²⁹

Article 14 DSA requires hosting services to put in place such mechanisms. Platform users (consumers, citizens) will, for the

²²⁷ Art 9 DSA.

²²⁸ Digital Services Act COM (2020) 825 final, 10.

²²⁹ BEUC, Digital Services Act (n 217) 10; BEUC, Notice and Action principles on illegal content (2012) <https://www.beuc.eu/publications/2012-00543-01-e.pdf>.

first time, be able to notify content that is suspected to be illegal, a tool so far reserved to intellectual property owners alongside enforcers under the Product safety pledge notably. **Platforms are required to have mandatory procedures in place to remove illegal products. Public authorities are given new tools to request the removal of unsafe products directly.**

In order to facilitate identification of content and action by diligent economic operator, the DSA lists the elements that notices must contain. Notices that contain all of those elements are deemed to give the platform actual knowledge or awareness and thus would trigger the need to take action.²³⁰

'Trusted flaggers' notifications defined in Art 19 are given priority. Trusted flaggers are not individuals. They are entities that have demonstrated they have particular expertise and competence in tackling illegal content, represent the collective interest and are independent from platforms. They carry out their activities for the purposes of submitting notices in a timely, diligent and objective manner.²³¹ This would include public authorities, but it seems, could also include consumer associations. The status of trusted flagger will be awarded by Digital Services coordinators. Under the DSA, the authority appointed with the task of supervising the application and enforcing the Regulation

²³⁰ Art 14(3) DSA.

²³¹ Recital 46 and Art 19 (2) DSA.

is identified as a Digital Services Coordinator. There is one in each Member State.²³²

Orders to act against illegal content or provide information should be issued in compliance with EU laws (in particular the GDPR) and the prohibition of general obligations to monitor information or to actively seek facts or circumstances indicating illegal content (recital 30). Rec 30 states that this Reg is without prejudice to the CPC Regulation 2017/2394 that confers specific powers to order the provision of information on Member State consumer law enforcement authorities, whilst the conditions and requirements that apply to orders to provide information are without prejudice to other Union acts providing for similar relevant rules for specific sector.

3.3.4.3. Due diligence and enforcement

All intermediary services will need to report activities relating to the removal and disabling of information considered to be illegal content or contrary to terms and conditions.²³³ **For very large platforms** (defined in article 25), **additional requirements are put in place.** They are defined in section 4 (articles 26-28). This includes notably some audited risk assessment and analysis of vulnerability to illegal goods on

²³² Recital 73 DSA.

²³³ Art 23 DSA.

their platforms and mitigation measures subject to annual audits. To further ensure compliance, vetted researchers are given access to data.²³⁴ Large platforms will also need to have compliance officers in place and are subject to reporting obligations.²³⁵ For activities of very large platforms, the Commission gains some enforcement powers (notably through articles 52 to 60). The key change resides in the ability to open proceedings where it is suspected that the platform may have infringed any of the provision of the DSA and the Digital Service Coordinator did not take action despite a request of the Commission; or at the request of a national Digital Services Coordinator; or because it is suspected the platform did not comply with its obligations to manage systemic risks under section 4 of chapter 3.

The distinction between operators (due to size) is problematic. According to BEUC, a high level of consumer protection should not depend on the size of a company. It will create a two-tier system of consumer protection although some targeted measures are possible to tackle market-related problems.²³⁶

The main downside with the additional requirements for large platforms is that they may also come to reinforce market positions, by signalling to consumers that large platforms are safer because they are more regulated. It also

²³⁴ Art 31 DSA.

²³⁵ Art 32 and 33 DSA.

²³⁶ BEUC, Digital Services Act (n 217) 8.

may lead to an exodus of rogue traders to smaller platforms to avoid detection, meaning that smaller platforms face higher risks.

3.3.5. The need for sector specific liability rules for protection against the sale of unsafe products

Overall, the **DSA will no doubt have a role to play in the fights against the sale of unsafe products on online platforms. However, the legal regime proposed does not go as far as imposing liability onto the platforms.** This means that specific legislation and liability rules are still required. Besides, the DSA also explains in Article 1(5) DSA that the Regulation is without prejudice to the rules laid down by Union law on consumer protection and product safety, including Regulation (EU) 2017/2394 (The CPC regulation). As a result, we explore specific product safety legislation and how it ought to be shaped to protect consumers against the sale of dangerous products on online platforms.

Notably, according to BEUC, and given the high incidence of dangerous products sold on platforms, *‘if online market places cannot be held liable for the defective products that they distribute, they may not be incentivised to prevent the circulation of such harmful goods’.*²³⁷ At the very least, platforms should

²³⁷ BEUC, product liability 2.0 (n 157) 9.

be clearly identified as suppliers under the Product Liability Directive, meaning that online market places would be subsidiarily liable when at least:

- the producer cannot be identified;
- the platforms fails to inform the consumer in due time of the identity of the producer and does not enable communication between the consumer and the producer by providing them with relevant contact details;
- the market place received clear evidence about non-compliant products on its platform;
- the producer is identified but does not take measures to remedy the harm;
- the marketplace has a predominant influence or control in the transaction chain.²³⁸

With regards to the application of the GPSD, marketplaces should be considered economic operators and have clear obligations to contribute to general product safety and market surveillance, be subject to sanctions by market surveillance authorities for failing to comply with product safety obligations, and ultimately be held liable for damages exposed by consumers. Regarding the status they may hold as economic operators, see section 3.1.4.2.

²³⁸ BEUC, product liability 2.0 (n 157) 19.

Liability measures under the GPSD ought to include enabling market authorities to address enforcement actions contained in the GPSD to online platforms. Regulation 2019/1020 appears to be a good starting point for defining obligations. Measures could include:

- withdrawing products from the supply chain, via delisting or withholding products ordered and not yet sent out (if acting as a fulfilment centre);
- respond to alerts and remove unsafe products in a very short time span²³⁹;
- Consult regularly the RAPEX listings and remove unsafe products in a short time span;
- prevent products removed from being re-listed;
- destroying products at fulfilment centres on instruction from authorities;
- recalling products from consumers;
- pushing recall notices on the platform and informing consumers proactively about dangerous products;
- providing consumers with warnings and instruction for safe use;
- cooperating with authorities on all matters relating to safety.²⁴⁰

²³⁹ BEUC proposes 24 hours. See BEUC, ANEC (n.30) 12.

²⁴⁰ BEUC, ANEC (n.30) 12.



4. International rule making and enforcement frameworks

A key issue the EU faces is that while within the EU the level of protection is high, the same level of protection is not in place uniformly further afield. There is however movement in the international community towards some level of harmonisation. UNCTAD research in international cooperation in consumer protection uncovered two convergent trends. First regional trade agreements are gradually considering consumer protection cooperation as a means to facilitate implementation of trade liberalisation measures. Second, consumer protection concerns in policy and enforcement are increasingly considered at multilateral discussions due to their global dimension.²⁴¹ In this part we unpack the international legal framework that shapes product safety and the sale of dangerous products online. This includes WTO rules, OECD and UNCTAD guidelines on consumer protection and product safety, as well as enforcement mechanisms.

4.1. WTO rules regulating the trade of unsafe products sold online

The WTO is not a framework for businesses but for States who, as members, negotiate and agree on rules to facilitate trade. There is evidence that free trade does in many ways contribute to offering consumers more product variety and higher quality. The lowering of tariff barriers does in theory has a positive effect on consumers. However, BEUC notes: *‘this is not an automatic effect. Importers will pay less, but they might not always pass on the gains of these tariff reductions to consumers. It will depend on various factors including the competitive pressure on the market.’*²⁴² Indeed, improvements in consumer welfare are not an objective of trade agreements and to date there is no formal requirement to indeed deliver or monitor those benefits once an agreement is in place. The spike in the trade of dangerous goods online highlights the limitations of free trade that can only yield benefits if appropriate measures are taken to preserve a level playing field and avoid unfair commercial practices.

4.1.1. GATT and the sale of unsafe goods

²⁴¹ UNCTAD, International Cooperation in Consumer Protection (UNCTAD/SER.RP/2020/13) research paper No.54 (2020) 43.

²⁴² BEUC, Trade Negotiations and Regulatory Trade Dialogue with the United States (2019).

Art 20 GATT enables governments to place some barriers on trade, to protect humans, animal or plant life or health providing that the measures do not in fact amount to protectionism.²⁴³ It is also possible to place restrictions and take measures 'necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices'.²⁴⁴ As a result, it is **possible to envisage some restrictions to avoid the online sale of unsafe goods to European consumers as they are a threat to human health and can amount to deceptive practices where the dangerous goods are sold to unsuspecting consumers.**

The online sale of dangerous products may fall within the application of the SPS if the goods sold are food (which is not within the remit of this report). It will also fall under the TBT regarding the safety standards imposed for goods and services. For food, animal and plant products, a specific agree-

²⁴³ Art XX (b) GATT. The article states that 'Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

(a) (...)

(b) *necessary to protect human, animal or plant life or health;*

(c) (... to (j) (...).

²⁴⁴ Art XX (d) GATT.

ment exists: the Sanitary and Phytosanitary Measures Agreement (SPS). Under this agreement, it is allowed to set standards. Those will have to be based on science and be applied only to the extent necessary to protect humans, animal or plant life or health. The measures cannot be arbitrary or discriminate. The use of international standards and guidelines is encouraged when they exist, although it is possible to go beyond and indeed set new standards providing that they are not discriminatory (usually penalising importers and favouring domestic producers). The measures can in this respect accommodate the precautionary principle prevalent in the EU albeit to a limited degree through Art 5.7 SPS on temporary precautionary measures. Technical Barriers to trade (TBT)²⁴⁵ is another agreement that sets up the framework for states' own processes and technical regulations providing that they are not an unjustified obstacle to trade. Each country remains free to adopt its own set of rules sufficient to protect human, animal or plant life or health or to meet other consumer interests. Any rule adopted however needs to be fair and equitable and not give domestically produced goods an unfair advantage.

4.1.2. Agreement on electronic commerce

²⁴⁵ https://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

The Ministerial Declaration of 20 May 1998 established a work programme on electronic commerce with an agreement resulting in not imposing customs duties on electronic transmissions. In 2017, the WTO Buenos Aires Joint Statement on electronic commerce initiated exploratory work towards future WTO negotiations on trade related aspect of electronic commerce. This was followed by a Davos' Joint Statement on Electronic Commerce dated 25 January 2019 announcing the intention to commence WTO negotiations on trade-related aspects of electronic commerce.²⁴⁶ The communication from China following this Joint Statement identifies consumer protection and online contracting as issues to be negotiated on. The G20 summit held in Japan in 2019 launched the 'Osaka Track', a 'process which demonstrates commitment to promote international policy discussions, inter alia, international rule making on trade-related aspects of electronic commerce at the WTO'.²⁴⁷ **Negotiations are now underway and are reported to have made good progress in a range of areas including building consumer trust in e-commerce and online consumer protection and the production of a consolidated text.**²⁴⁸

²⁴⁶ https://www.wto.org/english/news_e/news19_e/dgra_25jan19_e.htm

²⁴⁷ Osaka Declaration on Digital Economy, https://www.g20.org/pdf/special_event/en/special_event_01.pdf

²⁴⁸ https://www.wto.org/english/news_e/news20_e/ecom_14dec20_e.pdf. Note that the text is not a public document and I was unable to check the content of the consumer protection text.

Building consumer trust can certainly include acting on product safety, a move that is encouraged by BEUC. Notably, BEUC explains that efforts must be taken to make sure consumers will not be harmed by dangerous products sold online and encourages cooperation on consumer protection, market surveillance, enforcement, competition, redress and dispute resolution.²⁴⁹ While consumer associations recommend keeping sensitive issues such as data protection out of any WTO deal, it seems those points have been included and could in future have important consequences for consumers in the EU, by effectively lowering the standard of protection that could be extended to consumers' personal data.²⁵⁰ **Including consumer safety rules within the agreement could also be somewhat risky as it could hamper the level of protection that can be offered in future.**

The direction of travel seems to be reaching a free trade agreement that essentially would remove any tax being paid on e-commerce. It is not certain that this is to be beneficial to consumers. **Tax discrimination in favour of electronic commerce may help support Internet giants (such as Amazon) and penalise brick and mortar shops. This in turn could penalise poorer consumers because it would contribute to**

²⁴⁹ BEUC, WTO e-commerce negotiations, BEUC recommendations (2019) BEUC-X-2019-014, 29.03.2019, 6 https://www.beuc.eu/publications/beuc-x-2019-014_wto_e-commerce_negotiations_-_beuc_recommendations.pdf

²⁵⁰ See https://www.wto.org/english/news_e/news20_e/ecom_14dec20_e.pdf, which states: 'discussions on the flow of data are key to a high standard and commercially meaningful outcome. Discussions on these issues are ongoing and will intensify from early 2021' and BEUC, WTO e-commerce negotiations (n 246) 7.

intensifying monopolies. Another potential problem is the cost of free e-commerce trade on the environment.

4.1.3. TRIPS Agreement and intellectual property rules

The TRIPS agreement was adopted in 1995. It is quite comprehensive in that it covers copyright and related rights, trademarks, geographical indications, designs, patents and even trade secrets. All rights have quite distinct rules applicable to them and remedies attached to their exercise. TRIPS includes some details regarding subject matter, substantive rights and possible exceptions as well duration of the protection granted to each right holders. The rights conferred are enshrined into binding law. The way the substantive rights are conferred is by reference to pre-existing international conventions (WIPO): Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention). All provisions of the Conventions are applicable except the provisions relating to moral rights in the Berne Convention. TRIPS goes beyond existing international law, because it 'adds a substantial number of additional obligations on matters where the pre-existing conventions are silent or were seen as being inadequate. The TRIPS Agreement is thus sometimes referred to as a Berne

and Paris-plus agreement.²⁵¹ The TRIPS Agreement is a minimum standards agreement. It allows to provide more extensive protection. TRIPS also leaves member states free to decide how best to implement the agreement in their own system. The rules contained in the TRIPS system are subject to the arbitration procedure of the WTO. However, **TRIPS has many downsides and notably it can be a tool to strengthen monopoly privileges. However, it can be useful to combat the sale of fake products that may prove dangerous** because it enables IP rights holders to enforce their rights more or less worldwide. This however may have some downsides (see section 0, Annex 1).

4.2. International standards on consumer safety and consumer protection

At a regional level, a number of regions have developed their own system of consumer protection. This includes for example, the European Union (EU), the Association of Southeast Asian Nations (ASEAN), the Caribbean Community (CARICOM) or the Southern Common Market (MERCOSUR), etc. Regional systems normally work towards the harmonisation of national laws and the sharing of institutions, although enforcement remains largely national in nature. In the EU however, the revised

²⁵¹ https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

Consumer Protection Cooperation Regulation 2017/2394 will offer much closer collaboration channels. **At international level, there is to date no harmonised system of consumer law in operation. Instead, soft law occupies that space.** Currently, the main instruments in this regard are the OECD recommendations²⁵² and the United Nations Guidelines on consumer protection. The latter offer a set of agreed principles agreed by the UN General Assembly.²⁵³ They are complementary texts. Both have recently been revised to take into account the impact digital technologies have on consumer protection.²⁵⁴ While they are not binding instruments, they have been widely acknowledged as standard setting and are often used by developing countries as blueprint for the development of their local laws. **Influencing international standard setting can help the EU protect its consumers against the sale of unsafe products online.**

4.2.1. The UNCTAD guidelines on consumer protection

A number of sections in the United Nations Guidelines for Consumer Protection (UNGCP) are of direct relevance to electronic

²⁵² OECD (2016), *Consumer Protection in E-commerce: OECD Recommendation*, OECD Publishing, Paris, <http://dx.doi.org/10.1787/9789264255258-en>.

²⁵³ Adopted by the General Assembly in its resolution 70/186 of 22 December 2015, A/RES/70/186.

²⁵⁴ UNCTAD, *Consumer Protection in electronic commerce*, Note by the UNCTAD Secretariat (TD/B/C.I/CPLP/7) April 2017, 2.

commerce and product safety. For example, the UNGCP Guideline 5 lists a number of 'legitimate needs' which the guidelines are intended to meet. Those include:

- c) the protection of consumers from hazards to their health and safety;
- j) a level of protection for consumers using electronic commerce that is no less than that afforded in other forms of commerce; and
- k) the protection of consumer privacy and the global free flow of information.²⁵⁵

Section VB is focused on physical safety and contains provisions encouraging the adoption of measures (such as legislation and standards) and the maintenance of safety records to ensure that products are safe for intended and foreseeable use.²⁵⁶ It also supports appropriate policies for the manufacture or safe product and provides for liability of those responsible for bringing goods to the market as well as obligations to report unsafe product but the measures fall short or requiring removal of products from the market. It limits itself to information. However, Guideline 19 provides for recall procedures where products are found to be seriously defective and/or constitute a sub-

²⁵⁵ Other UNCTAD Guidelines are relevant: G11, G14, G79-94 on enforcement.

²⁵⁶ UNCTAD Guideline 16.

stantial and severe hazard even when properly used. Consumers can be compensated when manufacturers or distributors fail to recall, replace or modify unsafe products within a reasonable period of time.²⁵⁷

In addition, in section VD, Guidelines 33 to 35 deal with standards for the safety and quality of consumer goods and services. In particular, Guideline 34 explains that 'where a standard lower than the generally accepted international standard is being applied because of local economic conditions, every effort should be made to raise that standard as soon as possible. This is possibly an important provision in order to raise the level of protection of consumers not only in the EU but further afield. Similarly, Guideline 35 encourages the availability of testing facilities and certification bodies.

Section VK on measures relating to specific areas refers to safety as product quality control and this in relation to a number of areas, including food, water and pharmaceuticals. It makes reference to the relevant international bodies including the *Codex Alimentarius* and the WHO.²⁵⁸

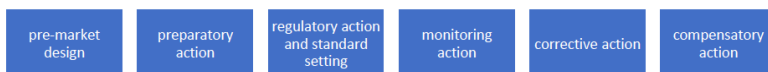
Section VI is dedicated to e-commerce and contains 2 guidelines of particular relevance. Guideline 63 states that 'Member States should work towards enhancing consumer confidence in

²⁵⁷ UNCTAD Guideline 19.

²⁵⁸ UNCTAD, Manual on Consumer Protection (2017) 60, <https://unctad.org/webflyer/manual-consumer-protection>.

electronic commerce by the continued development of transparent and effective consumer protection policies, ensuring a level of protection that is not less than that afforded to other forms of commerce'. This can be interpreted in such way as ensuring that dangerous products can be eradicated as widespread harm to consumers would erode trust in electronic commerce. Guideline 64 explains that 'Member State should, where appropriate, review existing consumer protection policies to accommodate the special features of electronic commerce and ensure that consumers and businesses are informed and aware of their rights and obligations in the digital marketplace'.

Alongside the Guidelines, UNCTAD released a Manual on Consumer Protection²⁵⁹ of which Chapter IX is devoted to product safety and liability. This chapter notably lays out the components of a comprehensive product safety policy, identifying 6 basic components alongside some developments on product



liability.

²⁵⁹ UNCTAD, Manual on Consumer Protection (2017) 60, <https://unctad.org/webflyer/manual-consumer-protection>.

Fig. 4. Components of a comprehensive product safety policy. Source UNCTAD Manual on Consumer Protection (2017).

Chapter XII is devoted to e-commerce. It provides useful background information and points to the key issues to tackle. The manual also contains a Chapter XIII on Privacy. Note that there is little mention of the latest technologies nor acknowledgments of the possible dangers of personalization and/or collection of data.

4.2.2. The OECD recommendations

The OECD Recommendation of the Council on Consumer Product Safety was adopted in July 2020. This recommendation updates pre-existing legal instruments on consumer product safety and builds on the work of the Committee on Consumer Policy and its Working Party on Consumer Product Safety (WPCPS). The OECD recommendation (2020) takes into account current and emerging challenges to consumer product safety brought about by new technologies, increased cross-border trade and more complex globalised supply chains.²⁶⁰ It has a wide reach in that it includes all actors in the supply chain, as well as purchases online and in stores. The

²⁶⁰ OECD, Recommendation of the Council on Consumer Product Safety, OECD/LEGAL/0459 (2020) 3.

recommendation recognises consumers' right to safe products and rapid alerts when unsafe products are on the market or are the subject of a ban or recall. This is an innovative feature as it already links a tool, rapid alerts, to the right to safety and elevates access to those notifications as a right of consumers. To do so it is guided by evidence and data sources including where possible injury data collection, a systemic risk management and assessment approach, information sharing and awareness initiatives. It also pays specific attention to vulnerable consumers.²⁶¹

The OECD Recommendation on electronic commerce²⁶² is also worthy of notice.²⁶³ It addresses privacy and security risks²⁶⁴ and encourages businesses not to offer, advertise or market goods or services that pose an unreasonable risk to the health or safety of consumers and to cooperate with enforcement authorities where such risk exists.²⁶⁵ Its scope includes B2C e-commerce, including 'commercial practices through which businesses enable and facilitate consumer-to-consumer transactions' (i.e. intermediaries are included). It covers also

261 Ibid.

262 https://read.oecd-ilibrary.org/industry-and-services/oecd-recommendation-of-the-council-on-consumer-protection-in-e-commerce_9789264255258-en#page3.

263 It is referred to in the UNCTAD Guidelines specific to e-commerce, Guideline 65.

264 Recommendations 48 and 49.

265 Recommendation 23.

'commercial practices related to both monetary and non-monetary transactions for goods and services, which include digital content products'. The recommendation also elaborates on global co-operation principles.²⁶⁶

4.2.3. International voluntary standards

In other international non-governmental fora, consumer protection is also being highlighted as a concern. ISO, the International Standards Organisation, is an independent, non-governmental organisation which brings experts to develop voluntary standards. Those are consensus based and market relevant. They aim to support innovation and provide solutions for global challenges.²⁶⁷ ISO hosts a committee on consumer policy (COPOLCO) which works on ensuring that consumer interests are represented in the adoption of standards. ISO has issued a number of relevant standards on product safety (mostly vertical standards on particular products such as toys or cosmetics) as well as:

²⁶⁶ Recommendation 54. This includes: Communication, co-ordination, co-operation should be developed including consensus-building, both at the national and international levels, on core consumer protections to further the goals of promoting consumer welfare and enhancing consumer trust, ensuring predictability for businesses, and protecting consumers. Emphasis is placed on the mutual recognition of judgments and considering the role of applicable law and jurisdiction to enhance trust in e-commerce.

²⁶⁷ <https://www.iso.org/about-us.html>.

- ISO 10377:2013 which provides practical guidance to suppliers on assessing and managing the safety of consumer products, including effective documentation of risk assessment and risk management to meet applicable requirements;
- B2C e-commerce (ISO 10008:2013).²⁶⁸

4.3. International enforcement of consumer safety laws

Consumer law enforcement is largely based on reliance on both private enforcement as well as public enforcement.²⁶⁹ In the context of dangerous products, this dichotomy is maintained at EU level, with two separate instruments applicable: the GPSD and the Product Liability Directive. International instruments also acknowledge this distinction with provisions both catering to international cooperation and access to redress for consumers. However, consumer enforcement is generally split between entities enforcing general consumer laws (such as the UCPD or the Consumer Rights Directive)²⁷⁰ and

²⁶⁸ <https://www.iso.org/standard/54081.html>. The standard was reviewed and confirmed in 2019.

²⁶⁹ Enforcement of consumer law is the object of a full module. This part only seeks to highlight the most pertinent points with regards to e-commerce and new technologies. It should be read in conjunction with the enforcement module.

²⁷⁰ In the EU, cooperation is formalised through the Consumer Protection Cooperation Network which is a network of authorities that are responsible for the enforcement of EU consumer protection law. The CPC network enables authorities to share best practices and provide mutual assistance mechanisms. The network is underpinned Regulation 2017/2394 (CPC) on Consumer Protection Cooperation. The Regulation seeks to provide the tools for better enforcement in the digital sphere.

entities specialising in market surveillance and thus specialising in consumer safety enforcement. Customs checks and enforcement by customs officer is also another piece of the jigsaw and is not always fully integrated into the enforcement systems.

4.3.1. Cross-border safety enforcement lacking infrastructures

Public enforcement is further complicated by the increasing need to cater for cross-border enforcement. Indeed, *‘ineffective enforcement in cases of cross-border infringements (...) in the digital environment enables traders to evade enforcement by relocating (...). It also gives rise to a distortion of competition for law-abiding traders (...) and thus directly harms consumers and undermines consumer confidence in cross-border transactions (...)*²⁷¹. The cross-border nature of electronic commerce compounds the effects of the three main structural challenges for enforcers, whatever their remit:

- The diversity of legal regimes applicable;
- The limitations in private enforcement mechanisms (or consumer engagement with them);
- The diversity of public enforcement mechanisms in place.

²⁷¹ Recital 3, CPC Regulation 2017/2394.

Unsurprisingly, UNCTAD notes that *‘cross-border international cooperation, especially in enforcement, is still relatively uncommon. With the exception of the European Union, it is currently based on inter-agency informal cooperation, which may be insufficient to adequately address the growing number of cross-border unfair commercial practices. Neither does it allow for satisfactory dispute resolution and redress for consumers, especially those who shop online, ultimately hindering trust in digital markets’*.²⁷²

There is currently no international body for enforcement cooperation. The closest incarnation is the International Consumer Protection and Enforcement Network (ICPEN²⁷³) and e-consumer.gov for consumer complaints. ICPEN brings together over 65 consumer enforcement authorities in the world and provide a framework for collaboration.²⁷⁴ Its mandate is to share information about cross-border commercial unfair practices that affect consumers’ interests and encourage international collaboration. It is thus not focussed on consumer safety enforcement. **However, in these areas, we can note the progress made by the OECD and UNCTAD.**

²⁷² UNCTAD, International Cooperation in Consumer Protection (UNCTAD/SER.RP/2020/13) research paper No.54 (2020) 43.

²⁷³ <https://www.icpen.org>

²⁷⁴ <https://www.icpen.org/who-we-are>.

4.3.2. International rapid exchange of information on unsafe non-food products

Surveillance and data collection are two cornerstones that are particularly pressing where goods are sold cross-borders. The need for access to information is acute to be able to improve international coordination between market surveillance authorities and enable consumers and businesses to also be made aware of potential issues.

UNCTAD can act as a promoter and allow consensus to emerge. This was recently the case with the adoption of the **recommendation on ‘Preventing Cross-border Distribution of Known Unsafe Consumer Products’ by the Eighth United Nations Conference on Competition and Consumer Protection** held in 2020.²⁷⁵ The recommendation notes the existence of information exchange mechanisms, notably the EU Rapex²⁷⁶, the Organisation of American States’ Consumer safety and Health Network²⁷⁷ and the OECD’s Global Recalls portal.²⁷⁸ It **urges action against rogue distributors who continue to distribute products that have been withdrawn**

²⁷⁵ https://unctad.org/system/files/information-document/tdrbpconf9_d01_consumer-products_en.pdf

²⁷⁶ https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.list-Notifications&lng=en

²⁷⁷ <https://www.sites.oas.org/rcss/en/Pages/default.aspx>

²⁷⁸ <https://globalrecalls.oecd.org/#/>

from the market due to non-compliance in one country but not yet assessed or acted upon in another.

The **OECD Recommendation**²⁷⁹ on Consumer Product Safety **recommends information sharing amongst safety government bodies as a main vehicle.** Recommendation IV(1) explains that those initiatives can include: *(a) consumer product safety legislation, regulations and guidelines, as well as officially published draft legislation and regulations; (b) individual measures, such as product withdrawals, bans, recalls and other corrective measures; (c) research projects developed or sponsored by governments, undertaken by universities, businesses and other organisations; as well as the result of analyses of injury data; (d) risk assessment methodologies and practices; and (e) emerging product safety risks.* Recommendation VIII instructs the Working Party on Consumer Product Safety (WPCPS) to serve as a forum for exchange of information regarding the implementation of the Recommendation, to develop best practice guidelines and serve as a forum using the **OECD Global Recalls portal for the rapid exchange of worldwide recall information.** The WPCPS is the entity that maintains the product recall portal²⁸⁰, an online platform to report and consult information on product recalls from over 47

²⁷⁹ OECD/LEGAL/0459. Note that an OECD recommendation is not legally binding but practice accords recommendations great moral force as it represents the political will of the members of the OECD. As a result, there is an expectation that members will do their utmost to fully implement a recommendation, unless they have abstained during the adoption process.

²⁸⁰ <https://globalrecalls.oecd.org/#/>

countries. On the portal, the largest number of notices²⁸¹ concern toys and games, followed by automotive, electrical supplies and clothing. The most reported problems concern products made in China followed by products made in the USA. The countries reporting most to the platform are EU, Australia, Canada and the United States.²⁸²

Cooperation and exchanging on dangerous products internationally is an important step. In this respect the EU is now collaborating with countries with similar markets notably Canada, to exchange information on dangerous products. And more exchanges with Australia and New Zealand are being pursued. Perhaps most significantly, the EU is engaging with China and is cooperating through the RAPEX-China system to pass on information to Chinese counterparts.²⁸³ This has helped in reducing the number of dangerous products entering the EU, although the figures clearly show that dangerous products from China are numerous. In addition, the Commission is planning to develop an action plan with China to strengthen product safety cooperation for products sold online. It is also focussing on other jurisdictions, notably Africa.

But cross-border enforcement faces many obstacles, not least the fact that enforcement authorities in different

²⁸¹ Data observed on the dashboard, on 15.12.2020 for a 10-year period spanning 2010 to 2020 (note the portal was launched 2012), <https://globalrecalls.oecd.org/#/dashboard>. If figures are adjusted for a 5-year period, results remain broadly similar

²⁸² Note that they are also project partners. See, <https://globalrecalls.oecd.org/#/project-partners>.

²⁸³ Communication from the Commission, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery COM (2020) 696 final 19.

States or Regions are only mandated to enforce within the confine of their own laws. The main barriers to co-operation include inadequate resources, lack of legal power, incompatibility of legal regimes, language, privacy and often data protection laws that may prevent disclosure of data about individuals or business practices. Besides, there is a gap both at national, regional and international level that needs to be plugged to increase the capacity of national enforcers to act in a global digital environment.²⁸⁴

4.3.3. Enforcement powers and tools for the digital age

Enforcers need to be able to conduct investigations to gather relevant data underpinning their enforcement efforts. This is an exercise that in itself, even at national level alone, can be challenging in a digital environment. When in the past, documents could be gathered by entering physical premises, most of the evidence that may now be necessary will be not only digital in nature, but can be hosted on servers abroad, even if the business being investigated has premises in the country where the enforcement authority is located. Furthermore, some specific

²⁸⁴ This is for example, an obstacle with regards to general enforcement of consumer law. See, FTC, CMA, *Cross-Border Enforcement Toolkit for Consumer Authorities and Legislators* (Intergovernmental Group of Experts on Consumer Law and Policy, 4th Session, 8-9 July 2019), https://unctad.org/meetings/en/SessionalDocuments/cicplp_Toolkit.pdf. The toolkit focusses on three areas: intelligence sharing and co-ordination, investigation and securing outcomes.

expertise may be required to understand the code and algorithms running a website or a mobile application or a particular product suspected of presenting safety risks.

This means that **a range of powers adapted to this new environment needs to be available to them, including investigative powers, which may include gathering information from third parties such as online platforms.** Yet, the OECD digital economy paper on Consumer protection enforcement in a global digital marketplace²⁸⁵ found that a small majority of countries surveyed (57%) had legal frameworks to address the ability of their consumer authorities to gather information from internet service providers. One other important tool in this regard is the conduct of **Internet Sweeps** and those have been used in the area of product safety notably by the OECD.²⁸⁶ UNGCP Guideline 83 which states that the consumer protection agencies of Member states should coordinate investigations and enforcement activities to avoid interference with the investigations and enforcement activities of consumer protection enforcement agencies taking place in other jurisdictions. In the area of product safety, the OECD mandates international cooperation as part of its Recommendations. A number of

²⁸⁵ OECD digital economy paper on Consumer protection enforcement in a global digital marketplace March 2018, no. 266 (2018) 13.

²⁸⁶ They are a set of checks carried out on websites simultaneously to identify breaches of consumer law in a particular sector. The sweeps are a two-step process whereby enforcers screen websites to find breaches and use this information to ask traders to take corrective actions or to enforce. Sweeps therefore require coordination

channels can be used to trigger investigations. Consumer complaints, information from consumer organisations, complaints by businesses, media reports and the experience of staff at the enforcement agency can all contribute to defining priorities. It is also important to use meaningful reporting mechanisms and complaints classification and analysis tools. The OECD Recommendation on Consumer Product Safety recommends that adherents work together with businesses and other stakeholders on the **development of a global injury data taxonomy and procedures for collecting and analysing injury data**, where appropriate, and take into account the value of aligning the taxonomy with well-established systems.²⁸⁷

It also goes without saying that enforcers need to have the ability to **obtain sanctions to ensure compliance and this may include being able to recall products when those liable for them are not**. However, focus should also be placed on preventive actions, such as consumer education or the issuance of guidance, codes of practice for industry as they can avoid consumer detriment, improve trust in markets and also potentially save costs for enforcers. One possibly important sanction may be to consider the ability to close down websites and try and ensure they are not able to be re-created under a different domain name or ask platforms to ensure re-offending sellers are no longer able to list on their sites.

²⁸⁷ Recommendation IV (8).

4.4. Role of Customs in stopping unsafe products reaching EU consumers

The role of customs is to control the movement of goods with a view to safeguard state's interest (for example with the protection of health and safety) and ensure revenue collection (ie import/export duties). **Customs law** is a complex area of law. It has a large number of components and its relationship with consumer protection is not well documented. However, it **has a critical role to play in ensuring that dangerous products manufactured and sold from outside of the EU do not reach consumers.**

The Consumers International survey indicates that some mandatory processes in clearing goods as safe, involved some custom checks. For example, 56% of respondents indicated that imported products needed to be cleared by customs as safe for the market and 24% said that a product is automatically cleared at customs if it has been certified by a foreign accredited conformity assessment body.²⁸⁸ Under WTO rules, it is also possible to make amendments to customs rules in order to protect consumers against dangerous products if the changes are compatible with the WTO rules (notably the GATT).

²⁸⁸ Consumers International, the challenge of protecting consumers from unsafe products, a global picture (May 2018) 12.

Within the EU, The Union has exclusive competence in the area of the customs union.²⁸⁹ No trade tariffs or measures having equivalent effect should apply between Member States.²⁹⁰ EU Member States are also bound to apply a common custom tariff for trade with countries outside of the EU. Common customs tariff duties are fixed by the Council on a proposal from the Commission.²⁹¹ **The main source of customs law in the EU, is the Union Customs Code (UCC)** as laid out by Regulation 952/2013 (recast).²⁹²

4.4.1. Customs procedures under the UCC

The UCC contains the 'substantive rules of application of customs duties and relevant measures to goods traded with third countries'.²⁹³ The Customs Code provides rules concerning the scope and the persons covered by customs duties, tariff classifications of goods, customs values, procedures to be followed for the introduction of goods into the territory of the customs union as well as customs controls and release of goods for free circulation, amongst other things. The UCC is supplemented by

²⁸⁹ Art 3(1)(a) TFEU.

²⁹⁰ Art 28 TFEU.

²⁹¹ Art 31 TFEU. Art 32 lays out the principles that should guide the Commission in carry out its tasks

²⁹² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0952&rid=1>

²⁹³ Massimo Fabio, Customs Law of the European Union (Kluwer Law International 2020) para 1.04.

Regulation 2015/2446 which contains detailed rules concerning certain aspects of the UCC²⁹⁴ and Regulation 2015/2447 which lays down rules for the implementation of certain provisions of Regulation 952/2013.

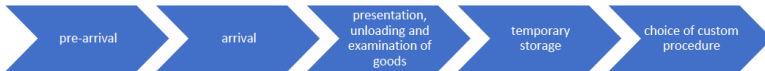
Customs authorities are primarily responsible for the supervision of the Union's international trade (...) and overall supply chain security. They fulfil their role by putting in place measures to protect:

- the financial interests of the Union and its Member States,
- **the Union from unfair and illegal trade** while supporting legitimate business activity,
- **the security and safety of the Union and its residents**, and the protection of the environment, where appropriate in close cooperation with other authorities,
- the maintenance of a proper balance between customs controls and facilitation of legitimate trade.²⁹⁵

Goods brought into the customs territory of the Union are regulated by Articles 127 et s. of the UCC. Prior to their arrival, the goods are subject to an entry summary declaration which can be waved in certain circumstances (notably for goods in transit)

²⁹⁴ This Regulation is further amended by Regulation 2016/341 which also supplements Regulation 952/2013.

²⁹⁵ Art 3 Reg 952/2013 recast.



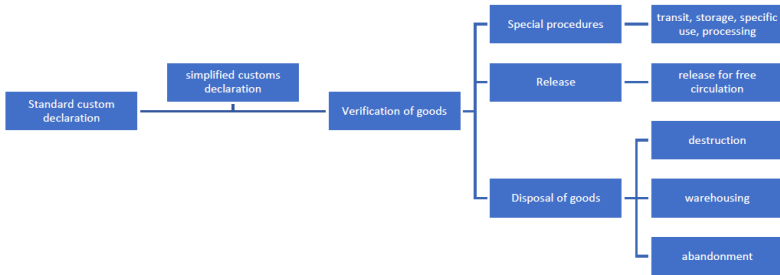
and is normally lodged by the carrier at first point of entry within a specified time limit before the goods are brought in.²⁹⁶ This entry declaration contains particulars necessary for risk analysis for security and safety purposes.²⁹⁷ Customs have a plan to roll out IT projects to be fully paperless by 2025.

Fig. 5. phases of customs checks

When goods arrive in the Union, the method of arrival may dictate different procedures. There are also different custom declarations available. **Customs procedures can be quite complex, but normally start with declaration followed by verification of goods and a decision on the goods, either for release if they are deemed compliant with customs laws or a disposal of goods if they are not.** The import control IT system being brought in will require an electronic summary declaration to be prepared in advance of arrival of the goods in the EU. There are different rules on how far in advance depending notably on mode of transport. The responsibility for filling in the electronic declaration will lie with the carrier. However, this does not apply if the items are sent by postal services, although

²⁹⁶ Art 127 Reg 952/2013 recast.

²⁹⁷ Art 127(5) Reg 952/2013 recast.



there are plans to develop new reporting rules that will require such declarations in the near future.

Fig. 6. Main customs procedures

It is envisaged that changes to the IT infrastructure will enable millions of additional data records being used and analyse to build a better picture of patterns of imports that can be used in detection. The Customs Action Plan 2020 also notes that as online platforms hold detailed data which spans the supply chain for each purchase, that data may be required

to be shared in future under an obligation to report relevant customs information. This could be achieved through a revision of the Union Customs Code.

4.4.2. Customs procedures under Regulation 2019/1020 on market surveillance

Regulation 2019/1020 on market surveillance (section 3.1.5.4), which applies to some specific products (but not all consumer products within the scope of the GPSD) **makes provisions for the control of products entering the Union. It could be used as a model to extend to all consumer goods subject to the GPSD.**

Regulation 2019/1020 on market surveillance makes specific references to products entering the Union market and products subject to union law that are placed under the custom procedure ‘release for free circulation’ shall be subject to controls performed by designated authorities to ensure the safety of products.²⁹⁸ The designated authorities are designated by Member States and can include customs authorities, market surveillance authorities (MSAs) or any other authority to be in charge of the control of product entering the Union market. Those entities should have the necessary powers and resources for the proper performance of their tasks.²⁹⁹ Notably

²⁹⁸ Art 25 Reg 2019/1020.

²⁹⁹ Art 25(2) Reg 2019/1020.

customs authorities ought to exchange risk related information with market surveillance authorities. Customs authorities at first point of entry also have a duty to transmit information when they suspect that products present a risk to the customs authorities at destination for goods placed in temporary storage or placed under a customs procedure (other than release for free circulation).³⁰⁰

Products that are to be placed under the customs procedure 'release for free circulation' shall be subject of controls performed by the relevant authorities (customs, MSA or other).³⁰¹

Controls are to be performed on the basis of risk analysis (as defined in the UCC, Art 46 and 47) and where relevant on the basis of risk-based approach. Risk-based information also needs to be exchanged between MSA and customs where products are placed in temporary storage or under another customs procedure (other than a release for free circulation) because the customs authorities at first point of entry have reasons to believe that the products present a risk. MSA also need to provide customs with information about risks they have identified.

Under Art 26 Reg 2019/1020 it is possible to suspend the release of a product for free circulation if a product lacks the appropriate documentation, or if there is reasonable doubts as to its authenticity, accuracy or completeness; the product is not

³⁰⁰ Art 25(4) Reg 2019/1020.

³⁰¹ Art 25(3) Reg 2019/1020.

marked or labelled as it should be; bears a misleading CE mark; there is no name or registered trademark and contact details of the economic operator; or where there is cause to believe that the product presents a serious risk to health, safety or the environment.³⁰² MSAs can request the suspension of release where they have reasonable grounds to believe that a product does not comply or presents a serious risk.³⁰³ However the efficacy of the provisions in Art 26 may be hampered because under Art 27, suspension can only last a short while. Indeed, a product will need to be released for free circulation after 4 working days if the MSA has not requested that the suspension be maintained, although release will not be deemed to be proof of conformity. This may be problematic where MSAs are overstretched and unable to respond promptly.³⁰⁴

Where an MSA concludes the product presents a serious risk or does not comply with Union law, it will need to take measures to prohibit the release. The product's paperwork will subsequently need to carry the mention: 'Dangerous product – release for free circulation not authorised – Regulation (EU) 2019/1020' or 'Product not in conformity release for free circulation not authorised – Regulation (EU) 2019/1020'. Information

³⁰² Art 26(1)(e) Reg 2019/1020.

³⁰³ Art 26(3) Reg 2019/1020.

³⁰⁴ BEUC, ANEC (n 30) 5.

needs to be immediately entered into the communication system provided for by Art 34 (RAPEX equivalent). The products can be destroyed at the expense of the natural or legal person declaring the product.³⁰⁵

4.4.3. International cooperation of customs administrations

The World Customs Organisation (WCO)³⁰⁶ is an independent intergovernmental body tasked with enhancing the effectiveness and efficiency of customs administrations. It represents 183 customs administrations across the globe (in 6 Regions) that collectively process approximately 98% of world trade. It is a forum for international cooperation in customs matters. This is done via working on technical aspects to attain the highest level of harmonisation and uniformity as well as via the preparation of Conventions and amendments to existing Conventions. For example, a number of Conventions apply relating to a common tariff nomenclature and customs valuation.³⁰⁷ The WCO also makes recommendations to ensure the uniform interpretation and application of the Conventions and provides advice and information. It also cooperates with other

³⁰⁵ Art 28(4) Reg 2019/1020.

³⁰⁶ <http://www.wcoomd.org/en.aspx>

³⁰⁷ Full list, <http://www.wcoomd.org/en/about-us/legal-instruments/conventions.aspx>

international organisations such as UNCTAD, the OECD or the WTO. Regarding tax collections, the OECD recommends applying the principles of the VAT/GST Guidelines³⁰⁸ and the collection mechanism included in the guidelines. **VAT should be collected in the country the consumer lives.** For sales taking place on online platforms, it is **possible to make the platforms liable for the VAT and GST on sales made by online traders through the platform.** The report also recommends some data sharing solutions and enhanced co-operation between tax authorities and digital platforms.³⁰⁹

The WCO hosts a working group on e-commerce (WGEC). The Working group has developed a set of documents (including standards, guidelines, recommendations) to help foster cross-border electronic commerce.³¹⁰ Some of the key concerns with regards to electronic commerce include:

- Growth in volumes (notably small B2C and C2C shipments)
- Lack of global standards and guidelines

³⁰⁸ OECD, International VAT/GST Guidelines (2017) <https://www.oecd.org/ctp/international-vat-gst-guidelines-9789264271401-en.htm> complemented by two reports: Mechanisms for the effective collection of VAT/GST – where the supplier is located in the jurisdiction of taxation (2017) <http://www.oecd.org/tax/tax-policy/mechanisms-for-the-effective-collection-of-VAT-GST.pdf> and Role of Digital Platforms in the Collection of VAT/GST on online sales (2019) <http://www.oecd.org/tax/beps/the-role-of-digital-platforms-in-the-collection-of-vat-gst-on-online-sales-e0e2dd2d-en.htm>.

³⁰⁹ OECD, Role of Digital Platforms in the Collection of VAT/GST on online sales (2019) <http://www.oecd.org/tax/beps/the-role-of-digital-platforms-in-the-collection-of-vat-gst-on-online-sales-e0e2dd2d-en.htm>.

³¹⁰ Those documents build on the WCO Framework of Standards Document that forms the basis for a globally harmonised approach to ensure the speedy delivery of parcels across borders while ensuring compliance with all regulatory requirements including safety, security and revenue collection.

- Timely and accurate information (for early risk assessment)
- Automated processes limiting physical interventions
- Expectation of rapid clearance.

Notably **the Cross-Border e-Commerce Framework of Standards (2018)**³¹¹ **developed collaborative solutions supporting the needs and expectations of all stakeholders in the E-Commerce supply chain.** The key to effective an efficient management of cross-border e-commerce is the use of timely and accurate information to allow the early risk assessment and clearance of legitimate transactions in an automated environment without the need for physical intervention.³¹² The Framework:

- *Establishes global standards to promote certainty, predictability, transparency, safety and security and efficiency in the e-commerce supply chain;*
- *Promotes a harmonised approach to risk assessment, clearance/ release, revenue collection and border cooperation in relation to cross-border e-commerce;*

³¹¹ WCO, Cross-Border e-Commerce Framework of Standards (2018) http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/facilitation/activities-and-programmes/ecommerce/wco-framework-of-standards-on-crossborder-e-commerce_en.pdf?db=web. This document builds on the WCO Luxor Resolution on Cross-border Ecommerce that adopted a set of guiding principles including advancing electronic data and risk management, procedural facilitation and simplification, safety and security, revenue collection, measurement and analysis, partnerships, public awareness, outreach and capacity building, harmonisation of legislative frameworks. Resolution of the Policy Commission of the World Customs Organisation on the Guiding Principles for Cross-Border e-Commerce (2017) http://www.wcoomd.org/-/media/wco/public/global/pdf/about-us/legal-instruments/resolutions/policy-commission-resolution-on-cross-border-e-commerce_en.pdf?la=fr

³¹² WCO, Cross-Border e-Commerce Framework of Standards (n 312) foreword, 3.

- *Establishes a standardised framework for advance electronic data exchange between e-commerce stakeholders and Customs and other relevant agencies with the aim to facilitate legitimate shipments, providing a more level playing field for various stakeholders;*
- *Seeks to strengthen co-operation between Customs administrations, other relevant government agencies and other stakeholders involved in cross-border e-commerce.*³¹³

The document notes that the legal and regulatory frameworks should address the control of physical goods through the provision of advance data across various business models and how to take care of the interests of e-vendors and e-platforms, intermediaries and customers and the facilitation of safe and secure cross-border e-commerce. It recommends leveraging existing WCO conventions, relevant WTO agreements (in particular the Trade Facilitation Agreement) and other international conventions, standards and tools. Another interesting set of recommendations in the e-commerce framework include the **adoption of data analytics and screening methodologies in conjunction with non-intrusive inspection equipment** and developing programmes that **leverage the role of intermediaries**. This of course pre-supposes adequate data collection

³¹³ WCO, Cross-Border e-Commerce Framework of Standards (n 312) 9.

followed by measurement and analysis. This is complemented with **introducing alternative tax collection models** (in collaboration with tax authorities), including moving away from tax collection at the border to a system whereby tax is collected prior to shipping or arrival of the goods.³¹⁴ Concerning safety, the recommendation is to ensuring the **sharing of information on risks** with other relevant Customs administrations, and cooperation with other relevant agencies. The goal is to **identify and stopping illicit and non-compliant goods moving through e-commerce channels**.³¹⁵ Information can enable customs to focus on high-risk shipments while quickly releasing low risks shipments. Collaboration and inter-agency cooperation are also promoted to prevent fraud and illicit trade at national and international level.commendations

³¹⁴ WCO, Cross-Border e-Commerce Framework of Standards (n 312) 13-14.

³¹⁵ *Ibid* 14.

Recommandations

This report has highlighted a large number of issues. What transpires is **a clear need for action on multiple fronts. The sale of unsafe products is not a new phenomenon, but the use**

of electronic commerce has exacerbated its spread and offered sellers some protection against enforcement as they have been able to avoid detection and sanctions. This presents a huge task, notably for enforcers but also for legislators as much of the regulatory framework is still playing catch up. The below highlights a number of key recommendations in order to protect consumers from the sale of dangerous products online³¹⁶. **The main recommendations include plugging regulatory gaps by updating key legislation, influencing the adoption of international standards that will offer a high level of protection to consumers in and out of the EU, improving enforcement and removing the incentives to buy from traders based outside of the EU.**

1. Plug EU regulatory gaps

Many reforms are underway at EU level. This presents a clear opportunity to shape rules that can assist consumers by curtailing access to dangerous good as well as ensuring adequate remedies are in place when consumers are harmed by unsafe

³¹⁶ The list however is not exhaustive and many peripheral issues could not be explored due to length.

products. All regulatory initiatives ought to focus on adopting legislation that can tackle new technological developments now, and in the future (tech neutrality), and adopt principle-based legislation that will be able to adapt legal responses as technologies develop.

To be effective, legislative reform cannot be contained in one single legal instrument because the sale of unsafe products is in fact a multi-faceted problem. However, it would be important to ensure that the rules contained in all instruments are consistent with one another. Changes are notably required concerning:

- Consumer safety legislation, particularly by refining the concept that only safe products can be placed on the market; This would include adopting legislation that instils respect for consumer safety at all stages of the supply chain, from design to retail and beyond.
- Consumer safety enforcement requiring that enforcers are given the right tools and powers to act;
- Product liability rules so that consumers can obtain compensation if they are harmed;
- The liability of intermediaries whether they are online intermediaries or act in the supply chain;
- Changes to the way customs officials are able to conduct their work;
- Changes to the VAT and postal fee regimes that advantage traders based outside of the EU.

- **Updates to the Consumer safety legislation**

Consumer safety for non-food product is in need of an overhaul. Action is required on many legal and technical aspects.

From a regulatory point of view, actions are needed principally to ensure that:

- the notion of a safe product can cater for goods but also digital products and include cyber-security;
- the safety of products is assessed not simply at the time they are placed on the market, but includes some consideration of the need for continued conformity so that they can remain safe for their lifetime;
- the precautionary principle continues to be a guiding principle;
- safety is promoted along the supply chain, from conception to post-sale;
- voluntary standards are complemented by legislative standards where there is a pressing need or a gap endangering consumers;
- labelling and packaging are clear to consumers notably when instructions do contribute to safe use of products;
- all in the supply chain (whether they affect the safety of goods or not) take due care and contribute to safety efforts;

- new intermediaries are placed under an obligation to protect consumers. This would notably include fulfilment service providers and online platforms that enable consumers to purchase goods and services from third parties.

With regards to enforcement, it would be desirable to work towards ensuring that:

- Market surveillance authorities are given the tools and powers they need to enforce legislation. This will require using technological tools and adapting analogue procedures to an online environment;
- Regulation 2019/1020 is used as a blueprint for improvements as it already contains many useful tools and powers, but its scope of applications is restricted;
- Monitoring of unsafe products which takes place via the Safety Gate in the EU is improved notably by looking at bolstering the level of information placed on the system and its turnaround time;
- Data is used to not only stop unsafe products but also predict trends and improve safety. This for example may include making better use of accident and injury data such as that contained in the European Injury Database; This would also require using consumer complaints data to improve feedback loops;

- Consumers are better aware of their rights, but also about how to detect unsafe goods and avoid their purchase; This may include enforcement authorities using campaigns and hosting consumer complaints systems to monitor unsafe products;
- Traceability of products is improved throughout the supply chain and recall procedures can be triggered quickly and effectively where necessary; This would need to rely on technological tools.
- Cooperation between authorities and Customs is smooth to maximise the effectiveness of actions taken by enforcement authorities. In this area, the Union Product Compliance Network established by Regulation 2019/1020 could be an important stepping-stone.

- **Updates to the Product Liability legislation**

The rules are outdated and require changes notably to account for digital products that may cause consumers some harm. The scope of application requires clarification to ensure that many modern consumer goods are caught by the rules. The way strict liability is triggered is by proving a damage, a defect and a causal link between the two. This has been criticised as it remains an obstacle for many consumers and inhibit their ability to seek compensation. To assist consumers it may be possible to:

- Adopt an extended notion of defect which will no longer need to be based on expectations of safety but rather can be based on expectation the users may have of their products;
- Understand defect not simply at the time the product is put on the market, but over its life cycle;
- Define the damage suffered more generously to ensure obligations fall on producers for all damage suffered to incentivise compliance. This will mean changing the threshold for damage to property (currently a minimum of €500 and a maximum cap on damages of €70 millions);
- Reverse the burden of proof;
- Defences opened to producers should be curtailed and limitation periods extended to ensure a high level of protection of consumers;
- Consider imposing some liability on new intermediaries and economic actors, including fulfilment centres and online intermediaries notably where the producer cannot be identified or refuses to remedy the harm or when platforms notably do not act to remove the product that they have clear knowledge is unsafe.

- **Updates to the liability regime for online platforms**

The liability of online intermediaries is a complex area and not all intermediaries would need the same obligations imposed upon them. Soft law approaches have not had the expected results, and regulation now appears essential. The new regime defined by the DSA may not go far enough to protect consumers against unsafe products sold online via platforms. However, it clearly states that it is without prejudice of other consumer safety laws, and thus it is possible to define a more stringent regime in the revision of the instruments dealing specifically with consumer safety and product liability. It may in fact be more desirable to focus efforts on specific legislation, but the DSA regime should offer a consistent approach and provide some minimum levels of liability. As it stands, the first draft of the DSA does address a number of areas of concern. However, it could be improved notably by looking at:

- The obligations imposed on online platforms that allow consumers to conclude distance contracts with traders. They will not be protected if consumers are unclear on their role, but this obligation is in fact a transparency obligation;
- The obligations imposed on platforms to check the identity of their traders which falls short of BEUC's recommendations to require robust product verification obligations;
- The distinction between operators (due to size) imposing more monitoring obligations on large platforms

which may lead to an exodus of rogue traders to smaller ones to avoid detection and reinforce market positions, while pushing costs of safety compliance to smaller players.

2. Influence the adoption of protective international norms

Protecting EU consumers against unsafe product requires some engagement with third countries in standard setting. It is clear that the nature of electronic commerce and the globalisation of supply chains requires an international response. In the New consumer Agenda, the Commission commits to continue to use its influence in international organisations, such as the WTO, UNCTAD, or the OECD to promote a high level of protection and safety at international level and protect consumers globally.³¹⁷ This is important and should be coupled with influencing capacity building abroad, notably in jurisdictions where unsafe products seems to be originating from to focus efforts on eliminating those products at source.

In this respect, the focus should be on:

- Harnessing the ability to vary rules under the WTO framework notably within the ongoing discussions on electronic commerce (with a view to adopt a regime that

³¹⁷ Communication from the Commission, New Consumer Agenda – Strengthening consumer resilience for sustainable recovery COM (2020) 696 final, 20.

does not advantage already big players and protects consumers effectively and durably);

- Making changes to the existing intellectual property law regimes to ensure IP owners can assist in the fight against dangerous products;
- Move towards minimum standards of safety at international level building on the work at the OECD and UNCTAD and advocate for international consensus to be placed at a high level of consumer protection;
- Seek to develop bi-lateral agreements with particular jurisdictions and target unsafe products geographical hotspots;
- Seek international enforcement cooperation where available and contribute to capacity building where it is lacking;
- Seek to develop an enforcement toolbox that can tackle the sale of unsafe products online and facilitate cross-border enforcement;
- Continue to work in collaboration with OECD for the improvement of the rapid exchange of information on unsafe products;
- Continue to mandate customs officers and seek to support improvements in international Customs collaborations;

- Pursue the implementation of the WCO cross-border e-commerce framework of standards and of the OECD VAT/GST Guidelines.

3. Removing incentives to buy from traders with poor safety records

Action here concerns three main areas:

- Closing VAT loopholes and other logistical advantages;
- Considering the need of 'vulnerable' and low-income consumers
- Focus on building awareness and educating consumers and traders.

Small traders based outside the EU have been able to exploit VAT loopholes and postal delivery rules giving them an unfair advantage notably on price, but also on their ability to evade enforcement. This needs to be addressed through reforms of the customs laws and postal services notably. Conversely, there is a need to educate sellers as to their obligations regarding regulatory compliance.³¹⁸

³¹⁸ WCO, Cross-Border e-Commerce Framework of Standards (n 312) 15.

Alongside, there is a need to ensure consumers are assisted in making safe choices. There is often a lack of consumer awareness with regards to product safety.³¹⁹ It seems imperative to ensure consumers are more informed about risks, can recognise safety marks, know how to check safety alerts before they buy and know what to do if their product is unsafe. Further, consumers may also need to be educated about the benefits of factoring price alongside other product features (such as safety, quality, environmental concerns) when choosing products. However, price will remain an important factor in purchasing decisions. To fight the sale of dangerous products online would need considering the needs of consumers and their ability to shop around more carefully. Vulnerable consumers, which may include those who cannot make the 'safe' choice due to limited funds, may continue to choose cheap alternatives despite being aware of the risk potential. Their needs also need to be considered along the supply chain and in the roll-out of recalls.

Consumer safety in Europe can only really be as safe as its lowest common denominator.

³¹⁹ BEUC, ANEC (n.30) 3.

Case study: Protecting consumers against online sales of fake Covid19 vaccines

Europol is predicting a rise in the sale of fake vaccine using both offline and online channels, a situation which poses grave risks to public health and has called for heightened vigilance issuing an early warning notification.³²⁰ The notice reports on the circulation of fake influenza vaccines in Mexico and advertisements for fake Covid 19 vaccines on the 'dark web'.³²¹ While still limited at this stage, it is anticipated that criminal activities in this area will increase as more vaccine get released on the market. Risks to the supply chain including disposal of vials (which could be refilled with fake substances) are likely to be high.

Drugs are regulated away from the standard consumer protection legal framework.³²² They are governed by the interaction of

³²⁰ Europol, Early Warning notification – Vaccine-related crime during the Covid 19 pandemic (04.12.2020) <https://www.europol.europa.eu/publications-documents/early-warning-notification-vaccine-related-crime-during-covid-19-pandemic>

³²¹ On this point, see Cynthia O'Murchu, Vaccine for sale of the dark web as criminals target pandemic profits, *Financial Times* (18.12.2020) <https://www.ft.com/content/8bfc674e-efe6-4ee0-b860-7fcb5716bed6>

³²² The sale of fake vaccine could come under the unfair commercial practices directive and be classified as a misleading omission. The failure to disclose the fact that the vaccine is fake is leading the average consumer to take a decision he would not have otherwise taken. This can lead to administrative fines and/ or criminal sanctions. However, the use of unfair practices as a vehicle for combatting the dissemination of fake vaccines will have limited reach, not least because international enforcement is notoriously

intellectual property laws (notably granting patents and trademarks), trade laws (notably the TRIPS agreement) and some regulatory oversight authorising drugs to be placed on the market. In the EU, the European Medicine Agency (EMA) oversees the centralised authorisation procedure for human and veterinary medicines.³²³

To protect consumers in the context of the Covid 19 pandemic, BEUC recommends³²⁴:

- Public research funding should go hand in hand with accessibility conditions;
- Vaccines' quality, safety and efficacy should be ensured;
- Advance purchase agreements must be transparent, and vaccine affordability and equitable access ensured;
- Vaccine users who suffer damage must get quick and adequate compensation;
- There should be a commitment to universal access to maximise impact at global level.

1. Operation of intellectual property laws and their impact on the prevalence of fake vaccines

difficult. The practices are more aligned to fraud and would thus necessitate the use of national criminal laws.

³²³

https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf

³²⁴ BEUC (A Santos), Ensuring access to safe, effective and affordable Covid-19 vaccines, BEUC-X-2020-110 - 09/11/2020 (updated on 20/11/2020) https://www.beuc.eu/publications/beuc-x-2020-110_ensuring_access_to_safe_effective_and_affordable_covid-19_vaccines.pdf

To resolve the issue of fake vaccines, one aspect to cater for is a modernisation of intellectual property law and notably the TRIPS agreement. Indeed, the occurrence of fake medicine is linked to the operation of the patent laws that protect pharmaceutical producers but can in fact hamper consumer protection. **It is because there will likely be bottlenecks in production (including high prices) unable to satisfy consumer demand, that a market for fake can develop, in particular online.**

- **IP law as a bottleneck**

Because of patents, many drugs are not available or are only available at inflated prices.³²⁵ This is problematic as in many instances, public money has supported research, but also because it can deny consumers access to vital drugs. Increase use of generic drugs and less restrictive patents can reduce the economic incentives for counterfeit drugs.

Under art 28(1)(a), a patent holder has exclusive rights to prevent third parties from making, using, offering for sale, selling or importing a product (although they can consent to such activities). Patent holders also have a right to assign, or transfer by succession, the patent and to conclude licensing contracts.

³²⁵ A leaked price list of the covid 19 virus showed a vast difference in the prices that were charged for the different vaccine already on/or to be shortly on the market. See for eg, FR24news article that published the full table, although the Tweet leaking the prices has now been deleted (19.12.2020) <https://www.fr24news.com/a/2020/12/the-eu-price-list-for-covid-19-vaccines-has-been-leaked-will-can-ada-publish-its-prices-national.html>

Article 30 enables member states to specify limited exceptions to the exclusive rights conferred. **Article 31 of TRIPS lays out the rules for the use of patents without authorisation from rights holders by governments or third parties authorised by government (compulsory licensing).** Notably, in those cases, it is expected that use is considered on individual merits, efforts have been made to obtain authorisation from the rights' holder (although this can be waived in cases of national emergency); use shall be limited in scope, duration and limited to the purpose for which it was authorised; the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation. The creation of a new medicine is a two-step process. It requires the manufacturing of active pharmaceutical ingredients (called API) from raw materials and the formulation of the API to transform it into a active drug. This process is now mostly split with about 80% of the APIs used in the USA believed to be manufactured in India and China.³²⁶ Countries wishing to compulsorily license drugs under Art 31, but lack the capacity to produce API, can instead use compulsory licenses to import a finished product or to import the API. However, to be able to do so, under the TRIPS agreement, the country of origin will also

326 <https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/>

have to grant a compulsory license because article 31(f) restricts the use of compulsory licenses ***‘predominantly for the supply of the domestic market of the member authorising such use’***. This thus undermined the use of Art 31 for compulsory licensing.

- **Special compulsory licensing**

A new Article 31bis was introduced in 2005 and entered into force in 2017 in a bid to fix the issue. The article deals with **granting special compulsory licences exclusively for the production and export of affordable generic medicines to other members that cannot domestically produce the needed medicines in sufficient quantities for their patients.** It waves the restriction in place under Art 31(f).³²⁷ Further details on the operation of Art 31bis are contained in the Annex of TRIPS.³²⁸

High income countries and the US and EU notably opted out of the Art 31bis system without giving themselves a way to opt back in it seems, although art 31bis could be used by any eligible importing member that made a notification to the council for TRIPs.

One condition imposed on the application of Art 31bis is specified in the Annex para 2 (iii). **An eligible importing member**

³²⁷ Art 31 bis (3).

³²⁸ https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm.

would need to establish that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product in question. The Appendix of TRIPs further defines how to assess manufacturing capacities. Yet, having **sufficient capacity may be a dynamic concept. For example, in the coronavirus crisis, even countries with well-developed capacity are struggling to meet the needs of their populations, but under current wording, would not be able to compulsorily license Covid vaccines or APIs needed for their manufacture.** Therefore, in the context of the Covid 19 crisis, BEUC advocates that it may be necessary to consider changes to the TRIPS agreement and support the possibility for Member States to import medicines produced elsewhere under a compulsory license, by reversing the opt-out of article 31bis of the World Trade Organization agreement on trade related aspects of intellectual property rights (TRIPS). Situations like the COVID-19 pandemic show how important it is to ensure that Member States can import cheaper versions of urgently needed medicines.³²⁹ Being able to produce sufficient quantities at speed would have an impact on the prevalence of fake vaccines and thus on the protection of consumers. In the case of coronavirus vaccines, the EU allowed state aid to be given to pharmaceutical companies, but it has made it contingent on

³²⁹ BEUC (A Santos), Ensuring access to safe, effective and affordable Covid-19 vaccines, BEUC-X-2020-110 - 09/11/2020 (updated on 20/11/2020) 5 https://www.beuc.eu/publications/beuc-x-2020-110_ensuring_access_to_safe_effective_and_affordable_covid-19_vaccines.pdf

granting non-exclusive licenses under non-discriminatory market conditions.³³⁰

2. Online sales of vaccines: application of Directive 2011/62/

EU for the prevention of falsified medicinal products entering the supply chain

Fake medicine may nevertheless become available on the marketplace and notably online. Directive 2011/62/EU provides the legal framework for the **prevention of the entry into the legal supply chain of falsified medicinal products.**³³¹

This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use³³² and is without prejudice to provisions concerning intellectual property rights.

Falsified medicinal products are defined in Art 1(1)(c) of Directive 2011/62/EU as:

‘Any Medicinal product with a false representation of:

³³⁰ Communication from the Commission, Amendment to the Temporary Framework for state aid measures to support the economy in the current Covid 19 outbreak, C (2020) 2215 final, para 18 amending s 3.6, para 35 (g) https://ec.europa.eu/competition/state_aid/what_is_new/sa_covid19_1st_amendment_temporary_framework_en.pdf

³³¹ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

³³² https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_cons_2012_en.pdf

(a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strengths of those ingredients;

(b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) Its history, including the records and documents relating to the distribution channels used.

The definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.’

- **Restrictions on online distribution and the common logo for authorized medicine retailers**

Aside from the obvious measures to ensure safe manufacture of products³³³, the CJEU has recognised the possibility to restrict the retail sale of medicinal products to pharmacists alone³³⁴ although flexibility is allowed to member states.³³⁵ One

³³³ It falls on the authorisation holder to verify the suitability, quality and authenticity of excipients and active substances. See Art 1(5) amending article 46(f) of Directive 2001/83/EC.

³³⁴ Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others v Saarland* ECR [2009] I-4171, paragraphs 34 and 35.

³³⁵ *Ibid.*, paras 19 and 31 concerning the discretion granted to set levels of protection in matters of public health.

way to restrict the introduction of falsified medicine is by restricting their distribution online. A new Title VIIA on sale at a distance to the public (introducing new articles 85(c) and (d)) is inserted in Directive 2001/83/EC. The Directive puts in place a system to assist the public in identifying websites which are legally offering medicinal products for sale at a distance to the public.³³⁶ The route chosen is the adoption of a ‘common logo’ recognisable throughout the Union and enabling the identification of the Member State where the person offering medicinal products for sale at a distance is established. The logo needs to be disclosed by authorised medicine retailers. A list of those websites is kept by the EMA as well as the authorities in the state where the site is established. The workings of the common logo to identify persons offering medicinal products for sale at a distance and the technical, electronic and cryptographic requirements for verification of its authenticity are regulated by Implementing Regulation No 699/2014.³³⁷

- **Cooperation and information**

The Directive also acknowledges that *‘the falsification of medicinal products is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective, in*

³³⁶ Recital 25.

³³⁷ OJ 25.06.2014, L184/5.

*particular as regards sale of such products via the Internet. To that end, the Commission and the Member States should cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol and the United Nations. In addition, the Commission, working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the trade in falsified medicinal products at a global level.*³³⁸

Notably the Working Group of Enforcement Officers is the vehicle for exchanges of information. There is a requirement that patients and consumers' organisations are kept informed about enforcement activities. In addition, the Directive mandates that *'the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website'*.³³⁹ It is not certain that information campaigns have had the desired effect. Any reliance on consumer information is well known to be an imperfect tool.

³³⁸ Recital 28.

³³⁹ Art 85(d).



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