Department for
Business, Energy
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3D Printing of Spare Parts for Consumer Appliances

Final report

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Contents

1 Introduction

1.1 3D printing (or additive manufacturing (**"AM"**)) allows for the manufacture of spare parts at a lower cost point than is achievable using traditional manufacturing techniques and methods. Non-traditional manufacturers, including end users, could make parts or components relatively easily and at a low price when this technology is used. However, spare parts which have not been manufactured by an authorised manufacturer could be of insufficient quality and present technical safety issues for various reasons.

1.2 In this report, "3D printing" means as follows:

"a manufacturing process for creating three dimensional physical objects in a range of materials based on a digital file and using specialised equipment (3D printer). Most commonly, this is done by layering successive thin layers of material such as polymer, ceramic, metal or other materials."

1.3 The Office for Product Safety and Standards ("**OPSS**") is responsible for executing the OPSS Strategic Research Programme, which provides strategic science-based research to strengthen the evidence base for safety and standards policy development, delivery and enforcement. As part of this programme, DLA Piper (UK) LLP ("**DLA Piper**") has undertaken research into the safety and legal issues relating to the manufacture, sale and installation of 3D printed spare parts by unauthorised manufacturers for consumer appliances (the "**Project**"). In doing so, DLA Piper has engaged Exponent, which provided input for the technical and scientific aspects of this project. This report sets out our findings for the Project.

1.4 3D printing technology has wide application in many areas (e.g. medical, automotive, household electrical appliances). However, this Project focuses only on its use in consumer appliances. See 4.1 and 5.1 for the matters which are excluded from the scope of this Project (and therefore have not been addressed in this report).

1.5 All information in this report is as of July 2019 and does not reflect any subsequent change to the law or anything else which affects its content or any analysis made in preparing the report.

2 Objectives

2.1 The Project was undertaken to assist OPSS in their understanding of the safety and legal issues relating to the manufacture, sale and installation of 3D printed spare parts, made by unauthorised manufacturers, for use in consumer appliances ("**unauthorised 3D printed parts**").

2.2 This report sets out the outcome of the Project by:

- explaining the technical safety issues arising in the design, manufacture and use of 3D printed spare parts made by unauthorised manufacturers ("**Objective 1**"); and
- identifying the regulatory requirements and legal responsibilities and liabilities of relevant stakeholders at key junctures of the supply chain when unauthorised 3D printed spare parts are used ("**Objective 2**").

2.3 For Objective 1 (see 4), a literature review has been carried out to define the state-of-the-art understanding of the limitations, industry trends and potential hazards created by the use of 3D printing and related additive manufacturing techniques (see 4.3). Additionally. stakeholders across the supply chain were invited to respond to a to identify practical challenges faced by the industry affected by 3D printed components and also to validate the outcome of the literature review (see 4.4). Based on these studies, a list of potential hazards and risks were compiled for various aspects of the 3D printing technology, including the material, equipment, design code and user (see 4.5).

2.4 For Objective 2 (see 5), we have outlined the ways in which the key stakeholders in the supply chain of unauthorised 3D printed parts are regulated in the UK (see 5.3.1). The report also includes an overview of the regulatory landscape in respect of 3D printing in the United States of America (under both federal law and the laws of the State of California), Canada, Japan, China and under EU legislation (see 5.3.2 to 5.3.6). Current legislative initiatives in this space are also listed in Annex 2.

2.5 The report also includes case studies to illustrate how legal and technical safety issues may present by the use of unauthorised 3D printed parts in consumer appliances (see 6).

2.6 At the request of OPSS, this report makes no recommendations.

2.7 Section 4 was written by Exponent. Section 5 and appendices were written by DLA Piper. Case studies were developed by Exponent and legal analysis for each scenario was conducted by DLA Piper.

2.8 3D printing parts, printing equipment, printing material or domestic appliance manufacturers, installers and/or retailers, safety professionals and two UK industry bodies contributed by responding to the questionnaire (see 4.4.44) and/or attending a round table meeting on 25 July 2019.

3 Executive Summary

3.1 Objective 1

3.1.1 Objective 1 comprised a literature review and a stakeholder engagement exercise.

3.1.2 The literature review revealed a current trend for appliance manufacturers to partner with third party AM service providers to allow for on-demand replacement parts manufacturing. Our review suggested that range of factors may be attributable to flaws or defective performance presenting in AM parts. The AM method, materials and equipment used, as well as part design and processing and post-processing factors can all have an effect on quality. Broader risks can be sector-specific , ethical or related to environmental health and safety. Commentary also highlights IP, counterfeiting and cyber security as focus areas. While some standards have been developed for AM processes or parts, researchers have identified gaps in safety or quality standards.

3.1.3 The stakeholder engagement exercise revealed certain key collective perspectives.

3.1.4 Numerous advantages regarding the use of 3D printing to make spare parts for consumer appliances were identified, including cost savings, time savings, and the flexibility to print remotely and on-demand. However, the importance of such parts being produced by reputable and qualified manufacturers was stressed. Stakeholders therefore noted a heightened risk profile around unauthorised spare parts.

3.1.5 Several challenges with 3D printed parts were identified by the stakeholders, and broadly fell into the following categories:

- variable quality;
- limitations of the technology; and
- operator expertise.

3.2 Objective 2

3.2.1 There is currently no legislation in the UK which is designed specifically to regulate 3D printing, nor in any other jurisdiction that fell within the scope of the Project.

3.2.2 Activities involving 3D printing are regulated under existing law, the application of which often varies depending on (i) what is being supplied, (ii) to whom the supply is being made, (iii) whether the supplier is a trader or a consumer and (iv) any activities other than supply of the item which are undertaken by the relevant party within the supply chain. A supplier can be liable and remedies may be available to the person affected by use of a 3D part not only under product safety regulations (which may be general or product-specific) but often under regulations setting out rules which apply to a supply of goods, services and digital content which regulate the quality and fitness of the goods, services or digital content being supplied. Depending on the information provided prior to sale, consumers may also be entitled to remedies under regulations on unfair commercial practices or for breach of contract. As the relationship between a trader and a consumer (**"B2C"**) is often regulated differently from that between traders (**"B2B"**), the supplier's liability and remedies under law can vary depending on whether the

supplier is a trader or a consumer and also whether the person to whom the item is supplied is a trader or a consumer.

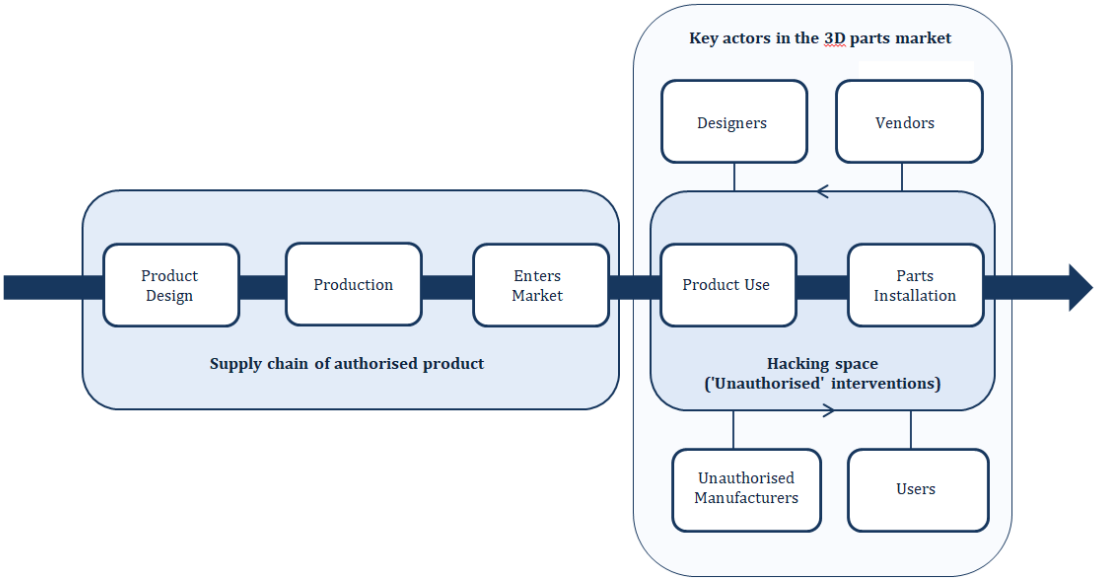

Figure 1: Stakeholders in supply chain of 3D printed parts (overview)

3.2.3 We have considered the legal requirements which apply to the following stakeholders:

- Designer of the component design file;
- Manufacturer of 3D printing machine;
- Manufacturer of 3D printing material;
- Installer of unauthorised 3D printed parts;
- Manufacturer of unauthorised 3D printed parts;
- Manufacturer of consumer appliances using unauthorised 3D printed parts; and
- Vendor of consumer appliances using unauthorised 3D printed parts.

3.2.4 An overview of current legislation which applies to each of the above stakeholders can be found in Appendix 1. Generally, stakeholders have obligations under existing statute or common law to ensure the safety of the products they manufacture and/or supply, either under the law on product safety or under sales rules concerning the quality of product that can be lawfully supplied. There are, however, areas where the application of law is not particularly clear due to a lack of express provisions in the relevant legislation. For example, the legal obligations of the supplier of the design component file of unauthorised 3D printed parts are not as clear as those who supply goods or services. This is because of a lack of clarity in law as to whether digital content (i.e. data which is not supplied in a physical medium, such as software) is a 'product', 'good' or 'service'.

3.2.5 Suppliers' obligations are typically limited to making the supply of what has been ordered in accordance with the agreed form (whether stated expressly or implied by operation of law) subject to general quality and safety legal requirements as applicable. There is no obligation for a supplier actively to seek information such as the purpose for

which the 3D printed part has been ordered or on which consumer appliance it is intended to be installed. Supply of an unauthorised 3D printed part which has no inherent quality or safety defect, and without knowledge on the part of the supplier as to its intended or foreseeable use, would not necessarily make the supplier in breach of applicable sales-related regulations or liable for any negative consequences of such part being used with a particular consumer appliance or category of consumer appliance.

4 Objective 1: Technical safety issues

4.1 Scope of work

We have applied the following methodology to understand the technical safety issues arising in the design, manufacture and use of unauthorised 3D printed spare parts:

- carry out a literature review in scientific and industrial publications;
- obtain feedback from stakeholders across the supply chain;
- consolidate a list of likely potential hazards and qualify / contextualize potential product safety risks; and
- provide case studies to illustrate particular tasks.

4.2 Summary

4.2.1 Literature review

The goal of the literature review was to identify trends and state-of-the-art documented thinking around risks associated with AM (i.e. 3D printing) as it relates to replacement parts for appliances. The literature review was conducted via key word searching of relevant terms (e.g., hazard, risk, spare part, defect, quality) of peer-reviewed AM literature and publicly available AM industry news and reviews. General risks and hazards associated with the use of AM were also investigated.

The primary findings of the literature review are as follows:

4.2.1.1 **Current industry trends of AM of spare parts for appliances:** Several original equipment manufacturers (**"OEMs"**) of appliances have partnered with third-party AM service providers with the goal of providing on-demand replacement part manufacturing. Some OEMs are taking a consumer-driven approach, with consumers having direct access to the part design, part ordering process, or part manufacturing process (i.e. consumers printing the parts themselves).

4.2.1.2 **AM of spare parts in general:** Literature surrounding the use of AM for spare parts more generally (i.e. not specific to appliances) has focused on supply-chain management and feasibility of AM for manufacturing spare parts, as well as the need for specification and qualification of printed spare parts in comparison to traditionally manufactured parts. The review identified issues surrounding the evaluation and selection of spare parts to be fabricated via AM including part criticality, part cost and suitability and design issues with the use of AM to manufacture the part.

4.2.1.3 **Potential flaws and performance issues in AM parts:** There is a plethora of articles focused on this topic, with potential flaws and performance issues in AM parts being specific to the individual AM method, equipment, part design, raw materials, processing and post-processing. Printed parts may suffer from issues related to quality (e.g. anisotropy, porosity, lack of fusion, material aging) or reliability (e.g. variability from part-to-part, machine-to-machine, operator-to-operator).

4.2.1.4 **Broader risks in 3D printing:** Broader risks associated with AM or 3D printing include regulatory issues, particularly in the medical sector, ethics related to printed weapons, intellectual property and counterfeiting, cyber security risks, and environmental health and safety related to AM.

4.2.1.5 **The role of standards in relation to safety and quality in AM:** The review identified that while some standards have been developed for AM processes or parts, researchers have identified gaps in safety or quality standards, stemming from for example AM raw materials, AM processes, and AM applications.

4.2.2 Stakeholder engagement exercise

The goal of the stakeholder interviews was to gain insight from various stakeholders across the AM value chain regarding their perspectives on potential risks associated with AM generally and in relation to unauthorized printing of spare parts. Stakeholders that were approached included:

- 3D printing equipment manufacturers;
- Material suppliers for additive manufacturing (e.g. resins, powdered metal, adhesives);
- Code developers for CAD/CAM and rapid manufacturing technologies;
- White goods/domestic appliance manufacturers; and
- Domestic appliance product safety specialists.

Stakeholders were interviewed to gather their opinions on various concepts related to risks and hazards associated with AM, appliances and spare parts. The key collective perspectives of the stakeholders are as follows:

4.2.2.1 Numerous advantages regarding the use of 3D printing to make spare parts for consumer appliances were identified, including cost savings, time savings, and the flexibility to print remotely and on-demand. In general, the stakeholders felt that if parts were printed by reputable manufacturers with approved processes and materials (i.e. the process and material were suitable to meet specifications), and have gone through an appropriate qualification program, the 3D printed parts should not present a greater risk than traditionally manufactured parts. Stakeholders also noted, however, that unauthorised parts may look similar but may be inferior, and that low cost methods of production may result in the proliferation of unauthorized parts in the future.

4.2.2.2 Several challenges with 3D printed parts were identified by the stakeholders which broadly fell into the following categories: variable quality, limitations of the technology and operator expertise. 3D printed part quality and part consistency may be affected by variations between printers, quality of feedstock, variations in how the operator uses the technology and combination of these factors. 3D printing technology may not be able to reproduce parts in the exact same way as traditional manufacturing methods, or may not be capable of making a part using the same material. 3D printing machine operator's expertise can affect part quality and consistency. The operator should have sufficient knowledge to identify if safety critical parts are suitable for 3D printing. It is a challenge to control the use of unauthorized programs or inexperienced operators (e.g. DIY repairs).

4.2.3 Potential hazards and safety risks

4.2.3.1 Using the learnings from the literature review and stakeholder interviews, a list was compiled of the potential hazards and factors contributing to safety risks presented by unauthorized replacement parts for appliances which are fabricated using AM. Exponent applied traditional approaches to risk assessment to map out potential hazards based on the research findings, their experience with consumer product risk assessment and prior knowledge in additive technologies.

4.2.3.2 Within the context of using AM to fabricate spare parts for appliances, a variety of potential types of hazards associated with potential injuries or product operation were identified.

4.2.3.3 Issues associated with potential injuries include hazards relating to:

- Size, shape and surface;
- Potential energy;
- Kinetic energy;
- Electrical energy;
- Fire and extreme temperatures;
- Toxicity; and
- Microbiological contamination resulting in an infection.

4.2.3.4 Examples of product operating hazards as a result of part failure (e.g. mechanical, electrical or thermal failure) include:

- Inadvertent (de)activation;
- Operational inadequacy;
- Failure to stop;
- Unexpected start;
- Inability to stop;
- Inadequately fitting parts; and
- Missing or incorrect fitting of parts.

4.2.3.5 With respect to the use of AM to fabricate replacement parts for consumer appliances, the primary sources for risks and hazards are presented by:

- 3D printing equipment variability;
- 3D printing material/feedstock compatibility and variability;
- 3D printing part design and code;
- 3D printing machine operator’s expertise; and

- 3D printed part quality and variability.

4.3 Literature review

4.3.1 Introduction and objective

The goal of this literature review was to identify the state-of-the-art documented thinking around risks associated with additive manufacturing (AM) or 3D printing, as they relate to replacement parts for appliances. General risks associated with 3D printing were also included, including standards and industry trends.

A search was conducted for relevant articles, with the following publications chosen as a priority:

- Rapid Prototyping Journal
- Virtual and Physical Prototyping
- Progress in Additive Manufacturing
- 3D Printing Industry
- Additive Manufacturing Magazine and Journal

The following search terms were utilized, in approximate order of importance:

- Hazard
- Risk
- Safety
- spare parts
- Replacement
- Failure
- Defect
- Probability
- Quality
- Reliability
- Hacking

Beyond these specific publications, a keyword-driven search was conducted on Google Scholar and Google in order to find other relevant literature, including perspective articles, information on relevant standards, and trends in the industry related to this topic.

4.3.2 Additive Manufacturing Technology

The subject of this literature review was not to detail the many types of AM technologies, however, a useful summary is provided in the infographic below:[1]

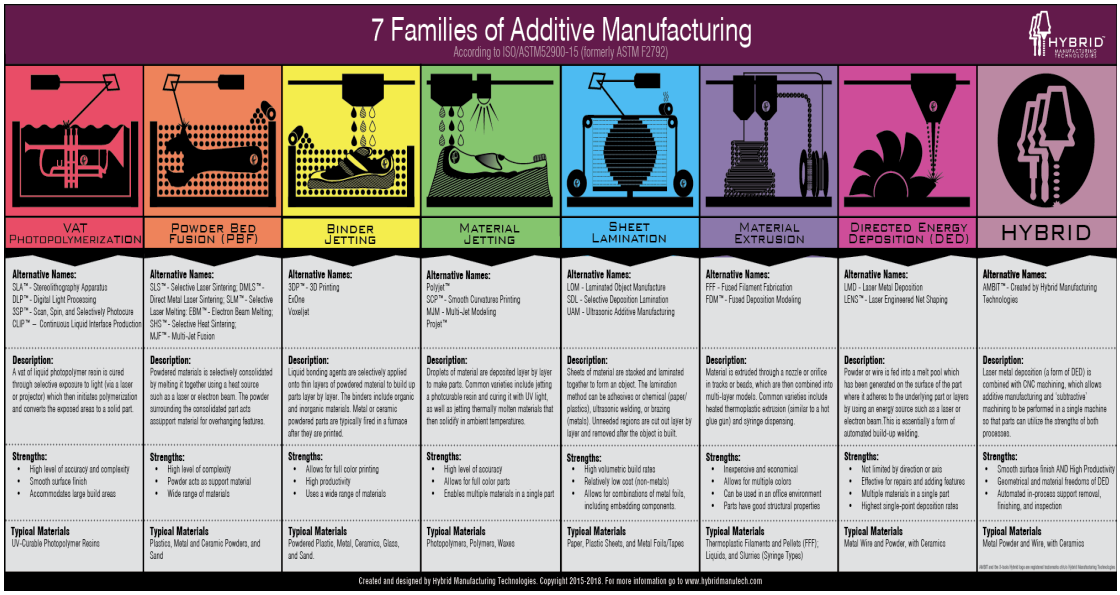

Figure 2

4.3.3 AM for spare parts in white goods

4.3.3.1 Literature studies

4.3.3.1.1 Dedoussis and Giannatsis[2] studied the use of stereolithography for functional prototypes of dish washer spraying arms. While they did not analyze these parts for functional end-use, the authors do highlight potential improvements that could be gained by replacing the original part with the AM part (e.g. improved energy efficiency, noise reduction, and lower water consumption).

4.3.3.1.2 3D printing has been evaluated to replace the plates involved with state-of-the-art thermoacoustic refrigerators[3], showing improved performance over the common-use parts.

4.3.3.2 Current industry trends

4.3.3.2.1 Whirlpool is collaborating with Spare Parts 3D, a Singapore-based printing service bureau to digitize Whirlpool's parts catalogue and enable printed spare parts:[4]

4.3.3.2.1.1 *"Spare Parts 3D's pilot project for Whirlpool started with an assessment of 150 parts in the company's catalog. For each of these parts, the Spare Parts 3D team tried different 3D printed topologies, materials and methods. The three methods that have been suitable selected by the company are FDM, SLA, and HP Multi*

[1] 7 Families of Additive Manufacturing according to ISO/ASTM52900, graphic source: Hybrid Manufacturing Technologies, http://www.hybridmanutech.com/resources.html
[2] Dedoussis, V. and Giannatsis, J. "Case study: Stereolithography assisted redesign and optimisation of a dishwasher spraying arm." Rapid Prototyping Journal (2004).
[3] https://3dprintingindustry.com/news/3d-printing-demonstrates-ability-refine-production-eco-friendly-refrigerators-115128/
[4] https://3dprintingindustry.com/news/whirlpool-to-introduce-3d-printing-to-appliance-aftersales-with-spare-parts-3d-143574/

Jet Fusion (MJF). Materials used across these platforms for Whirlpool parts cover ABS, ABS V0, PA12, a rubber-like resin, and PP-like resins.

4.3.3.2.1.2 *"The first part to pass all internal verification is a push button made using PA12 on an MJF system. This part, and others, have already been delivered to the customers as a trial. The goal now is to expand the available component pool. Spare Parts 3D is also set to launch its "Digipart" software platform, which will help partners identify 3D printed cost savings and impact, by the end of the year."*

4.3.3.2.2 Electrolux is investigating 3D printed spare parts in collaboration with Spare Parts 3D using a five stage evaluation process:[5]

4.3.3.2.2.1 *"The first stage involves establishing the right criteria for 3D printing and choosing the best business case for Electrolux. As part of this, both printability and profitability of the spare parts on offer will be assessed.*

4.3.3.2.2.2 *"Following this, Spare Parts 3D will conduct industrial engineering tests and reverse engineering to determine the best materials and machines for producing parts. The results of these tests are expected to be digitally catalogued.*

4.3.3.2.2.3 *"After tests prints of spare parts are made, quality checks will be performed. The final stage will see a profitability analysis of 3D printing spare parts against traditional production methods."*

4.3.3.2.3 Boulanger, a French electronics and home appliance distributor, launched Happy3d, a platform where anyone can download 3D printable spare parts for specific products and print them themselves.[6]

4.3.3.2.4 MyMiniFactory introduced a 3D spare parts initiative for products from IKEA, Smeg, Kenwood and others, with the goal of consumers directly printing replacement parts.[7]

4.3.3.2.5 Hoover in collaboration with Thingiverse (an online 3D printing community) has enabled consumers to directly print custom vacuum accessories.[8]

4.3.3.2.6 Startup Formeo has developed a secure platform for printing of parts on-demand, and has partnered with an unnamed Swedish appliance manufacturer:[9]

4.3.3.2.6.1 *"This means that a retailer would be able to have its products 3D printed on-demand by a 3D printing service provider. The platform will not initially support home 3D printing because it will focus on higher quality requirements. The primary technology that will be used is likely to be selective laser sintering (SLS).*

4.3.3.2.6.2 *"We are currently in an initial phase and have begun collaborating with a Swedish home appliances manufacturer. We also have close relationships with both desktop 3D printer manufacturers and manufacturers of industrial additive manufacturing systems, and we have a strong network that includes researchers,*

[5] https://3dprintingindustry.com/news/electrolux-trials-3d-printed-spare-parts-demand-spare-parts-3d-123050/
[6] https://3dprintingindustry.com/news/myminifactory-boulanger-bringing-3d-printed-spare-parts-closer-82315/
[7] https://3dprintingindustry.com/news/myminifactory-boulanger-bringing-3d-printed-spare-parts-closer-82315/
[8] https://3dprintingindustry.com/news/hoover-invites-thingiverse-community-3d-print-vacuum-accessories-38794/
[9] https://3dprintingindustry.com/news/using-3d-printing-eliminate-supply-chain-27930/

entrepreneurs and developers within the industry" said Formeo co-founder Christopher Lejon.

4.3.3.2.7 FirstBuild by GE Appliances, in collaboration with other entities including Stratasys, allows for consumers to be directly involved with the design and manufacturing process for appliances:[10]

4.3.3.2.7.1 *"The inherent safety standards of manufacturing kitchen appliances and electrical goods is not something that can be overlooked, and that is why FirstBuild is about building a community — both online and physical — that allows customers to put forward their ideas for a refrigerator / dishwasher / vacuum cleaner (you get the idea) and the concept is crowdsourced out to a talent pool of designers, engineers, and makers that understands how to bring the product into the physical world in line with design constraints and standards."*

4.3.3.2.7.2 Six consumer-driven 3D printed concepts have resulted from the initiative.[11]

4.3.3.2.8 A consumer reports the use of Shapeways (a printing service bureau) to print a ceramic replacement part for a component in a Panasonic bread maker.[12]

4.3.4 AM of spare parts in general

4.3.4.1 Literature studies

4.3.4.1.1 Delgado[13] found that SLM parts were in some cases mechanically superior to forged metal parts of identical design.

4.3.4.1.2 Berger[14] and Islam[15] found that AM of typical engineering components such as gears and bolts had mixed results: some processes/parameters and materials resulted in sufficient performance while others would be insufficient for final part use.

4.3.4.1.3 A study[16] assessing feasibility of AM for use on board the International Space Station found that conservative design requirements in order to minimize defects and failure occurrence was necessary, and that safety of such parts was not yet determined

4.3.4.2 Current industry trends

4.3.4.2.1 Volvo is printing and delivering spare parts for use in their construction equipment division. Notably, the "3D [printed] parts have the same specifications and go through the same processes as the original, and get the same warranty."[17]

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[10] https://3dprintingindustry.com/news/market-next-home-appliance-crowd-source-33177/
[11] https://3dprintingindustry.com/news/ge-makerbot-hack-a-thon-yields-6-3d-printed-smart-fridge-accessories-51670/
[12] https://3dprintingindustry.com/news/repairing-appliances-with-shapeways-3d-printed-ceramic-parts-8783/
[13] Delgado, J., *et al.* "Comparison of forming manufacturing processes and selective laser melting technology based on the mechanical properties of products." Virtual and Physical Prototyping (2011).
[14] Berger, U. "Aspects of accuracy and precision in the additive manufacturing of plastic gears." Virtual and Physical Prototyping (2015).
[15] Islamn, M.N. "Errors in different geometric aspects of common engineering parts during rapid prototyping using a Z Corp 3D printer." Progress in Additive Manufacturing (2016).
[16] Ohara, W.J. "Turn-Key Use of an Onboard 3D Printer for International Space Station Operations." Additive Manufacturing (2018).
[17] https://3dprintingindustry.com/news/volvo-ce-3d-printing-delivering-replacement-parts-131213/

4.3.4.2.2 A Chinese military tanker has been repaired with AM to produce replacement parts in emergency situations.[18]

4.3.4.2.3 German railway company Deutsche Bahn has collaborated with 3YOURMIND, a software developer, to create a digital spare parts warehouse. To date, the company had printed over 15,000 spare parts and new product components.[19]

4.3.4.2.4 The US Army is utilizing replacement metal AM parts which are stronger than traditional components. Notably, army researchers are aware of risks and challenges. Nonetheless, the researchers understand the hurdles of qualification for new materials. *"In terms of a battlefield scenario [this] may be good enough to be able to get your tank running again for hours or days if that's important to the mission, but on the other hand, we still need to be able to answer, does this perform as good as the OEM part? Does this perform better?"*[20]

4.3.5 Potential flaws and performance issues in AM parts

There is a plethora of articles focused on the potential flaws and performance issues for parts made by using AM, particularly for mechanical performance of AM parts. Each printing process, specific equipment, print parameters, and materials will all have a great influence on AM part performance. Below are a few highlights for four common printing methods: metal powder-based AM, polymer stereolithography, polymer selective laser sintering (**"SLS"**) and polymer fused deposition modelling (**"FDM"**). Potential flaws and relevant parameters when using each of these printing methods are highlighted below:

4.3.5.1.1 Metal powder

4.3.5.1.1.1 Porosity and lack of fusion in metal powder-based printing methods is of particular note as a risk for unpredictable part performance.[21, 22] Researchers note: *"There is a relationship between the raw material, process parameters, post-processing steps, on one side, and the type of discontinuity that can exist for the as-manufactured part or occur during the in-service life of a part, on the other. At this time,* ***definite metrics to characterize the AM part quality are missing****."* (Emphasis added.)

4.3.5.1.1.2 Researchers cite other potential defects as trapped powder, layer shift, unconsolidated powder, inclusions, and delamination, and highlight the current lack of "effect-of-defect" understanding requires remedy by further qualification and certification. Here, raw material properties (e.g. powder density, particle size distribution, melting temperatures, and powder flowability) can all influence the mechanical and aesthetic properties of a printed part. Residual stresses caused by thermal gradients and varying solidification profiles can lead to deformation and cracking, and thus must be accounted for in the design process and post-processing. Researchers propose several non-destructive evaluation techniques

[18] https://3dprintingindustry.com/news/chinese-military-tanker-uses-3d-printing-for-replacement-couplings-55575/
[19] https://3dprintingindustry.com/news/deutsche-bahn-extends-partnership-with-3yourmind-to-develop-digital-spare-parts-warehouse-151173/
[20] https://3dprintingindustry.com/news/u-s-army-develop-ultra-strong-3d-printed-steel-parts-to-revolutionize-battlefield-logistics-150367/
[21] Mandache, C. "Overview of non-destructive evaluation techniques for metal-based additive manufacturing." Materials Science and Technology (2019).
[22] Cai, X. "Measurement and characterization of porosity in aluminium selective laser melting parts using Xray CT." Virtual and Physical Prototyping (2015).

to identify such flaws, including the use of ultrasonic, radiographic, optical, acoustic, electromagnetic, and thermographic techniques.[20, 21]

4.3.5.1.1.3 X-ray tomography has also been utilized to identify porosity-type defects in powder-based printed parts.[23]

4.3.5.1.1.4 Corrosion in metal AM:[24] There are questions as to the role of variable microstructure in metal printing and the potential for increased corrosion and stress cracking susceptibility.

4.3.5.1.2 Stereolithography

4.3.5.1.2.1 Puebla et al.[25] studied the effects of build orientation, aging, and pre-conditioning on the mechanical properties of stereolithographic parts, which summarized the findings of similar studies as follows: statistically significant deviations in mechanical properties can occur from changes in any of these processing parameters/conditions.

4.3.5.1.3 Selective layer sintering (SLS) of polymer

4.3.5.1.3.1 Cooke[26] found that there is anisotropy in SLS printing that can affect mechanical properties, and there is a possibility that storage and aging can affect raw materials. Local inhomogeneity was also of concern in this study.

4.3.5.1.4 Fused deposition modelling (FDM)

4.3.5.1.4.1 While many studies have been conducted in this space, Durao[27] conducted a DOE (design of experiments) for FDM parts to highlight the statistical differences in quality and performance based on small changes in processing parameters, even for same machine and material. *"The expansion of other sectors such as the distributed spare part manufacturing, small-batch production, customized manufacturing and even household self-manufacturing businesses is being studied and implemented with the use of FDM technology... However, AM technology dissemination and increasing application for the production of final parts demand a better process control."*

4.3.5.1.4.2 Dizon[28] summarizes several polymeric AM techniques and the typical mechanical properties based on printing parameters and raw materials. There can be a wide variation in part properties in performance, particularly with FDM based technologies*: "Although* ***it is still not possible to replace parts with the same material considering the anisotropy and the relatively lower strength of Additively Manufactured parts****, there is a strong possibility that, with the wide variety of materials available for AM, the needed material properties could still be satisfied. And in some cases, exceed the original parts or those produced*

[23] Du Plessis, A., *et al*. "Standardized X-ray tomography testing of additively manufactured parts: a round robin test." Additive Manufacturing (2018).
[24] Ornek, C. "Additive manufacturing – a general corrosion perspective." Corrosion Engineering, Science and Technology (2018).
[25] Puebla, K., *et al*. Effects of environmental conditions, aging, and build orientations on the mechanical properties of ASTM type I specimens manufactured via stereolithography." Rapid Prototyping Journal (2012).
[26] Cooke, W., *et al*. "Anisotropy, homogeneity and ageing in an SLS polymer." Rapid Prototyping Journal (2011).
[27] Durao, L., *et al*. "Optimizing additive manufacturing parameters for the fused deposition modeling technology using a design of experiments." Progress in Additive Manufacturing (2019).
[28] Dizon, J., *et al*. "Mechanical characterization of 3D-printed polymers." Additive Manufacturing (2018).

*via traditional methods. With the different additive manufacturing technologies, printing parameters and considerations**, it seems that we will not be seeing a single standard for a particular mechanical test. In the end, what is important is to have test standards in order to set a foundation to make the products more reproducible, reliable and safe."*** (Emphases added.)

4.3.6 Broader risks in 3D printing

A number of publications focus on the broader risks of 3D printing independent of end-use application. A few examples are highlighted below:

4.3.6.1.1 Medical and regulatory issues

4.3.6.1.1.1 Researchers[29] argue that the specific regulatory-based risk profiles are necessary for medical devices manufactured by AM, and that continued development in standards and consistent terminology is critical in this risk management. The authors cite the manufacturing parameters which may influence mechanical and physiochemical properties, and the legal risks associated with the concept that with AM adoption, *"everyone will become the manufacturer."* In addition, there have been suggestions that there is less control over the process compared to mass-manufacturer parts which may lead to quality and safety concerns.

4.3.6.1.2 Military ethics (printed weapons)

4.3.6.1.2.1 There is a growing concern for the use of AM to enable *"rapid, uncontrolled replication of highly sophisticated tools of violent action"* (i.e. printed weapons).[30]

4.3.6.1.3 IP risks and concerns

4.3.6.1.3.1 Even for replacement parts, some authors[31, 32] suggest that intellectual property risks are a concern for 3D printed parts, even for the creation of replacement parts: *"The legality of copying—**even for simple and seemingly benign purposes such as repair**— remains unclear... The possibilities additive manufacturing offers for counterfeiting parts or products present additional challenges to both the legal system and manufacturers—challenges that existing IP protection systems may not be able to address adequately. Given the recent rise of the technology, it is critical that innovators understand both its possibilities and its perils."*

4.3.6.1.4 Cyber security risk

4.3.6.1.4.1 Two major potential sources of attack are theft of technical data (IP and trade secrets) and AM sabotage (with knowledge of what parameters can change the

[29] Horst, A., *et al*. "A clarion call for understanding regulatory processes for additive manufacturing in the health sector." Expert Review of Medical Devices (2019).
[30] Mattox, J.M. "Additive Manufacturing and its Implications for Military Ethics." Journal of Military Ethics (2013).
[31] Kurfess, T., *et al*. "Rethinking Additive Manufacturing and Intellectual Property Protection." Research-Technology Management (2014).
[32] Esmond, R.W., *et al*. "The additive manufacturing revolution and the corresponding legal landscape." Virtual and Physical Prototyping (2015).

dimensions or functional properties of the parts, "hackers" can make subtle changes to these in order to sabotage part).[33]

4.3.6.1.5 There are many reviews which are outside the scope of this Project such as those regarding potential environmental and health risks associated with the use of 3D printing materials and processes and the risks to the end-user of 3D printed parts. The following reviews provide further insight:

- Short (2015)34
- Deak (1999)35
- Drizo (2006)36
- Kek (2016)37
- Faludi (2015)38
- Healy (2016)[39]

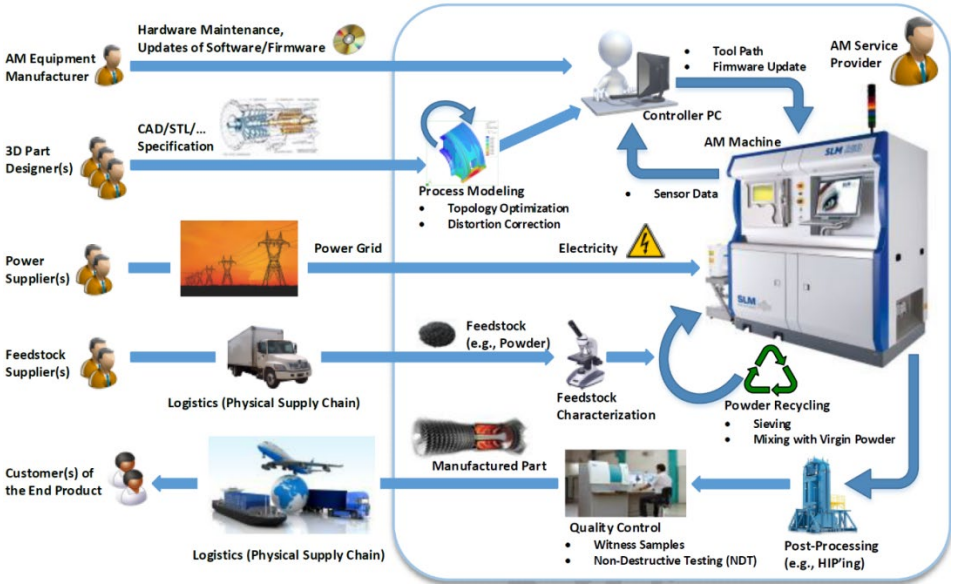

Figure 3: From Yampolskiy 2018 - The AM workflow, highlight the various routes where hacking or security risks may be present in the production of a part.

4.3.7 AM spare parts: current thoughts on evaluation and selection

[33] Yampolskiy, M. "Security of Additive Manufacturing: Attack Taxonomy and Survey." Additive Manufacturing (2018).
[34] Short, D., *et al*. "Environmental, Health, and Safety Issues in Rapid Prototyping." Rapid Prototyping Journal (2015).
[35] Deak, S. "Safe work practices for rapid prototyping." Rapid Prototyping Journal (1999).
[36] Drizo, A., *et al*. "Environmental impacts of rapid prototyping: an overview of research to date." Rapid Prototyping Journal (2006).
[37] Kek, V., *et al*. "Rapid prototyping process selection using multi criteria decision making considering environmental
criteria and its decision support system." Rapid Prototyping Journal (2016).
[38] Faludi, J., *et al*. "Comparing Environmental Impacts of Additive Manufacturing vs. Traditional Machining via Life-Cycle Assessment." Rapid Prototyping Journal (2015).
[39] Healy, C., *et al*.. "3D Printing of Manufactured Goods: An Updated Analysis." (2016).

To date, AM part manufacturers have relied on practice and experience that they have generated in spec parts: *"By disclosing strategies for their everyday operation, it is intended to show how the internal expertise acquired overtime copes with the lack of standards within this industry."*[40]

Among the global risks associated with additive manufacturing of parts, there has been little formal review for identification of the suitability or appropriateness of AM for specific spare parts applications. One review highlights the dearth in this area as follows: *"The review found that there is limited research that addresses identifying processes for spare parts selection for AM, even though companies have identified this to be a key challenge in adopting AM."*[41]

The authors highlight that the management of spare parts is difficult due to the high level of variety and low volume of manufactured parts. This makes AM an attractive solution, and certain industries with high cost downtimes (e.g. the energy sector including mining, oil exploration, and wind energy farms) are some of the first adopters of AM for spare parts. However, selecting the appropriate spare parts for manufacture via AM is not well understood.

Notably, the authors of the reviewed articles do not appear to highlight potential risks associated with 3D printed parts, but rather focus on suitability of AM from a supply chain perspective, cost, and part criticality. This is similar to a prior spare parts management review, independent of manufacturing technique (and notably published in 1988 before the widespread adoption of AM).[42] Other researchers have focused on similar economic and supply chain management issues associated with the AM of spare parts.[43]

Researchers[44] which have focused on product development processes for AM parts (spare or otherwise), highlight that while some standards during the part design process have been developed, a more specific product development pathway for AM needs to be developed.

A review[45] has identified suggested methods for evaluating and selecting spare parts for AM, including proposed new research directions in this area:

- Spare parts screening for AM with limited data availability.
- Cross-functional process for selection spare parts suitable for AM.
- Methodology for spare parts selection for AM.
- Understanding characteristics of spare parts suitable for AM.
- Design for AM and impact on part selection.
- Impact of AM on product modularity and intergrality.

[40] Munguia, J., *et al*. "Pursuing successful rapid manufacturing: a users' best-practices approach." Rapid Prototyping Journal (2008).
[41] Frandsen, C.S., *et al*. "In search for classification and selection of spare parts suitable for additive manufacturing: a literature review." International Journal of Production Research (2019).
[42] Duchessi, P., *et al*. "A Conceptual Approach for Managing of Spare Parts." International Journal of Physical Distribution & Materials Management (1988).
[43] Zhang, Y., *et al*. "Modeling and analysis of the on-demand spare parts supply using additive manufacturing." Rapid Prototyping Journal (2018).
[44] Rohde, J., *et al*. "Standardised product development for technology integration of additive manufacturing." Virtual and Physical Prototyping (2018).
[45] Frandsen, C.S., *et al*. "In search for classification and selection of spare parts suitable for additive manufacturing: a literature review." International Journal of Production Research (2019).

- Considering usage of AM in conjunction with conventional manufacturing technologies for spare parts production.

Lindemann[46] highlights guidelines and strategies for identifying candidates for AM-manufactured parts, and notes that simply printing a part with identical geometry to a traditionally manufactured part is not typically appropriate – separate design rules should apply and the part should be analyzed holistically (see Figure 4 below):

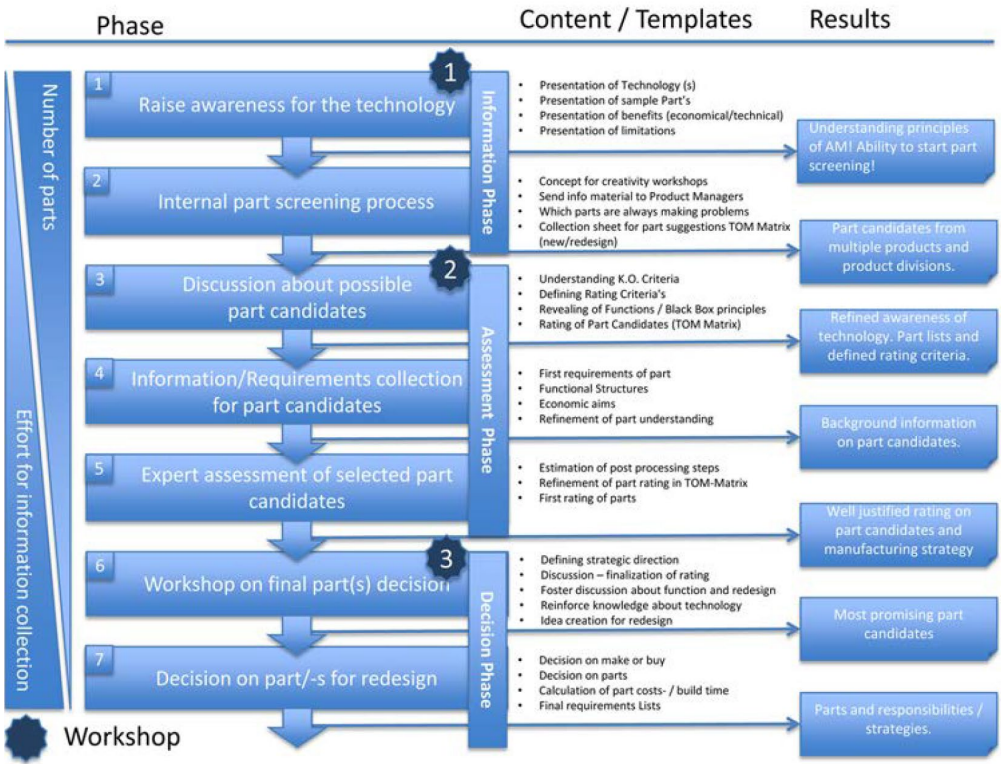

Figure 4: Methodology for part selection

4.3.8 The role of standards: safety and quality in AM

One of the greatest risks reported for AM generally is the lack of standards and qualification compared to traditional manufacturing. Some progress in this area has been made.

4.3.8.1.1 UL has introduced guidance documents, standards, training, and other information for the entire 3D printing supply chain[47] including the new Blue Card for AM materials[48] which is complementary to the traditional Yellow Card for traditionally manufactured materials. This is generally considered to be the most robust safety-related guidance for AM based on current knowledge.[49]

[46] Lindemann, C., *et al*. "Towards a sustainable and economic selection of part candidates for additive manufacturing." Rapid Prototyping Journal (2015).
[47] https://industries.ul.com/additive-manufacturing
[48] https://3dprintingindustry.com/news/ul-introduces-blue-card-for-global-recognition-of-3d-printing-materials-146742/
[49] Lockheed Martin became the first UL-certified AM facility in Oct. 2018 (https://3dprintingindustry.com/news/lockheed-martin-becomes-first-ul-certified-additive-manufacturing-facility-141986/).Markforged has released a flame-retardant AM material certified by UL (https://3dprintingindustry.com/news/markforged-releases-flame-retardant-3d-printing-material-onyx-fr-154814/) with HP (https://www.sculpteo.com/media/imagecontent/UL%2094%20and%20UL%20746A%20Certification.pdf) and others (https://www.protolabs.com/resources/blog/flame-retardant-thermoplastics-and-ul-classifications/).

4.3.8.1.2 ANSI, in collaboration with America Makes, has written a standardization roadmap for AM[50] which includes 93 "gaps" in coverage by current AM standards, including design guidelines, specific AM process specifications, machine calibration and qualification, machine operator training, and printed part non-destructive evaluation, among others. Additive manufacturing repairs are one particular area where the roadmap considered to be lacking in standards.

4.3.8.1.3 Chua, et al.[51] attempt to highlight all of the applicable standards for additive manufacturing processes and materials, notably, the high priority areas for AM standards include standards for integration, environmental sustainability, quality and performance, service standards, and "derisking" standards. A schematic on international AM standards is provided below:

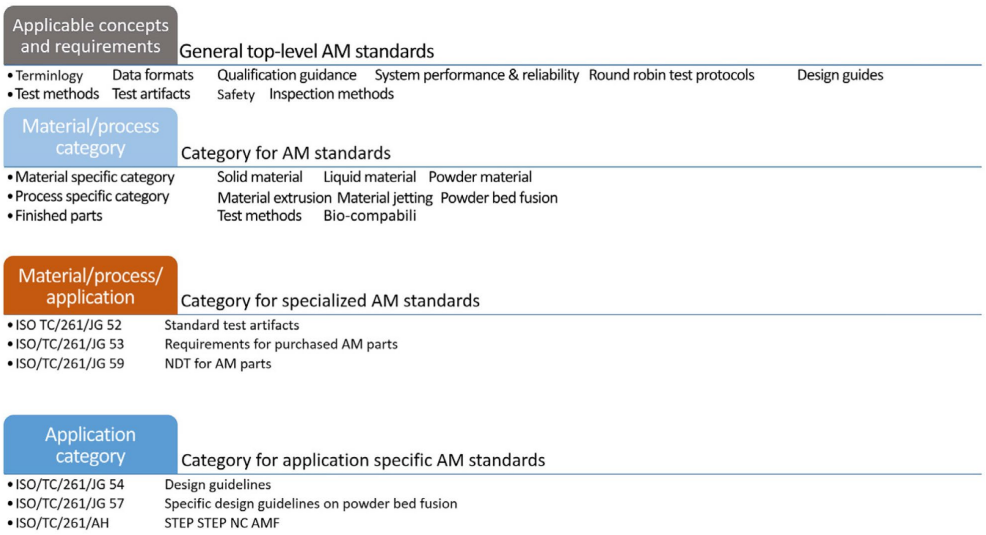

Figure 5: Structure of AM Standards (Courtesy of ASTM and ISO)

4.3.8.1.4 Spare Parts 3D (printing service bureau) and DNV GL (global quality assurance and risk assessment company) are collaborating to develop maritime standards for 3D printing.[52]

4.3.8.1.5 Zurich (the insurance company) is assessing the risks of 3D printing[53]

4.3.9 Perspective studies

Wohler's Report 2016 has highlighted that approximately one third of all AM-produced objects were used as functional parts.

[50] https://share.ansi.org/Shared%20Documents/Standards%20Activities/AMSC/AMSC_Roadmap_June_2018.pdf
[51] Chua, *et al*. Standards, Quality Control, and Measurement Sciences in 3D Printing and Additive Manufacturing. Chapter 2: Roadmap on Additive manufacturing Standards. (2017)
[52] https://3dprintingindustry.com/news/spare-parts-3d-and-dnv-gl-collaborate-on-3d-printing-maritime-standard-140557/
[53] "Zurich's focus goes from product liability to long-tail employers' liability. However, the company does admit that the real perils associated to intense 3D printing use (if any) are yet to be defined. To do this, the insurance group is currently assessing the associated risks at each stage, from manufacturing the product through to testing, distribution and the end user."(https://3dprintingindustry.com/news/zurich-assesses-risks-3d-printing-28220/)

PwC has summarized in a white paper the challenges and opportunities in 3DP of spare parts as shown in the diagram below.[54]

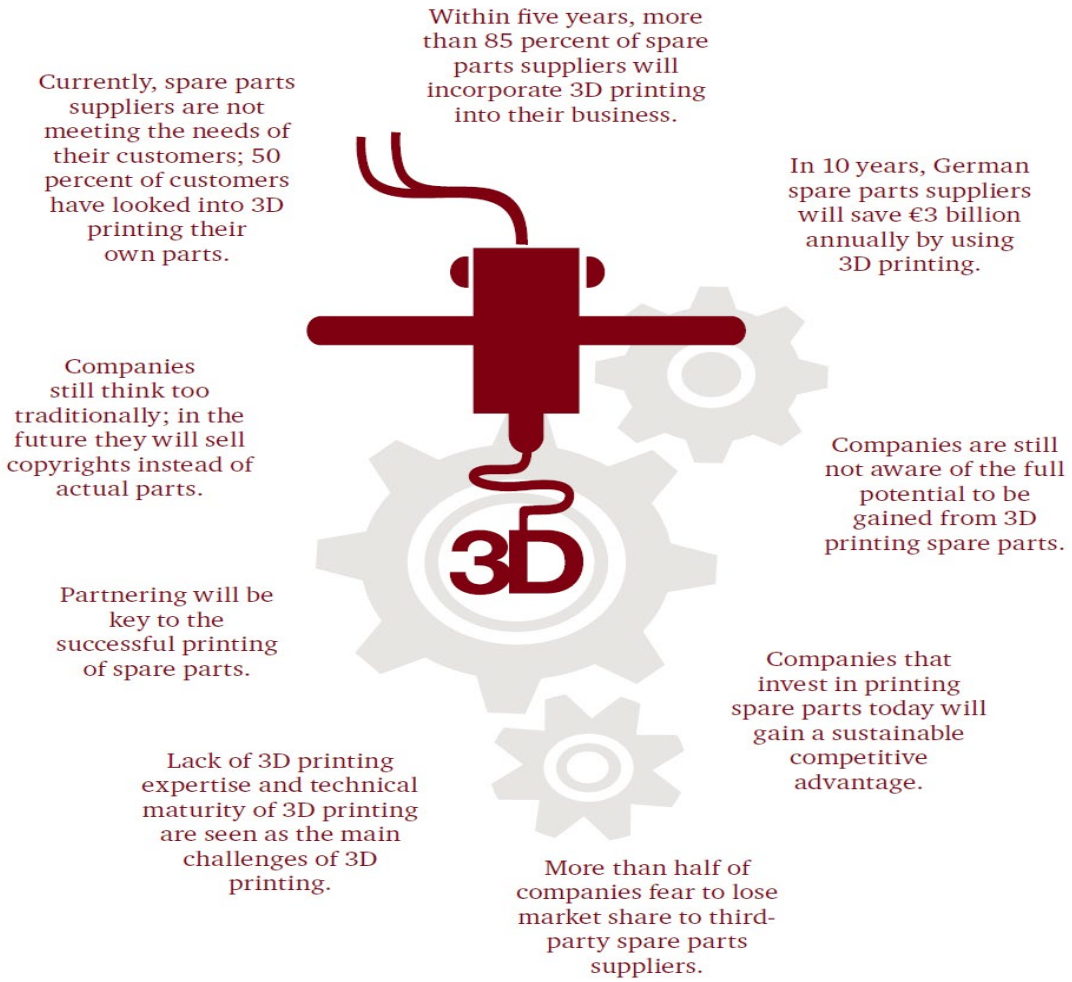

Figure 6: The future of spare parts is 3D: A look at the challenges and opportunities of 3D printing.

Their report also provides the following survey results:

[54] PwC. "The future of spare parts is 3D: A look at the challenges and opportunities of 3D printing." (2017)

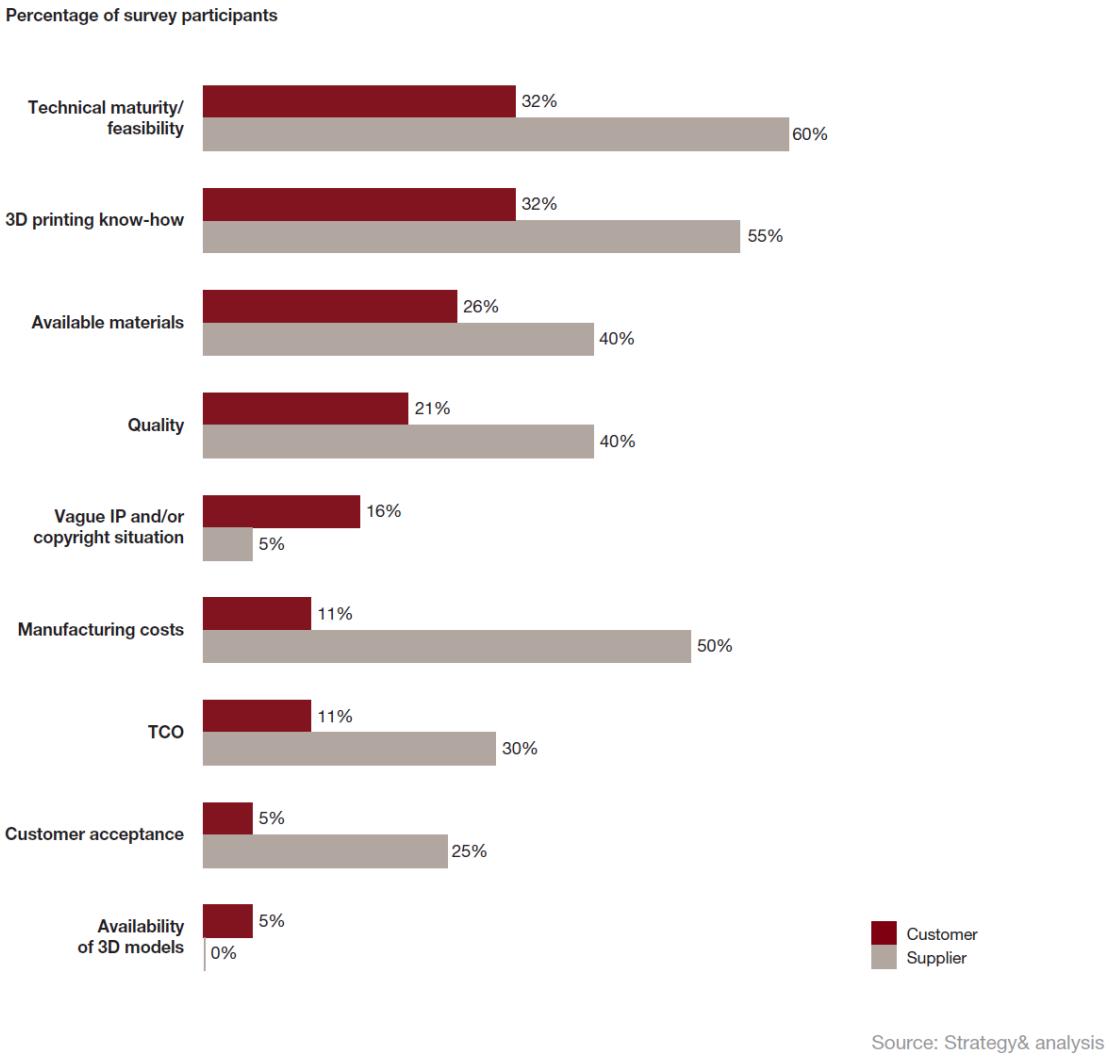

Figure 7: What are the biggest challenges to the adoption of 3D printing for spare parts?

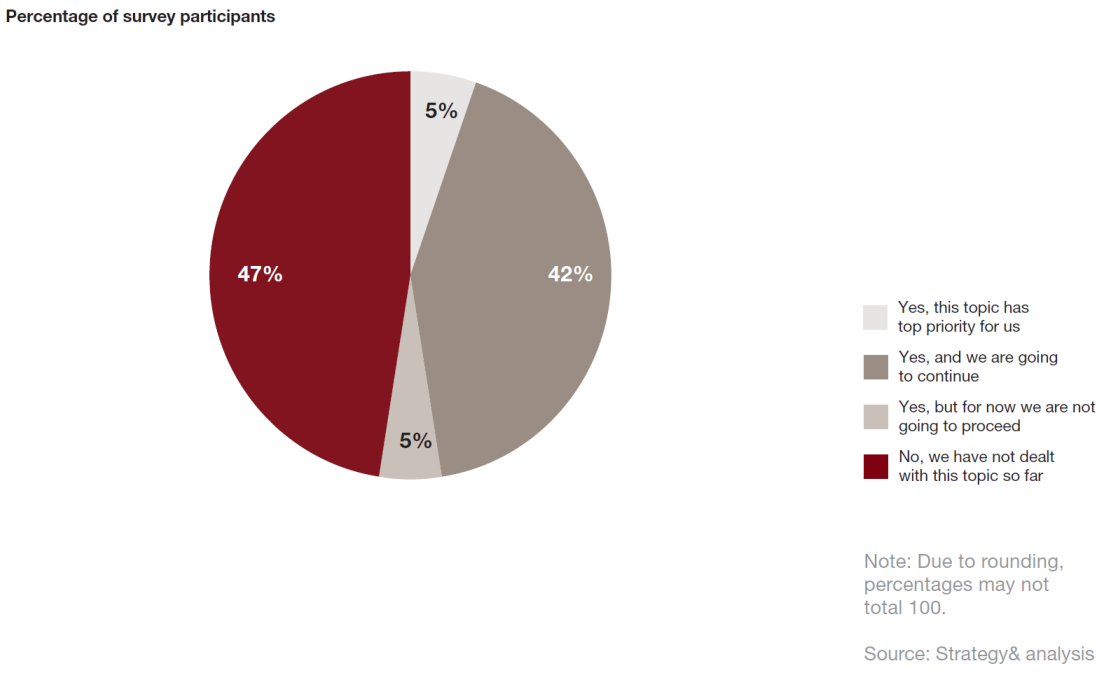

Figure 8: For customers: Are you investigating the viability of printing your own spare parts?

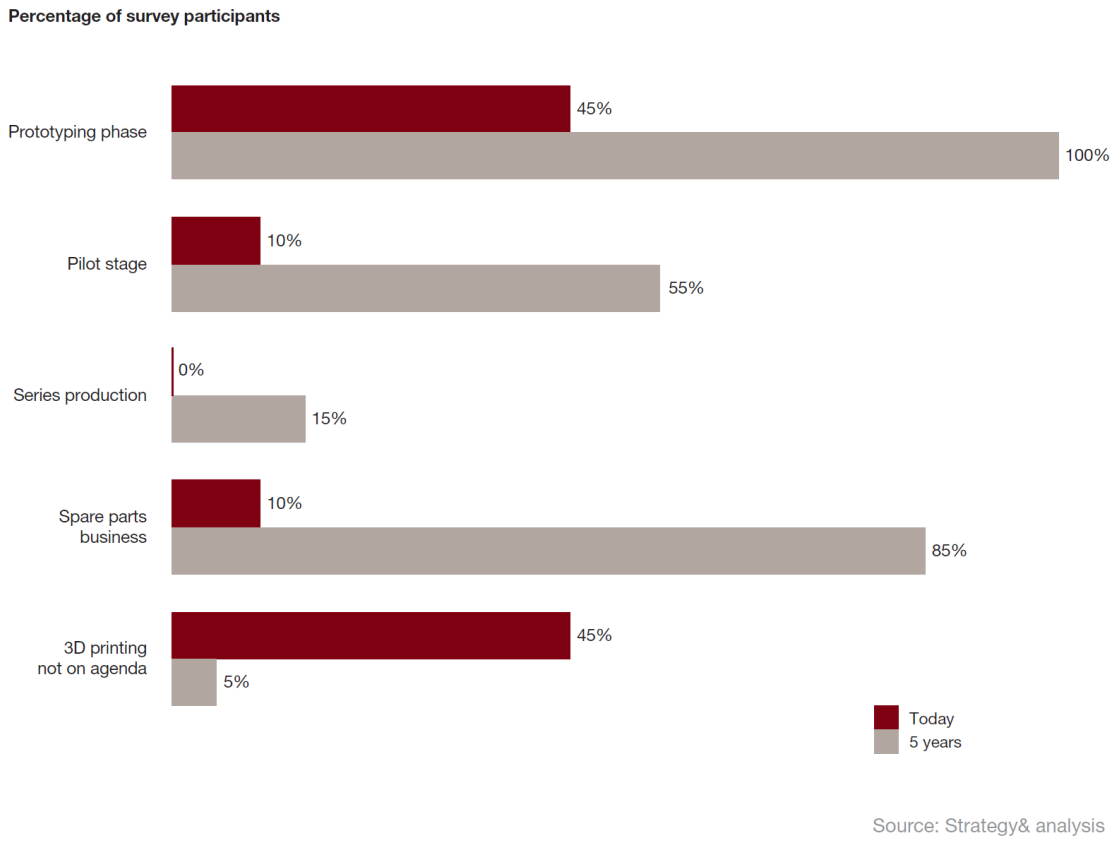

Figure 9: Where does 3D printing fit into your product life cycle today? Where do you expect it to fit in five years?

4.4 Stakeholder engagement

4.4.1 Introduction and objective

Stakeholders across the AM or 3D printing value chain were interviewed for their experiences with potential issues associated with AM. The goal of the stakeholder interviews was to gain insight from different perspectives on the practical aspects concerning potential risks associated with AM or 3D printing in general and as they relate to replacement parts for consumer appliances.

4.4.2 Approach

A list of stakeholders who represent various aspects of the domestic appliance and AM value chain was developed. At least two representatives from each category listed below were contacted as part of this engagement exercise:

- 3D printing equipment manufacturers;
- Material suppliers for additive manufacturing, (e.g., resins, powdered metal, adhesives);
- Code developers for CAD/CAM and rapid manufacturing technologies;
- White goods/domestic appliance manufacturers; and
- Domestic appliance product safety specialists.

A questionnaire was developed for interviews to elicit responses in a consistent and efficient way from the stakeholders. The questionnaire was emailed to 19 stakeholders, and we received eleven responses from those listed in Appendix 1. Respondents had the option to provide their feedback anonymously.

The stakeholders were asked the following questions in the questionnaire:

4.4.2.1.1 Please select from the following the roles that you or your organisation (as applicable) most identifies with (please select more than one if applicable):

- Domestic Appliance manufacturer
- Domestic Appliance installer/repairer
- 3D printing equipment manufacturer
- 3D printing material (consumables) manufacturer or supplier
- 3D printed part designer/programmer/applications engineer (the designer of the component design file)
- 3D printed parts manufacturer
- 3D printing device user (please describe how 3D printing device is used)
- professional user
- consumer / personal user
- Safety professional
- 3D printing academic (please describe your area of expertise)
- Industry body (please also tick the boxes above that apply to the members of your organization)
- Other (please describe)

4.4.2.2 What do you understand to be potential safety hazards associated with consumer appliances (e.g., washing machines, dishwashers, ovens, clothes dryers)?

4.4.2.3 Do you have any experience with the use of 3D printing to fabricate replacement parts for consumer products which have originally been manufactured without using 3D printing technologies ("traditionally manufactured")? If so, please describe your experience.

4.4.2.4 Do you feel a 3D printed part/process should undergo a different qualification process to traditionally manufactured parts? If so, please explain the reason.

4.4.2.5 How would you describe the benefits of using 3D printing to manufacture functional replacement parts for consumer products, in particular white goods/domestic appliances?

4.4.2.6 What challenges (e.g., performance, safety, quality, etc.) have you experienced or would you expect in the use of 3D printing to manufacture functional replacement parts, in particular for consumer appliances?

4.4.2.7 Do you find there to be particular 3D printing methods and/or materials that have more or less safety concerns than others? If so, please explain the reason.

4.4.2.8 Do you feel that 3D printed parts have more or less safety concerns than traditionally manufactured parts? If so, please explain the reason.

A physical meeting with some of the UK-based stakeholders was also held after receiving responses to the questionnaire.

The following is a summary of the responses collected from the stakeholder engagement.

4.4.3 Executive Summary

Stakeholder feedback was received across the domestic appliance and AM value chain, representing appliance manufacturers, appliance repairers/installers, 3D printing equipment and consumables suppliers, 3D part printers, safety professionals, and academics. Numerous advantages regarding the use of 3D printing to make spare parts for consumer appliances were identified, including cost savings, time savings, and the flexibility to print remotely and on-demand. In general, the stakeholders felt that if parts were printed by reputable manufacturers with approved processes and materials (i.e., the process and material were suitable to meet specifications), and have gone through an appropriate qualification program, the 3D printed parts should not present a greater risk than traditionally manufactured parts. Stakeholders also noted, however, that unauthorised parts may look similar but may be inferior, and that low cost methods of production may result in the proliferation of unauthorized parts in the future.

Several challenges with 3D printed parts were identified by the stakeholders which broadly fell into the following categories: variable quality, limitations of the technology, and operator expertise. 3D printed part quality and part consistency may be affected by variations between printers, quality of feedstock, variations in how the operator uses the technology, and combination of these factors. 3D printing technology may not be able to reproduce parts in the exact same way as traditional manufacturing methods, or may not be capable of making a part using the intended material. Operator expertise can affect part quality and consistency. The operator should have sufficient knowledge to identify if safety critical parts are suitable for such printing. It is a challenge to control the use of unauthorized programs or inexperienced operators, e.g., DIY repairs.

4.4.4 Summary of Responses

4.4.4.1 **Question 1: Please select from the following the roles that you or your organisation (as applicable) most identifies with (please select more than one if applicable):**

Eleven completed surveys were returned from the stakeholder interviews. Stakeholders were provided with the option to select as many different categories as they identified with from a set list, with an option to write in additional categories as required. In many cases, stakeholders selected multiple categories they identified with, e.g. one stakeholder identified with 4 different categories. Stakeholders identified themselves or their organisations as:

- Five domestic appliance manufacturers
- Three domestic appliance installers or repairers
- Three safety professionals

- Two 3D printing equipment manufacturers
- Two 3D printed parts manufacturers
- Two industry bodies
- One 3D printing material (consumables) manufacturer or supplier
- One 3D printed part designer/programmer/ applications engineer (the designer of the component design file)
- One 3D printing device user – professional
- One 3D printing academic - expertise in processing of 3D printing, typically with polymeric or paste-based colloidal inks
- One other - domestic appliance retailer
- One other - a role in product quality assurance

4.4.4.2 Question 2: What do you understand to be potential safety hazards associated with consumer appliances (e.g., washing machines, dishwashers, ovens, clothes dryers)?

Stakeholders identified a number of potential hazards associated with consumer appliances, including:

- Fires
- Electrocution
- Gas leak
- Water leak
- Overheating and burns
- Microbiological, (e.g. pathogen build up)
- Physical and mechanical hazards, including:
- Product tipping
- Rotating parts
- Sharp edges
- General part failure (e.g., mechanical failure) leading to in-operation or other safety issue
- Environmental and chemical hazards, in particular if there is failure to comply with the Restriction of the Use of Certain Hazardous Substances in Electrical and Equipment Regulations 2008 (**"RoHS"**) and the Regulation (EC) No 1907 / 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Chemical and toxicological hazards associated with off gassing of materials

- Stakeholders also identified other potential hazards associated with the foreseeable use and expected performance of domestic appliances. In particular:
  - *"Domestic appliances work in hostile environments: wide temperature variations, water, humidity, etc. Customers view them as workhorse products and treat them as such… Through all of this, they expect it to be durable, reliable, and safe."*
  - The circular economy and environmental/waste concerns are pushing products to last longer. There is a *"need to promote safe and authorized repair, and to be able to make repairs in home."* This gives rise *to "concerns around unlicensed repairs or things being misused like overloading appliances."*
- Counterfeit parts are also a concern.

4.4.4.3 Question 3: Do you have any experience with the use of 3D printing to fabricate replacement parts for consumer products which have originally been manufactured without using 3D printing technologies ("traditionally manufactured")? If so, please describe your experience:

The majority of the stakeholders, eight respondents, did not have any experience with the use of 3D printing to fabricate parts for consumer products. Three stakeholders responded positively to this question and provided the following descriptions of their experience:

- *"Yes, parts are mainly non-hazardous/critical."*
- Experience making metal components for a shoe manufacturer and experience making parts for the automotive sector.
- "As a company we have a number of large-scale industrial 3D printers but these tend to be used in product development and prototyping rather than for fabricating spare parts for consumer products. However, there is no doubt that 3D printing of consumer parts will come at some point."

4.4.4.4 Question 4: Do you feel a 3D printed part/process should undergo a different qualification process to traditionally manufactured parts? If so, please explain the reason:

A majority of the responding stakeholders (six) noted that they felt that 3D printed parts/process should not undergo a different qualification process. Regardless of how a part is manufactured, the end-product must be safe, comply with applicable regulations and standards, and meet performance requirements. When 3D printed spare parts are made using an approved process with approved materials, which have been shown to produce parts to the same standard as the original part, the stakeholders feel that there should be no need for additional testing. The overall validation process for such replacement parts should be the same irrespective of the manufacturing process. Requiring a different qualification process for spares would imply that the existing validation process is not sufficiently stringent. Further to this, part traceability and accountability will remain fundamentally the same. The above applies to parts which are made according to an approved process with approved materials.

Two of the stakeholders responded that they felt that 3D printed parts/process should undergo a different qualification process. The failure modes for 3D printed parts are unique to each printing process and material, and current standards may not adequately address these failures. "Parts are created layer by layer, so mechanical properties can differ across the vertical axis and in the plane of printing. Properties such as tensile modulus should be

measured and reported at different layer orientations, and a value range made available to a manufacturer." For UV cured resins, the mechanical properties may evolve over time and/or with exposure to UV, which could result in materials becoming brittle faster than traditionally manufactured parts. It was felt that part qualification needs to be approached in a different way than what is done for traditionally manufactured parts.

Three of the stakeholders responded that it depends on the particular application and part. It was noted that current standards and test methods may not always be applicable for parts made by 3D printing. The qualification process is industry specific rather than manufacturing specific, so it will depend on what industry certification process is already in place for a given industry. Furthermore, traditionally manufactured parts may be made from a grade of material that is distinct form a 3D printed part, and this difference could influence the final properties of the part. "There are potential approaches now being considered in industry for per-part certifications that account for the distinct manufacturing of 3D printing."

4.4.4.5 Question 5: How would you describe the benefits of using 3D printing to manufacture functional replacement parts for consumer products, in particular white goods/domestic appliances?

The stakeholders identified a number of benefits of using 3D printing to manufacture functional replacement parts for consumer products which result in cost savings, time savings, and/or potential improved part performance, including:

- Reducing part weight
- Improving part function
- Ease of design changes
- Reduced lead times
- Ability to reverse engineer
- Reducing need to hold onto large stocks of spares
- Avoid need for extra tooling
- Part consolidation
- Ability to manufacture complex geometries without additional assembly processes
- On-demand and remote part production
- Bespoke and rare parts production
- Reduced need for transport, logistics, and inventory/warehousing
- Waste reduction and reduced environmental impact
- One stakeholder noted that 3D printed parts might require re-qualification, which could increase cost.

4.4.4.6 Question 6: What challenges (e.g., performance, safety, quality, etc.) have you experienced or would you expect in the use of 3D printing to manufacture functional replacement parts, in particular for consumer appliances?

Several challenges were identified by the stakeholders which broadly fell into the following categories: variable quality, limitations of the technology, and operator expertise.

3D printed part quality and consistency may be affected by variations between printers, quality of feedstock, variations in how the operator uses the technology, and combination of these factors. Printer calibration and compatibility with desired materials can affect quality as well. Software updates for printers could result in consistency issues between similar printers if they are running different versions of the software. As printers become more "widely available, (the breadth of their) quality, durability, and reliability will be even more variable, as will the potential risks".

3D printing technology may not be able to reproduce parts in the exact same way as traditional manufacturing methods, or may not be capable of making a part using the intended material. Glass shelves, for example, are not suitable for 3D printing, and it is currently difficult to reliably print parts that flex, for example, living hinges. For one off parts, there is a challenge to ensure the materials comply with specific requirements, such as flammability or electrical insulation. This can create the potential for cheap counterfeit products with inferior parts that do not meet requirements. "The original manufacturer cannot be expected to provide any warranty or guarantee in respect of parts that they have not seen nor have any control over."

Parts that are suitable for 3D printing may still require post-processing, such as machining or surface finishing. Depending on the availability of material for 3D printing, spare parts which are a pure replication of the original part geometry may result in a lower quality, or the same quality but at a higher cost. A redesign of the part or use of a different material could overcome these challenges.

Operator expertise can affect part quality and consistency. The 3D printing machine operator should have sufficient knowledge to identify if safety critical parts are suitable for 3D printing. It is a challenge to control the use of unauthorized programs or inexperienced operators (e.g. DIY repairs). Furthermore, original component designs or material specifications may not be available which can present numerous challenges for the operator; this situation mirrors what is already encountered with "pattern spares". The consumer "will simply not know what (they) are getting".

4.4.4.7 Question 7: Do you find there to be particular 3D printing methods and/or materials that have more or less safety concerns than others? If so, please explain the reason:

The stakeholders identified a number of factors that may affect product safety. An overall risk is that the supply chain for 3D printing is relatively new, and it is a complex technology that many people do not understand. The technology may be best understood in the prototyping community, however, this does not mean that the same technology is suitable for production quality. A lack of understanding could result in quality as well as safety issues, such as the wrong materials being used in printers.

How the operator makes the part may be more important than the suitability of the material. For example, the effects of layer size and settings can affect mechanical properties. The layer deposition technologies may be susceptible to being very weak in at least one plane. Some methods, such as fuse deposition modelling or filament based printing have the risk of delaminating, whereas other methods chemically or physically bond layers to reduce this risk. Some materials used in AM are hydroscopic and will warp and change properties when they are in contact with humid air.

One stakeholder noted that there are toxicological safety concerns related to chemical exposure during the 3D printing process.

Overall, if the parts that are made by 3D printing are different from the original, they may not offer the same level of compliance as the original.

4.4.4.8 **Question 8: Do you feel that 3D printed parts have more or less safety concerns than traditionally manufactured parts? If so, please explain the reason:**

The majority of stakeholders (seven) responded that, in general, the safety concerns of 3D printed parts should be about the same as traditionally manufactured parts. This is on the basis that such parts were made by reputable manufacturers with approved processes and materials, and have gone through an appropriate qualification program. As there are legal requirements that all products must be safe, professionally made 3D printed parts would still be required to meet relevant standards, or they cannot be used. Not all parts should be 3D printed, and safety considerations should be made when deciding what is appropriate to 3D print. Stakeholders noted that unauthorised parts may look similar but may be inferior, and that low cost methods of production "means that the availability of non-compliant 3D products will proliferate even more rapidly in future…" Using incorrect materials could lead to a safety issue (e.g. insulation issues, thermal resilience issues, mechanical strength issues).

Four stakeholders responded that 3D printed parts have more safety concerns than traditionally manufactured parts. This is due to many of the factors previously mentioned in the responses: limited experience with the technology, variation between printers, operator inexperience, uncertainty of the longevity of components produced, and variations in quality and control processes. 3D printed parts have unique issues related to the bonding between layers which are not typically considered for traditionally manufactured parts. Any change to the printing process (i.e., path) will affect the part performance. Another factor is that while the overall part geometry may look the same, the physical properties of the 3D printed part may be different from the traditionally manufactured part and there is little visibility to the end user regarding how the part was created. This can present challenges to make design changes to the part for future improvements (an issue for the brand owner more than the consumer).

4.4.4.9 **Other comments:**

- Several other comments were received in the stakeholder responses which did not specifically address one of the set questions. They are summarized as follows:
- Fabricators of 3D parts should bear responsibility to ensure conformity; consumers should be aware that any non-authorised parts void the warranty and could expose them to hazards
- As 3D printed spare parts are used, the link between the consumer and the appliance brand may be lost. If something were to go wrong with the appliance, how does the customer get redress, who is liable, and how would misuse be calculated?

4.5 Potential hazard and safety risks

4.5.1 Introduction and Objective

Using the learnings from the literature review and stakeholder interviews, Exponent has compiled a list of potential hazards which may be presented by 3D printed components when used with domestic appliances.

4.5.2 Approach

Using the aforementioned learnings, along with Exponent's expertise in both additive technologies and consumer product risk assessment, Exponent defined the context for potential risks for various aspects of 3D printing technology that may relate to the printing of spare parts for domestic appliances, including but not limited to:

- 3D printing equipment and printed part quality and variability;
- Computer code/design for component parts;
- Material formulation, selection, and use for printing (e.g. polymers, metals);
- Operator of the equipment; and
- Printed part processing and installation.

We applied traditional approaches to risk assessment to map out potential hazards, based on our research findings. In particular, we considered how each of the aspects of the technology could contribute to a particular safety issue, the severity of the impact on the safety issue, and sought to define the conditions which create the opportunity for risk to be presented to a consumer.

An overview list of the potential hazards and factors contributing to safety risks is presented below.

4.5.3 Potential Hazards and Safety Risks

4.5.3.1 Types of Hazards

4.5.3.1.1 Potential hazards presented by domestic appliances to consumers as a result of the failure of 3D printed spare parts may be classified as either potential injuries or product operating/performance hazards. Potential injuries are those which cause harm to a person and could result in the loss of life, limb, or function. Such injuries may be classified as follows[55]:

4.5.3.1.1.1 Size, shape, and surface, e.g.:

- Sharp edge or point resulting in a laceration
- Gap or opening between parts resulting in entrapment, pinching, or an amputation

4.5.3.1.1.2 Potential energy, e.g.:

- Low mechanical stability resulting in crushing
- Low mechanical strength resulting in crushing, electric shock, or burns

[55] RAPEX Guidelines, Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system.

4.5.3.1.1.3 Kinetic Energy, e.g.:

- Parts moving against or past one another resulting in a laceration, fracture, or amputation
- Rotating parts close to one another resulting in crushing or amputation

4.5.3.1.1.4 Electrical Energy, e.g.:

- High/low voltage resulting in electric shock
- Heat production resulting in a burn

4.5.3.1.1.5 Fire and Extreme Temperatures, e.g.:

- Open flames or hot surfaces resulting in burns
- Overheating resulting in burns
- Flammable substances resulting in burns

4.5.3.1.1.6 Toxicity, e.g.:

- Toxic solid or fluid resulting in poisoning
- Toxic gas, vapour, or dust resulting in acute poisoning
- CMR (carcinogenic, mutagenic or toxic to reproduction) substances and other chemicals exceeding regulatory limits

4.5.3.1.1.7 Microbiological Contamination resulting in an infection

4.5.3.1.2 Potential hazards, which affect the appliance's operation or performance that may be attributed to the failure of a 3D printed spare part, include the following categories: mechanical failure, electrical failure, and thermal failure. Such parts may range from those used primarily for aesthetic purposes, or for more functional purposes, such as insulating components, electrical connectors, mechanical fittings (e.g. gears or handles), to more complicated parts such as printed circuit boards. Failure of these parts can potentially cause a poor consumer experience with the product as well as various injuries, many of which are noted above. For example, the latch on a dishwasher door fails to operate properly resulting in a nuisance in some instances, or potentially someone tripping and falling over the open door. Examples of a product's potential operating hazards include[56]:

- Inadvertent (de)activation
- Operational inadequacy
- Failure to stop
- Unexpected start
- Inability to stop

[56] Commission Implementing Decision (EU) 2019/417 of 8 November 2018, Table 2

- Inadequately fitting parts
- Missing or incorrectly fitted

4.5.3.1.3 Product risk is assessed by examining the potential severity of harm and the probability of the harm occurring. The specific level of risk associated with any of the aforementioned hazards requires a case-by-case assessment specific to a particular appliance and spare part failure. The issues identified and described below present the factors that may contribute to an unauthorised 3D printed spare part's failure, i.e. the process, printer, feedstock, and operator have not been approved and/or certified by the appliance brand/manufacturer.

4.5.3.2 Types of Safety Risks

4.5.3.2.1 3D Printing Equipment Variability

4.5.3.2.1.1 3D printed part quality is directly related to the performance and quality of the 3D printer which has been used, along with the feedstock, process and code, and how the operator used the printer. There is a wide range in quality of printers on the market, in particular within the desktop/DIY sector. Variability in quality may be less in the professional device (i.e. non-consumer product), however, it is still present. In addition, the type of printer, i.e. the technology and process it employs, will affect the quality of the 3D printed part, and will also limit the types of material/feedstock which can be used. For one type/model of 3D printer, variability may be introduced by the way in which the printer is used, or changed by the operator ("hacked"), such as changing operating conditions, machine settings, or print paths. Sources of variability may be characterized as:

- Variability between brands and models of printer
- Variability between different printing technologies and processes
- Duty cycle of printer
- Variability due to the materials available for one printer compared to another
- Variability within any one specific printer based on how it is hacked, e.g.

  Using different nozzles

  Adding extra material for adhesion

  Introducing additional heating or cooling

- Variability due to software discrepancies among the same printer model

  Version control (updated printer models and software updates can perform differently from prior versions)

4.5.3.2.2 3D Printing Material/Feedstock Compatibility and Variability

4.5.3.2.2.1 A wide variety of materials is available for 3D printing, including polymers, metals, and ceramics; however, not all grades of materials used in traditional manufacturing are available or suitable for 3D printing. Some materials which are compatible for use with one type of 3D printer may not be compatible with

another, which could affect the material grade and specification that is ultimately selected. The person who ultimately selects the specific material to print with may not be aware of the safety or performance requirements of the part that will be printed, and they may make their material selection based on availability, compatibility, and familiarity with the printer and process.

4.5.3.2.2.2 Additives which may be used in traditional manufacturing, such as certain flame retardants, reinforcing fillers, or antioxidants, may not be compatible with 3D printing feedstock. Various material properties, such as mechanical, thermal, electrical, may not be the same for 3D printing feedstock compared to its traditional manufacturing counterpart, particularly due to limitations in available 3D printing feedstock grades. Performance standards for parts are typically developed based on material samples that have been made using traditional techniques. However, samples made using 3D printing will not always perform in the same way, and performance and safety standards for these 3D printing materials are not as mature. Issues with 3D printing feedstock may include:

- Limited material availability

  Not all materials are compatible with 3D printing

  If a material is compatible, not all grades of that material may be compatible

  Each printer and process will have unique compatibility issues

- Material qualification and performance standards are less mature for 3D printed materials
- 3D printing materials may have different dimensional stability, mechanical, chemical, thermal, electrical, and ageing properties than traditional materials
- Fewer options for custom grades and additives

4.5.3.2.3 3D Printing Part Design and Code

4.5.3.2.3.1 Design for manufacture is an important aspect to good quality part production. In order for a 3D part to be printed, a computer code which defines the geometric design of the part as well as the path that the printer will take to print the part ("print path") must be written. For spare parts which are traditionally manufactured, their designs may not have considered other means of manufacture. It may also be possible that the original designs are not available for the spare part, resulting in a new design being made so that the part may be printed. Each 3D printer will have its own way of printing a given design, i.e. path, and the path could potentially be changed by the operator to affect part strength, material use, printing speed, or other reasons. Intentional code manipulation, hacking, or unintentional code manipulation, or "human error" can also affect part quality. 3D printing part design issues may include:

- Designs for parts may not account for requirements of 3D printing

  Requirements may be different for each type of 3D printing technology and printer

  Designs may only be suitable for traditional manufacturing techniques

- Original part designs may not be available to the 3D printer

  Designs of the original parts may be available but other aspects of the code may not be

- Printing paths may not be adequately defined, as they are related to the part geometry, performance specifications, printing material, and printer
- Product and path codes may be amended intentionally or unintentionally
- Version control of part designs and codes

4.5.3.2.4 Operator's Expertise

4.5.3.2.4.1 The individuals involved in 3D printing the part will have a profound impact on the part quality. It is likely that unauthorised operators will not have direct communication with the brand/manufacturer whose spare part they are printing. They may not only be responsible for operating the printer (as well as setting up and maintaining it), but they may also be responsible for other critical aspects, including part design and material selection. It is possible that the operator will not have a sufficient understanding of the requirements and function of the part they are making. The operator will be free to use the printer as they see fit, and may not be locked into specific settings if they believe that others are suitable. The level of experience with both direct usage of the 3D printer and hacking could lead the operator to make changes to the intended operation of the printer. Subtle changes to printer operation could significantly affect the 3D printed part quality. Furthermore, the environment in which the operator uses the printer could have an effect (e.g. using in a clean and climate controlled space may produce a different product compared to operating a printer in a dirty space which is exposed to the elements). Issues related to operator expertise include:

- 3D printing machine operator's experience with:

  3D printing in general

  With one particular method versus another method

  With one particular printer versus other printers

  Making modifications and hacking

  Setting up and maintenance of the printer

- Motivation of the printer operator
- Environment in which the printer is stored and used
- Printer operator's understanding of the part’s performance requirements and part design

4.5.3.2.5 3D Printed Part Quality and Variability

4.5.3.2.5.1 There are other factors inherent with 3D printing that can affect part quality and variability. 3D printing is traditionally used to create items with a focus on aesthetic quality rather than functional quality or performance, due to the

historical focus of 3D printing for prototyping rather than functional part production. However, there has been a recent push to utilize 3D printing to create functional parts. Because of the traditional focus on aesthetics, and the primarily layer-by-layer manufacturing methods used in 3D printing, 3D printed parts may suffer from various issues that are less likely to affect traditionally manufactured parts made with analogous materials, such as porosity, anisotropy, heterogeneity, dimensional accuracy and stability, interlayer adhesion, lack of fusion, etc. Mechanical properties of the parts may be affected when 3D printed vs traditionally manufactured, such as reductions in tensile and compressive strength, toughness, and impact resistance. The lifetime quality and performance of 3D printed parts compared to traditionally manufactured products could also be different due to factors such as how they are affected by exposure to household chemicals, moisture or UV radiation. The failure modes of traditionally manufactured parts may be well understood and accounted for in the design, whereas the failure modes of 3D printed parts may not be well understood and could be different based on the particular way in which the part was made. Given the multitude of ways a product could fail, it could be challenging for brands to have sufficient visibility of the failures and quality issues to suggest appropriate corrective actions.

4.5.3.2.5.2 Repeatability can also be an issue, even when using the same printer. Feedstock batch variability, differences between suppliers, and uniformity of material can result in variation of product quality. The age and maintenance of the printer is also a factor affecting repeatability.

4.5.3.2.5.3 3D printed parts may require post processing, which is not typically standardized. Parts may require, for example, polishing, painting, or an acetone vapour bath which would not be required for a traditionally manufactured part and introduce the potential for residual chemicals to be present on the final part.

4.5.3.2.5.4 Factors related to 3D printed part quality and variability include:

- Part quality issues

  Porosity and voids

  Anisotropy

  Heterogeneity

  Dimensional stability

  Dimensional accuracy

  Interlayer adhesion

  Lack of fusion

- Part mechanical performance

  Tensile strength

  Compressive strength

Toughness

Impact resistance

Fatigue

Effect of exposure to temperature

Effect of exposure to moisture

Effect of exposure to UV

Effect of exposure to chemicals

- Differences in part failure modes for 3D printed parts versus traditionally manufactured parts
- Repeatability

  Age of printer

  Maintenance of equipment

  Supplier of material

  Uniformity of material

  Batch to batch variation

- Post processing

  Not a standardized approach

  Polishing, painting, acetone vapour bath

  Residual chemicals or other material

  Design for aesthetics vs design for function/performance

- Atmospheric conditions (e.g. pressure, humidity, temperature)

  During material storage, printing, or post-processing

- During printed part use

5 Objective 2: Legal responsibilities of the stakeholders

5.1 Scope of work

5.1.1 In this section, we have provided an overview of how the current legal framework addresses the risks that unauthorised 3D printed parts present to the stakeholders along the supply chain.

5.1.2 We have first identified the current UK legal framework within which 3D printing operates and legal obligations of the following stakeholders within the supply chain who can be held liable for any safety issue with or caused by unauthorised 3D printed parts:

- the non-consumer designer of the component design file;
- the non-consumer manufacturer of the device / machine which allows 3D printing;
- the non-consumer manufacturer of the material used for 3D printing;
- the installer of unauthorised 3D printed parts for installation, repair or maintenance of consumer appliances. This can be:
    - a non-consumer installer; or
    - a consumer installer (e.g. a householder using such part / component to replace the original part / component made by the authorised manufacturer);
- the manufacturer of unauthorised 3D printed parts. This can be:
    - a non-consumer manufacturer; or
    - a consumer (e.g. a householder producing the part for use in consumer appliances that they own by using a 3D printing device / machine);
- the manufacturer of consumer appliances who uses unauthorised 3D printed parts in producing consumer appliances. This can be:
    - non-consumer manufacturer; or
    - a consumer (e.g. creating a new appliance out of unauthorised 3D printed parts);
- the non-consumer vendor of consumer appliances which use unauthorised 3D printed part(s) (other than (e)). The assumption is that the vendor does not know that the appliances they sell use unauthorised 3D printed parts. This can be:
    - a distributor (i.e. B2B); or
    - a retailer (i.e. B2C).

5.1.3 We have also looked at the legal landscape in the EU, USA (federal and California), Canada, Japan and China in light of their importance to the UK trade, for being legislative progressive or supply chain critical.

5.1.4 The legal analysis in this report does **not** extend to:

- C2C (consumer-to-consumer relationship) (e.g. a consumer using an unauthorised 3D printed part made by another consumer, a householder's liability toward a friend visiting the house and being affected by an incident caused by a consumer device using an unauthorised 3D printed part that has been installed by the householder);
- product specific regulations i.e. the legal requirements which may apply depending on the materials used (e.g. chemicals or hazardous substances, recycling, air quality or environmental regulations);
- data protection in particular General Data Protection Regulation (Regulation (EU) 2016/679);
- intellectual property law; or
- the analysis of product liability case law.

5.2 Summary

5.2.1 None of the countries that have been considered has legislation which specifically regulates 3D printing. The analysis as to which existing law applies, and to what extent, depends on: what is supplied; and to whom; whether such supply is made by a trader or a consumer; and any other activities undertaken by the stakeholder in addition to the production or supply of the product. Such analysis is required for each case by applying the fact and circumstances of the case.

5.2.2 In the UK, where the seller or supplier is a trader:

5.2.2.1 there are general requirements for the products supplied to be safe, a breach of which is a criminal offence;

5.2.2.2 if there is a defect in the product, the producer is liable for any damage that is caused by the defect (other than the damage to the product itself) if the damage exceeds £275;

5.2.2.3 a product sold must be of satisfactory quality, which includes safety, and fitness for the purposes for which goods of that kind are usually or commonly supplied. If any particular purpose for which the goods are sold is made known to the seller, those goods must be reasonably fit for that purpose. These quality requirements are treated as terms of the sales contract (unless agreed otherwise in B2B sales contracts);

5.2.2.4 where services are provided (e.g. installation), they must be carried out with reasonable care and skill. This is treated as a term of the service contract (unless agreed otherwise in B2B service contract);

5.2.2.5 in B2C, a consumer must be provided with certain information such as the main characteristics of what is sold and (where applicable) the functionality of digital content. Information so provided is treated as a term of the sales contract;

5.2.2.6 in B2C, if the main characteristics (which include the product's risks, benefits, composition, the method of manufacture, fitness for purpose, specification, origin,

results to be expected from its use, results and material features of tests or checks carried out as well as the risks that the consumer may face) contain false information or its overall presentation in any way deceives or is likely to deceive the average consumer, and causes or likely to cause the average consumer to take a transactional decision he would not have taken otherwise (e.g. buy the product), this is a prohibited unfair commercial practice, a commission of which is made subject to criminal penalties. Consumers have statutory rights to unwind the contract or are entitled to a discount, depending on the circumstances.

5.2.3 Supply of an unauthorised 3D printed part which has no quality or safety issue itself without knowledge of its intended or foreseeable use, does not necessarily make the supplier in breach of the relevant sales regulations or liable for the consequences of such part being used with a particular consumer appliance or a category of consumer appliance. The Supplier's obligations are essentially to supply what is requested by the customer (i.e. to conform to the terms of the supply contract, whether expressly agreed or included by operation of law) while satisfying the general quality and safety legal requirements where applicable. A supplier is not obliged to supply the 3D printed part which is suitable for particular use or for a specific consumer appliance unless such purpose is made known (implied or expressly) by the customer or is reasonably foreseeable. There is no obligation for the supplier actively to seek information that is not provided by the customer. A 3D printed part is not unsafe or defective merely because it is not suitable for use with a specific product or a category of product.

5.2.4 In other countries which were considered as part of this Project, the requirements which apply to a 3D printed part can differ depending on whether the purchaser is a consumer or non-consumer, whether the item is a "product" and if so whether it is a consumer product, and whether the item is subject to product or material-specific regulations. Depending on the jurisdiction, such requirements are expressed under different types of rules. Regulations can also be found in case law as well as general consumer protection legislation.

5.2.5 Overall, stakeholders have obligations under existing statute or common law to ensure the safety of the product they manufacture and/or supply, either under the law on product safety or sales rules concerning the quality of product that can be supplied. However, across the countries within the scope of this Project, legal obligations of the supplier of the design component file of unauthorised 3D printed parts are often not as clear as the obligations of those supplying goods or services. This is because whether digital content (data which is not supplied in a physical medium such as software) is a 'product', 'good' or 'service' to which the relevant regulations apply is not necessarily clear. The relevant legislation often does not expressly provide whether or not digital content is within the scope of the item to which the legislation applies. In the UK, B2C supply of digital content is expressly regulated separately from B2C sale of goods and services under Consumer Rights Act 2015 whereas the corresponding provisions are not found in the Sale of Goods Act 1979, which is the B2B equivalent and predates the Consumer Rights Act 2015. In other countries within the scope of this Project, there is a lack or shortage of case law determining whether or not digital content is regulated by relevant legislation.

5.3 Existing legal framework

5.3.1 UK

5.3.1.1 The following rules apply in the UK depending on the type of product, the stakeholder's role, and the purchaser (B2B or B2C).

5.3.1.1.1 Product safety

- Health and Safety at Work etc. Act 1974 (if a non-consumer product)(see 5.3.1.8)
- General Product Safety Regulations 2005 (if a consumer product)(see 5.3.1.13)

5.3.1.1.2 Product liability - Consumer Protection Act 1987 (see 5.3.1.16) and tort of negligence (see 5.3.1.17)

5.3.1.1.3 Sale of goods

- Sale of Goods Act 1979 (if B2B) (see 5.3.1.18.1)
- Consumer Rights Act 2015 (if B2C) (see 5.3.1.18.2)

5.3.1.1.4 Sale of digital content

- Case law on the application of the Sale of Goods Act 1979 (if B2B) (see 5.3.1.19.1)
- Consumer Rights Act 2015 (if B2C) (see 5.3.1.19.2)

5.3.1.1.5 Supply of service

- Supply of Goods and Services Act 1982 (if B2B) (see 5.3.1.20.1)
- Consumer Rights Act 2015 (if B2C)(see 5.3.1.20.2)

5.3.1.1.6 Provision of information

- Provision of Services Regulations 2009 (see 5.3.1.21.1)
- Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 (see 5.3.1.21.3), Consumer Protection from Unfair Trading Regulations 2008 (see 5.3.1.22) (both if B2C)

5.3.1.2 There is no legislation which specifically regulates 3D printing. 3D printing device material and 3D printed parts must comply with product specific regulations, if applicable, depending on the product or materials used. For example, such product specific regulations may be:

5.3.1.2.1 in the case of a non-consumer product, the Machinery (Safety) Regulations 2008, under which the responsible person of the machinery or partly completed machinery must not place machinery on the market or put it into service unless it is safe. Regulations set out various additional safety and CE marking requirements.

"Machinery" broadly includes (unless expressly excluded under these regulations or Directives other than Directive 2006/42/EC); (a) an assembly, fitted with or intended to be fitted with a drive system or components and partially completed machinery (drive systems and other assemblies which are almost machinery, cannot themselves perform a specific application and are only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery); (b) interchangeable equipment (devices

which, after putting the machine into service, are assembled with that machinery by operators in order to change its function or attribute a new function, in so far as they are not tools); and (c) safety components (components which serve to fulfil a safety function, placed on the market independently, its failure or malfunction endangers the safety of persons but are not necessary for the machinery to function).

Before placing machinery on the market or put into service, the manufacturer and its authorised representative must ensure (among other things) that applicable health and safety requirements are satisfied in respect of the machinery and provide information necessary for its safe operation (such as instructions). In the case of partly completed machinery, the responsible person must ensure (among other things) that assembly instructions are prepared in accordance with these regulations and those instructions accompany partly completed machinery until it is incorporated into the final product. In doing so, the responsible person must carry out or procure the carrying out of all the necessary research and tests on components, fittings or the partly completed machinery to determine whether, by its design and construction, it is capable of being assembled and used safely.

A breach of these obligations is a criminal offence. Defences are available if (among other things):

- a person is shown to have taken all reasonable steps and exercised all due diligence to avoid committing the offence; or
- the commission is due to another person's act or default, in which case that other person is guilty of the offence.

5.3.1.2.2 In the case of a consumer product, depending on the make and material used, the Electrical Equipment (Safety) Regulations 2016, Electromagnetic Compatibility Regulations 2016 and REACH (Regulation (EC) No 1907/2006) may apply.

5.3.1.3 In the absence of product specific regulation, the Health and Safety at Work etc. Act 1974 applies to safety of non-consumer products and the General Product Safety Regulations 2005 (**"GPSR"**) apply to safety of the consumer products.

5.3.1.4 Under the Health and Safety at Work etc. Act 1974:

5.3.1.4.1 any person who designs, manufactures, imports or supplies any article for use at work must:

- ensure, so far as is reasonably practicable, that the article is so designed and constructed that it will be safe and without risks to health at all times when it is being set, used, cleaned or maintained by a person at work (the **"Relevant Activities"**). Any relevant information or advice which has been provided by the person who designed, manufactured, imported or supplied is taken into consideration in determining whether this duty has been performed;
- carry out or arrange for the carrying out of such testing and examination as may be necessary for the Relevant Activities;
- take such steps as are necessary to secure that those supplied with the article ("**users**") are provided with adequate information about (a) the use for which the article is designed or has been tested, and (b) any conditions necessary to ensure

that it will be safe and without risks to health at all times during the Relevant Activities and when it is being dismantled or disposed of; and

- take such steps as are necessary to ensure, so far as is reasonably practicable, that the users are provided with all revisions to the information provided to them above that are necessary to ensure that new information giving rise to a serious risk to health or safety is supplied with the users.

The obligations above also apply to articles used for the purpose of or in connection with entertainment by members of the public.

5.3.1.4.2 Any person who undertakes the design or manufacture of any article for use at work must carry out or arrange for the carrying out of any necessary research with a view to discovering and, so far as is reasonably practicable, eliminating or minimising any risks to health or safety to which the design or article may give rise.

5.3.1.4.3 Any person who erects or installs any article for use at work in any premises where that article is to be used by a person at work must ensure, so far as is reasonably practicable, that nothing about the way in which the article is erected or installed makes it unsafe or a risk to health at any time during the Relevant Activities.

5.3.1.4.4 Any person who manufactures, imports or supplies any substance must:

- ensure, so far as is reasonably practicable, that the substance will be safe and without risk to health at all times when it is used, handled, processed, stored or transported ("**Processing Activities**") by a person at work. Any relevant information or advice which has been provided by the person who manufactured, imported or supplied the substance is taken into consideration in determining whether this duty has been performed;

- carry out or arrange for the carrying out of such testing and examination as may be necessary for the Processing Activities;

- take such steps as are necessary to ensure that the users of the substance supplied are provided with adequate information about (a) any risks to health or safety to which the inherent properties of the substance may give rise, (b) the results of any relevant tests which have been carried out on or in connection with the substance and (c) any conditions necessary to ensure that the substance will be safe and without risk to health at all times during the Processing Activities and when the substance is being disposed of; and

- take such steps as are necessary to secure, so far as is reasonably practicable, that the users of the substance supplied are provided with all revisions of information provided to them above as are necessary because it becomes known as giving rise to a serious risk to health or safety.

5.3.1.4.5 Any person who undertakes the manufacture of any substance must carry out or arrange for the carrying out of any necessary research with a view to discovering and, so far as is reasonably practicable, eliminating or minimising any risks to health or safety to which the substance may give rise. However, this obligation only extends to things within his control and which are done in the course of business (whether or not for profit), and there is no need to repeat any testing, examination or research which has been carried out by others, in so far as it is reasonable for him to rely on the results.

5.3.1.4.6 If it is shown that the occurrence of the circumstance could not reasonably be foreseen, lack of safety or a risk to health is disregarded and therefore the obligations mentioned above under the Health and Safety at Work etc. Act 1974 do not apply.

A breach of any of the above duties is a criminal offence but would not give rise to a civil right of action in respect of any failure to comply with any such duty. A defence is available where (among other things) the breach is due to another person's act or default, in which case that other person is guilty of the offence.

5.3.1.5 GPSR applies to a "product", which is defined to mean a product intended for consumers or, even if not intended for them, is likely to be used by consumers and is supplied or made available in the course of business. For the purposes of GPSR, "products" include new, used or reconditioned products and a product supplied or made available to consumers for their own use while a trader provides a service. However, second-hand products (supplied for repair or reconditioning prior to use) are not subject to GPSR if the supplier clearly informs the person to whom he supplies the product that the products need to be repaired or reconditioned.

5.3.1.5.1 Under GPSR, for a product to be considered "safe", under normal or reasonably foreseeable conditions of use (including when put in service, installed, and maintained), the product must not present any risk or only the minimum risk compatible with its use which are considered to be acceptable and consistent with a high level of protection for the safety and health of persons. The following is taken into consideration in determining whether a product is safe:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, instructions for installation and maintenance;
- the effect of the product on other products, where it is reasonably foreseeable that it will be used with other products;
- 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; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

5.3.1.5.2 The obligations under GPSR differ depending on the role of the party within the supply chain:

5.3.1.5.2.1 A producer must:

- not place a product on the market unless it is a safe product;
- provide consumers with the relevant information to enable them to (a) assess the risks inherent in a product throughout the normal or reasonably foreseeable period of use and (b) take precautions against such risks; and
- within the limits of the producer's activities, adopt measures so that he (a) is informed of the risks which the products might pose and (b) is able to take appropriate action including product withdrawal, issuing consumer warnings and/or recall. This includes sample testing of marketed products and keeping distributors informed of the results of monitoring where a product presents a risk.

A "producer" means: (a) the manufacturer established in the EU, (b) the 'brand owner' (a person who presents himself as the manufacture by affixing to the product his name, trade mark or other distinctive mark), (c) where the manufacturer is not established in the EU, his representative established in the EU or in other case the first importer into the EU, (d) other professionals in the supply chain to the extent their activities may affect the safety properties of a product.

5.3.1.5.2.2 A distributor must (among other things):

- not possess for supply, or offer, or agree to supply, or supply a product which he knows (or should have presumed, based on the information he possesses and professional expertise), is a dangerous product; and
- within the limits of the distributor's activities, participate in monitoring the safety of the product by passing on information on the product's risks and producing the documentation necessary for tracing the product's origin.

A "distributor" means a professional in the supply chain whose activity does not affect the safety properties of a product.

5.3.1.5.2.3 Where a producer or distributor knows that a product placed on the market or otherwise supplied poses risks to the consumer, he must:

- notify an enforcement authority of the actions taken to prevent the risks to the consumer in the UK (and, if supplied outside the UK, the EU Member States in which the product is marketed or supplied to the best of his knowledge);
- in the case of serious risk, also notify (a) information allowing the product or batch to be identified, (b) descriptions of the risks, (c) all available information for tracing the product and (d) descriptions of the action undertaken to prevent the risks to the consumer; and
- within the limits of his activities, cooperate with an enforcement authority in taking corrective action to avoid such risks being posed by the product.

A breach of these obligations is a criminal offence (apart from the second bullet point of 5.3.1.15.2 above). A defence is available where (among other things) the person can prove that (i) the commission of the offence was due to (1) the act or default of another, or (2) reliance on information given by another (and it was reasonable in all the circumstances to have relied on such information), and (ii) he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence; or

5.3.1.6 Product liability rules apply where there is a defect in the product.

5.3.1.6.1 Under the Consumer Protection Act 1987, the following persons are liable where there is any damage that is caused wholly or partly by a defect in a product:

- the producer of the product;
- any person who, by putting his name on the product or using a trade mark or other distinguishing mark in relation to the product, has held himself out to be the producer of the product; and

- any person who has imported the product into a member State from a place outside the Member States in order, in the course of any business of his, to supply it to another.

In this context, "producer" means (a) the person who manufactured it, (b) in the case of a substance which has not been manufactured but has been won or abstracted, the person who won or abstracted it, and (c) where a product has not been manufactured, won or abstracted but essential requirements of which are attributable to an industrial or other process having been carried out, the person who carried out that process.

The supplier is liable if (i) asked by the person who suffered the damage to identify one or more of the persons described in paragraph 5.3.1.16.1 above within a reasonable time after the damage occurs, (ii) at a time when it is not reasonably practicable for the person making the request to identify such persons, and (iii) fails to do so within a reasonable period of time.

Where two or more persons are liable for the same damage, they are jointly and severally liable.

5.3.1.6.2 A product is "defective" if its safety is not such as persons are entitled to expect (taking all the circumstances into account). For this purpose, "safety" includes safety with respect to products comprised in that product, safety in the context of risks of damage to property and safety in the context of death or personal injury and "damage" means death or personal injury or any damage to property, including land.

The level of safety persons are generally entitled to expect in relation to a product is determined by taking into account all the circumstances including the manners in which and purposes for which the product has been marketed, what might reasonably be expected to be done with or in relation to the product and the time when the product was supplied by its producer to another. However:

5.3.1.6.2.1 A defect is not inferred from the fact alone that a product supplied at a later time is safer than the product which caused the damage.

5.3.1.6.2.2 Liability will not arise in respect of:

- loss or damage to the product itself;
- loss or any damage to the whole or any part of any product which has been supplied with the product in question or comprising part of it;
- loss of or damage to any property which, at the time it is lost or damaged is not (i) of a description of property ordinarily intended for private use, and (ii) intended by the person suffering the loss / damage mainly for his own private use; or
- for loss / damage to property where the value of such damage does not exceed £275.

5.3.1.7 Under common law, a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care (*Donoghue v Stevenson* [1932] A.C. 562 at 599). When such duty is breached and a loss is caused, the person who suffered

the loss may sue for damages under tort of negligence. Under common law, a duty of care would arise if someone possessed of a special skill undertook, quite irrespective of contract, to apply that skill for the assistance of another person who relied on such skill (*Hedley Byrne & Co. Ltd. V Heller & Partners Ltd.* [1964] A.C. 465 at 502-503). Such special relationships also include circumstances where there is an assumption of responsibility and in which, but for the absence of consideration, there would be a contract (*Henderson v Merrett* [1995] 2 A.C. 145 at 159).

5.3.1.8 A buyer of goods has the following rights against the seller:

5.3.1.8.1 If the buyer is a not a consumer, under the Sale of Goods Act 1979, it is an implied term of the contract that the goods supplied:

- are of satisfactory quality (i.e. they meet the standard that a reasonable person would consider satisfactory, taking account of the description of the goods, the price (if relevant) and all other relevant circumstances). For this purpose, the quality of goods includes safety, durability and freedom from minor defects;
- are reasonably fit for any particular purpose for which the buyer is contracting the goods and which is made known by the buyer to the seller (expressly or impliedly) before entering into the sales contract (except where the circumstances show that the buyer does not rely, or that it is unreasonable for him to rely, on the skill or judgment of the seller); and
- match the description if sold by description.

A trader's obligations relating to paid-for supply of goods under the Sale of Goods Act 1979 are contractual obligations owed towards the non-consumer purchaser. A breach amounts to a breach of a term (warranty) of the sales contract. The buyer cannot reject the goods but may seek for a price reduction or damages for the breach of warranty.

Trac Time Control Ltd v Moss Plastic Parts Ltd (t/a Rowan Plastic Parts Centre)[2004] EWHC 3298 (QB) provides a useful example of the liability of intermediaries within the supply chain and the skills and judgment that can be relied upon. In this case, the claimant lighting manufacturer (T) ordered housings for some lights from the moulder, Rown Mouldings Limited (R), which purchased the raw material from Anglo Polymers Limited (A), who in turn purchased it from Regents Chemicals Ltd (Regents), a compounder who blends different qualities of polycarbonate to order. The properties of the polycarbonate housing used for the housings for the lights was critical to the quality for the housing. Polycarbonate is suitable for recycling but loses quality in the process. The specification of the polycarbonate for use in manufacturing the housing was made known to R and R was allowed to source it from a third party so long as it complied with the specification or had a similar quality. The material Regents supplied to A was low grade polycarbonate and R sourced it from A because it was cheaper than the polycarbonate supplied by the company from which it was ordinarily purchased. T brought a claim against R for breach of contract under the Sale of Goods Act 1979 pursuant to which the bullet-point terms described in paragraph 5.3.1.18.1 above are implied The court held that (i) the housings were not of satisfactory quality, and (ii) if the term of contract between R and A was merely that A supply polycarbonate, T did rely on R's marketing manager's skill and judgment in securing that polycarbonate supplied was fit for purpose as only he had the key information which could have indicated that the polycarbonate might not be all that it was held out to be (and therefore the implied term of fitness for purpose applies). R was in breach of all its contracts to supply

housings where housings were made of polycarbonate supplied by A: T was entitled to rely on the fact that it had agreed a specification with R and R's contractual obligations to deliver housings that corresponded to description, were of satisfactory quality and fit for purpose, and the fact that T did not carry out unspecified detailed tests of the housings supplied by R does not have the effect of obliterating R's breaches, and the low quality of the polycarbonate used by R to mould the housings was the cause of T's losses.

Whilst R was liable to T for breach of the terms implied under the Sale of Goods Act 1979, A was held liable to R for breach of the implied term that the polycarbonate would be of satisfactory quality (the polycarbonate supplied by A to R was not fit for the purpose of being moulded into housings for lights, R relied on the skill and judgement of A to procure polycarbonate that was fit for the purpose). However, Regent was under no contractual duty to supply polycarbonate which conformed with the specification for T's lighting housing and between Regent and Anglo the polycarbonate supplied was of satisfactory quality.

5.3.1.8.2 If the buyer is a consumer, under Consumer Rights Act 2015:

5.3.1.8.2.1 A trader's obligations relating to paid-for supply of goods, services or digital content under the Consumer Rights Act 2015 are contractual obligations owed towards the consumer as follows. Under this Act, "trader" means a person acting for purposes relating to that person's trade, business, craft or profession, whether acting personally or through another person acting in the trader's name or on the trader's behalf. "Consumer" means an individual acting for purposes that are wholly or mainly outside that individual's trade, business, craft or profession.

5.3.1.8.2.2 Where goods are supplied, as a term of a contract, the goods must:

- be of satisfactory quality i.e. they must meet the standard that a reasonable person would consider satisfactory, taking account of the description of the goods, the price or other considerations for the goods (if relevant) and all other relevant circumstances including public statement made in advertising and labelling about the specific characteristics of the goods made by the trader, the producer or any of their representative. For this purpose, the quality of goods includes safety, durability and freedom from minor defects. A public statement is not a relevant circumstance if (a) the trader was not, and could not reasonably have been, aware of the statement, (b) before the contract was made, the statement has been publicly withdrawn or corrected to the extent it contained anything which was incorrect or misleading or (c) the consumer's decision to contract for the goods could not have been influenced by the statement;

- be reasonably fit for any particular purpose for which the consumer is contracting the goods where the consumer makes known to the trader (expressly or impliedly) before entering into the sales contract (except where the circumstances show that the consumer does not rely, or that it is unreasonable for the consumer to rely, on the skill or judgment of the trader); and

- match the description if supplied by description.

Goods are also treated as not in conformity if (a) installation was part of the contract and the goods are incorrectly installed by the trader or (b) includes digital content and

the digital content does not conform to the quality that applies to digital content (see 5.3.1.19 below).

If there is a breach of the matters set out above, the consumer buyer has the following rights depending on the circumstances:

- reject and receive a refund within 30 days of ownership transfer and delivery;
- require repair or replacement. This does not apply if such repair or replacement (a) is impossible or would be disproportionate (costs are unreasonable on the trader), (b) could not carried out within a reasonable time without significant inconvenience or (c) does not conform the contract after one repair or replacement;
- price reduction. This does not apply if the goods cannot be divided up or returned by the consumer in its original state; or
- final right to reject for a refund.

5.3.1.9 A buyer of digital content has the following rights against the seller:

5.3.1.9.1 If the buyer is a non-consumer, jurisprudence indicates that digital content which is not supplied in a physical medium (such as software downloaded onto a computer) is not a "good" for the purposes of Sale of Goods 1979 and therefore the Sale of Goods 1979 does not apply. In *St Albans City and District Council v International Computers Ltd* [1997] F.S.R. 251, a computer disc onto which a program designed and intended to instruct or enable a computer to achieve a particular function has been encoded should be "goods"; however the program itself is not. The supply contract of the program is subject to an implied term that it will be reasonably fit for, that is, reasonably capable of achieving the intended purpose (at 266). In *London Borough of Southwark v IBM UK Limited* [2011] EWHC 549, it was held that in principle software whose property or title transfers can be "goods" for the purposes of Sale of Goods 1979 (which was distinguished from a grant of licence to use software without transfer of property or title (at para. 97)).

5.3.1.9.2 If the buyer is a consumer under Consumer Rights Act 2015:

5.3.1.9.3 Where digital content (data which are produced and supplied in digital form) is supplied, as a term of a contract, digital content must:

- be of satisfactory quality (see 5.3.1.18.2.2 above);
- be reasonably fit for any particular purpose for which the consumer is contracting the goods that is made known by the consumer to the trader (expressly or impliedly) before entering into the supply contact; and
- match the description given by the trader.

5.3.1.9.4 Where the digital content (and/or the digital content component of the goods) does not conform, the consumer buyer has the following rights depending on the circumstances:

- to require repair or replacement. This does not apply if such repair or replacement (a) would be impossible or disproportionate (costs are unreasonable on the trader),

(b) could not be carried out within a reasonable time without significant inconvenience or (c) does not conform the contract after one repair or replacement;

- to claim a price reduction; or
- to receive a refund.

5.3.1.9.5 If the digital content (1) causes damage to a device or other digital content, (2) the damaged device / digital content belongs to the consumer and (3) the damage is of a kind that would not have occurred had the trader exercised reasonable care and skill, then the consumer can also require:

- that the damage to such other device or content be repaired; or
- that he be compensated for such damage.

5.3.1.10 A recipient of a service has the following rights against the seller:

5.3.1.10.1 If the service recipient is not a consumer, under the Supply of Goods and Services Act 1982, a trader's obligations relating to supply of services are contractual obligations owed towards the non-consumer purchaser.

5.3.1.10.1.1 Where a service is supplied, it is an implied term of the contract that the supplier will carry out the service with reasonable care and skill.

5.3.1.10.1.2 Where a service provides goods to non-consumers without having a separate contract for sale of goods (e.g. when providing parts as part of the installation or repair services without having a separate sales contract for the parts used in such services), it is an implied term of the contract that such goods are:

- of satisfactory quality i.e. meet the standard that a reasonable person would consider satisfactory, taking account of the description of the goods, the price (if relevant) and all other relevant circumstances. For this purpose, the quality of goods includes safety, durability and freedom from minor defects;
- reasonably fit for any particular purpose for which the buyer is contracting that is made known by the buyer to the seller (expressly or impliedly) before entering into the sales contract (except where the circumstances show that the buyer does not rely, or that it is unreasonable for him to rely, on the skill or judgment of the seller); and
- match the description if sold by description.

A breach amounts to a breach of a term (warranty) of the sales contract. The buyer cannot reject the goods but may seek for a price reduction or damages for the breach of warranty.

5.3.1.10.2 If the service is supplied to a consumer, under the Consumer Rights Act 2015, as a term of the contract, the trader must perform the service with reasonable care and skill. Anything that is said or written to the consumer, by or on behalf of the trader, about the trader or the service is also treated as a term if it is taken into account by the consumer when deciding to enter into the contract or making any decision about the service after entering into the contract.

If the implied term above is breached, the consumer has the right to:

- seek re-performance of the service to the extent necessary to be in conformity with the contract. This does not apply if impossible to re-perform or the trader fails to re-perform within a reasonable time without significant inconvenience to consumer; or

- claim a price reduction.

5.3.1.11 In terms of the information made available to the purchaser before purchase:

5.3.1.11.1 under the Provision of Services Regulations 2009, a service provider also have to provide at its own initiative (among other things), in good time before the conclusion of the contract and in a clear and unambiguous manner, its contact details, terms and conditions, the main features of the service (if not apparent from the context), after-sales guarantees and insurance information (if applicable) and certain information on request (including any applicable professional rules or codes of conduct).

A "service provider" means a person who provides or offers to provide services and is either an individual who is a national or a legal person established in an EEA state. A "service" means any self-employed economic activity which is normally provided for remuneration (subject to certain exclusions) but not (among other things) to: (i) electronic communications services and networks, and associated facilities and services with respect to matters covered by the EU directives set out in reg (2)(b) (the Access Directive, Authorisation Directive, Framework Directive, Universal Service Directive and the e-Privacy Directive); and (ii) audio-visual services including cinematographic services and radio broadcasting.

5.3.1.11.2 If B2C, under the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013, a trader has to give or make available (among other things) the following information to the consumer in a clear and comprehensive manner before the consumer is bound by contract (unless it is a type of contract that is excluded from the application of these regulations):

- the main characteristics of the goods, services or digital content;

- in the case of a sales contract, a reminder that the trader is under a legal duty to supply goods that are in conformity with the contract;

- where applicable, the existence and the conditions of after-sale customer assistance, after-sales services and commercial guarantees;

- where applicable, the functionality, including applicable technical protection measures, of digital content; and

- where applicable, any relevant compatibility of digital content with hardware and software that the trader is aware of or can reasonably be expected to have been aware of.

Failure to provide the information amounts to a breach of contract.

It is also a criminal offence if the contract is an "off-premises contract" (in essence, concluded in a place which is not the trader's business premises when both parties are physically present ("**off-premises**"); the consumer's offer of the contact was made off-premises; concluded by distance communication immediately after the consumer

was personally and individually addressed off-premises; or concluded during an excursion organised by the trader with the aim or effect of promoting and selling goods or services to the consumer). A defence is available if the trader can prove that: (a) the commission of the offence was due to (i) the act or default of another or (ii) reliance on information given by another, and (b) the trader took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.

5.3.1.12 The accuracy of information provided to consumers is also regulated by the common law of misrepresentation, Misrepresentation Act 1967 or, if B2C, Consumer Protection from Unfair Trading Regulations 2008 which prohibit unfair commercial practices.

Where a person enters into a contract as a result misrepresentation (an untrue statement of fact or law), the remedies would be rescission of the contract under common law or, under the Misrepresentation Act 1967, damages may be awarded in lieu of rescission of the contract depending on the circumstances.

If B2C, Consumer Protection from Unfair Trading Regulations 2008 apply to a "commercial practice", which means any act, omission, course of conduct, representation or commercial communication (including advertising and marketing) by a trader, which is directly connected with the promotion, sale or supply of a product to or from consumers, whether occurring before, during or after a commercial transaction (if any) in relation to a product. A commercial practice is unfair (among other things) and prohibited if it is (i) a misleading action, (ii) a misleading omission or (iii) one of the practices listed in schedule 1 ("**black-listed practices**").

5.3.1.12.1 A commercial practice is a misleading action if the commercial practice:

- contains false information and is therefore untruthful in relation to certain matters specified in these Regulations or if it or its overall presentation in any way deceives or is likely to deceive the average consumer in relation to any such matters, even if the information is factually correct. Such matters include (a) the main characteristics of the product (which include the product's risks, benefits, composition, the method of manufacture, fitness for purpose, specification, origin, results to be expected from its use, results and material features of tests or checks carried out), (b) the attributes and rights of the trader (which include the trader's qualification, ownership of industrial / commercial / intellectual property rights) and (c) the consumer's rights or the risks he may face; and

- causes or is likely to cause the average consumer to take a transactional decision he would not have taken otherwise.

5.3.1.12.2 A commercial practice is a misleading omission and is prohibited if, in its factual context, the commercial practice:

- omits or hides material information, provides material information in a manner which is unclear, unintelligible, ambiguous or untimely or fails to identify its commercial intent, unless this is already apparent from the context. Material information means (a) the information which the average consumer needs, according to the context, to take an informed transactional decision and (b) any information requirement which applies in relation to a commercial communication as a result of an EU obligation. If

the commercial practice is an invitation to purchase, the main characteristics of the product is also considered as material information; and

- as a result causes or likely to cause the average consumer to take a transaction decision that he would not have taken otherwise.

5.3.1.12.3 The black-listed practices are prohibited and include:

- stating or otherwise creating the impression that a product can legally be sold when it cannot;
- promoting a product similar to a product made by a particular manufacturer in such a manner as deliberately to mislead the consumer into believing that the product is made by that same manufacturer when it is not;
- passing on materially inaccurate information on market conditions or on the possibility of finding the product with the intention of inducing the consumer to acquire the product at conditions less favourable than normal market conditions; or
- falsely claiming or creating the impression that the trader is not acting for purposes relating to his trade, business, craft or profession, or falsely representing oneself as a consumer.

5.3.1.12.4 The consumer has the right to (i) unwind the contract and get a full refund within 90 days of the latter of entering into the contract and the first delivery or supply, if the goods / service / digital content is capable of being rejected at the time the consumer indicates to the trader that he rejects it or (ii) a 25% to 100% discount (depending on the behaviour, impact on consumer and time that has elapsed since the misleading action) up to a maximum value of £5,000 against the manufacturer, importer or 'brand owner' (a person who purports to be a producer by placing the person's name, trade mark or other distinctive sign on the goods or using it in connection with the digital content) of the goods ("**producer**") if:

- there is a misleading action resulting in a consumer entering into a business to consumer contract for goods or digital content and, when the contract is entered into, the trader is aware of the commercial practice that constitutes the prohibited practice or could reasonably be expected to be aware of it or (ii) otherwise the consumer enters into a contract with a trader (e.g. service contract) or makes a payment to the trader for the supply of goods, services or digital content; and
- the misleading action is a significant factor in the consumer's decision to enter into the contract or make the payment.

The consumer also has the right to damages in respect of loss, or alarm, distress or physical inconvenience or discomfort that was reasonably foreseeable at the time of the misleading action if the consumer has incurred financial loss which the consumer would not have incurred if the misleading act had not taken place. In addition, the behaviours described in paragraphs 5.3.1.22.1 and 5.3.1.22.2, and certain black-listed practices are criminal offences.

5.3.2 EU

5.3.2.1 There is no legislation which specifically regulates 3D printing. The requirements which apply in the absence of such legislation are effectively the same as the

transposing UK legislation. The EU Directives which introduced the relevant law in the UK (as discussed in 5.3.1) (references to the UK legislation which transposed the relevant rules is in the brackets) except for Directive 1999/44/EC are as follows:

- Directive 2001/95/EC (General Product Safety Directive)(if a consumer product - see 5.3.1.13);
- Directive 1999/44/EC (Consumer Sales and Guarantees Directive)(if B2C - see 5.3.2.2);
- Directive 2011/83/EU (Consumer Rights Directive) (see 5.3.1.21);
- Directive 2005/29/EC (Unfair Commercial Practices Directive) (see 5.3.1.22);
- Directive 2006/123/EC (Services Directive) (see 5.3.1.21.1);
- Directive 2006/42/EC (Machinery Directive) (see 5.3.1.2); and
- Directive 85/374/EEC (Product Liability Directive) (see 5.3.1.16).

5.3.2.2 Directive 1999/44/EC has less requirements than the Consumer Rights Act 2015 in the UK (see 5.3.1.18.2, 5.3.1.19, 5.3.1.20.2) which is broader in its scope and requirements as Member States are allowed to adopt more stringent provisions. Under Directive 1999/44/EC:

5.3.2.2.1 The seller must deliver goods to the consumer which are in conformity with the contract of sale. Conformity is presumed if the goods:

5.3.2.2.1.1 comply with the description;

5.3.2.2.1.2 are fit for any particular purpose for which the consumer requires them and which has been made known to the seller at the time of contract and accepted by the seller;

5.3.2.2.1.3 are fit for the purpose for which goods of the same type are normally used; and

5.3.2.2.1.4 show the quality and performance which are normal in goods of the same type and which the consumer can reasonably expect, given the nature of the goods and taking into account any public statements on the specific characteristics of the goods made about them by the seller, the producer or his representative, particularly in advertising or on labelling.

However, it is not treated as a lack of conformity if, at the time of contracting the consumer was aware, or could not reasonably be unaware of, such lack of conformity. The seller is also not bound by public statements if he shows that (a) he was not, and could not reasonably have been, aware of the statement, (b) the statement had been corrected before contract or (c) the decision to buy the consumer goods could not have been influenced by the statement.

5.3.2.2.2 Any lack of conformity resulting from incorrect installation of the consumer goods is deemed to be lack of conformity of the goods if installation forms part of the contract for sale of goods and the goods were installed by the seller or under his responsibility.

5.3.2.2.3 5.3.2.2.2 above also applies if the product, intended to be installed by the consumer, is installed by the consumer and the incorrect installation is due to a shortcoming in the installation instructions.

5.3.2.2.4 If there is a lack of conformity, the consumer may require the following for not less than two years from delivery under national law:

- repair or replacement unless this is impossible or disproportionate (i.e. such repair or replacement would impose costs on the seller which are unreasonable in comparison to the alternative remedy); or
- if repair or replacement is not available, or not provided within a reasonable time or without significant inconvenience to the consumer, an appropriate reduction in the price or rescission of contract (unless the lack of conformity is minor).

5.3.2.2.5 Where the final seller is liable to the consumer because of a lack of conformity resulting from an act or omission by the producer (manufacturer, first importer into the EU or any 'brand owner' (person purporting to be a producer by placing his name, trade mark or other distinctive sign on the consumer goods)), a previous seller in the same chain of contracts or any other intermediary, the final seller must have the right to pursue remedies against them under national law.

5.3.3 UNITED STATES OF AMERICA / STATE OF CALIFORNIA

The following rules apply under US Federal law and the laws of State of California:

- Product safety - Consumer Product Safety Act of 1972 (if a consumer product) (see 5.3.3.2)
- Product liability - Restatement (Second) Tort and Restatement (Third) Tort (see 5.3.3.3)
- Sale of goods - Uniform Commercial Code (see 5.3.3.4)
- Supply of services - common law (see 5.3.3.5)
- Provision of information - Federal and state laws (see 5.3.3.6)
- Case law on design files (see 5.3.3.7)

5.3.3.1 There is no legislation which specifically regulates 3D printing. However, there are general product safety requirements, product liability rules and implied warranties which can apply to 3D printing machines, 3D printed parts or consumer appliances.

5.3.3.2 Under the Consumer Product Safety Act of 1972 ("**CPSA**"), all product manufacturers, distributors, and retailers have a duty to notify the Consumer Product Safety Commission ("**CPSC**") promptly when they have any information that "reasonably supports the conclusion" that a product contains a substantial product hazard.

When the CPSC learns of a substantial product hazard, it may order the seller, after conducting a hearing, either to give public notice of the product defect, to mail notice to distributors and retailers for publication, or to mail notice directly to known purchasers of the product. It may also require a seller to repair, replace, or refund all instances of the product sold or even order the manufacturer to recall the product

and prohibit further sale of the product. Sanctions include both civil penalties, up to a current maximum of USD $15.15 million; and criminal penalties, including a fine, imprisonment of the responsible individual(s) for not more than five years, and forfeiture of assets associated with the criminal violation(s). In addition, companies and individuals may be enjoined from continuing to violate CPSC statutes and regulations, and pursuant to court order, violative products may be seized to prevent distribution in commerce.

The CPSA also gives private individuals the rights to sue product sellers who violate the consumer product safety standards.

5.3.3.3 The following product liability rules are in the Restatement (Second) of Torts and Restatement (Third) of Torts:

5.3.3.3.1 One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if: (i) the seller is engaged in the business of selling such a product; and (ii) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

5.3.3.3.2 One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect. A product is "defective" when, at the time of sale or distribution, it (i) contains a manufacturing defect, (ii) is defective in design, or (iii) is defective because of inadequate instructions or warnings.

5.3.3.3.3 One engaged in the business of selling or otherwise distributing product components who sells or distributes a component is subject to liability for harm to persons or property caused by a product into which the component is integrated if:

5.3.3.3.3.1 the component is "defective" (as defined in 5.3.3.3.2 above) in itself and the defect causes the harm; or

5.3.3.3.3.2 (1) the seller or distributor of the component substantially participates in the integration of the component into the design of the product; (2) the integration of the component causes the product to be "defective"; and (3) the defect in the product causes the harm.

The definition of "defect" is unlikely to change due to the method of production. Products are typically considered "defective" in the United States if they pose "unreasonable danger" to intended or foreseeable users. That can be determined either by consumer expectations (is the danger "unknowable and unacceptable to an ordinary consumer") or by "risk/utility", which is based on a balancing of a wide variety of factors, including alternative designs, obviousness of the danger, and warnings. A defect can also arise in the manufacturing of a product if it fails to meet the specifications that the manufacturer intended it to have. If the component design file is somehow corrupted, 3D printing could easily produce products with manufacturing defects.

As long as 3D printers are used to create tangible objects and remain in the hands of traditional manufacturers, those manufacturers and their products will still be subject to traditional product liability litigation. However, due to numerous players involved in

3D printing a product, there will likely be issues in determining causation, especially if the product substantially changed from the time of design until the time it was "printed". Determining where in the chain the defect occurred may be complicated, and a plaintiff may sue multiple parties in an attempt to determine where possible liability may exist.

5.3.3.4 Under the Uniform Commercial Code ("**UCC**"), the following warranties are implied:

5.3.3.4.1 Implied warranty of merchantability: The implied warranty of merchantability is based on the unstated, reasonable expectation of the buyer that the goods purchased are not defective and fit for the ordinary purposes for which they are used. To be merchantable, the goods must at least: (i) pass without objection in the trade under the contract descriptions; (ii) in case of fungible goods, be of fair average quality within the description; (iii) be fit for the ordinary purposes for which they are used; (iv) within variations permitted by the agreement, be of even kind, quality, and quantity within each unit and among all units; (v) be adequately packaged and labelled as the agreement may be required; and (vi) conform to any promises or affirmation of facts on the container or label, if any. This warranty extends to information / description or representation of the products provided by the seller or manufacturer prior to the sale of product.

5.3.3.4.2 Implied warranty of fitness for a particular purpose: The implied warranty of fitness for a particular purpose is based on the specialised needs of the buyer. The creation of the implied warranty of fitness for a particular purpose requires that the seller, when entering into the contract, knows or has reason to know both (i) the particular purpose for which the buyer is purchasing the goods and (ii) that the buyer is relying on the seller's skill and judgment to provide suitable goods.

5.3.3.4.3 Implied warranty against infringement: the implied warranty against infringement is based on the buyer's reasonable expectation that the goods purchased do not infringe on the intellectual property rights of third parties. Under the UCC, if the seller is a merchant regularly dealing in goods of the kind sold, then there is an implied warranty that the goods will be delivered free from a third party's claim of infringement, including infringement of patent, trademark and other IP rights.

5.3.3.5 In most US states, including California, UCC is not applied directly to installation contracts because the UCC addresses contracts for the sale of goods, and installation contracts are deemed to be for the sale of services. However, common law counterparts to some of the UCC's concepts have arisen with regard to construction contracts, such as the implied warranty of workmanlike quality for services. As such, the standard or quality of installation services is measured against a contractor that will use appropriate and reasonable skill and care.

5.3.3.6 Various Federal and state laws regulate the use of false or misleading descriptions of products in advertisements in addition to the implied warranty of merchantability:

5.3.3.6.1 Under Federal law, Section 43(a) of the Lanham Act (15 USC § 1125(a)) provides a private right of action to any person who believes that he or she is or is likely to be damaged by the use of any false description or representation in connection with any goods or services in commerce. Anyone engaged in false advertising under Section 43(a) may be held liable.

5.3.3.6.2 California Business and Professions Code, Section 17500 prohibits untrue or misleading statements in connection with the sale of goods or services. A $2500 fine can be assessed per violation, in cases brought by the state Attorney General, which can be determined by the number of persons to whom the misrepresentations were made.

5.3.3.6.3 California's unfair competition law, which is broader than the false advertising law, gives both private individuals and public prosecutors the right to bring an action. The state can seek civil penalties not to exceed $2500 per violation. Further, when an injunction is issued, penalties of up to $6000 per day are allowed for intentional violations of the injunction. Private plaintiffs may seek "restitution", which may be calculated based on "money or property, real or personal, which may have been acquired by means of the unfair practice".

5.3.3.7 The following court decisions concern the question as to whether a design file is a product to which the product safety and liability rules apply. There is no established rule determining whether digital content is considered a product for the purposes of general product safety regulations. It is also uncertain if US courts will find that electronic files are products under the Restatement of Torts either.

5.3.3.7.1 ClearCorrect Operating, LLC v. Int'l Trade Commission, 810 F.3d 1283 (Fed. Cir. 2015) - 10 October 2015

In this non-product liability case, the Federal Circuit addressed 3D printing digital files specifically, and held they are not material things. A manufacturer of 3D printed products was sued for importing CAD files used in 3D printing, allegedly in violation of the plaintiff's patent. The Federal Circuit held that digital files used in 3D printing were not "articles" under the Tariff Act of 1930 because digital files were not "articles". Articles must be "material things". Since CAD files were not "articles" under the statute, no administrative authority existed to stop their importation. The extensive discussion in *ClearCorrect* suggests, by analogy, that digital files used in 3D printing may not themselves be "products".

5.3.3.7.2 *Corley v. Stryker Corp.*, No. 6:13-CV-02571, 2014 WL 3375596 (W.D. La. May 27, 2014) - 27 May 2014

A product liability case addressing a non-3D printed product may be instructive in determining whether an electronic file may be considered a "product". Although the product in *Corley* was not 3D printed, the Class II medical device was customizable and used electronic files and patient-matched imaging data. The device was a "single-use, disposable, cutting guide". Therefore, the plaintiff's allegations that the software was defective*, "sufficiently alleged that the cutting guide used during [plaintiff's] surgery was unreasonably dangerous in design due to the alleged software defects"*, and could sustain a product liability claim.

Corley has implications for the software used to create similarly customized 3D printed medical devices, since both use electronic files and patient-matched image. Courts may find the reasoning of *Corley* persuasive and hold that since the file is part and parcel of the completed product, it is therefore subject to product liability laws. Thus, if the software or electronic file is defective, the entire system is defective.

5.3.3.8 As 3D printing becomes more commonplace, it is only a matter of time before courts are faced with the question of whether traditional tort liability principles will apply to 3D printed products and manufacturing techniques or whether new laws will need to be created. However, as of the date of this analysis, we are unaware of any product liability lawsuit where the product is manufactured using additive manufacturing techniques. Moreover, there is no federal or state legislation on the horizon that seeks to impose mandatory standards on commercial 3D printing although national and international organization are creating voluntary standards.

5.3.3.9 There is no federal or state legislation on the horizon that seeks to impose mandatory standards on commercial 3D printing although national and international organization are creating voluntary standards.

5.3.4 CANADA

The following rules apply under Canadian Federal law, together with provincial laws, some of which are mentioned in this section by way of examples only:

- Product safety - Canada Consumer Product Safety Act (if a consumer product) (see 5.3.4.2)
- Product liability - common law (see 5.3.4.3)
- Sale of goods - provincial law (see 5.3.4.4)
- Supply of service - provincial law (see 5.3.4.5)
- Provision of information - Federal and provincial law (see 5.3.4.6)

5.3.4.1 There is no specific legislation for 3D printing. Federal law regulates general product safety and labelling while provincial law regulates sale of goods and other consumer protection rules.

5.3.4.2 Under Canada Consumer Product Safety Act:

5.3.4.2.1 No manufacturer or importer shall manufacture, import, advertise or sell a consumer product that is a danger to humanhealth or safety.

5.3.4.2.2 No person shall advertise or sell a consumer product that they know is a danger to human health or safety, is the subject of a recall order or a voluntary recall in Canada because the product is a danger to human health or safety or is the subject of a measure that is required to be carried out and has not been carried out.

"Danger to human health or safety" means any unreasonable hazard, existing or potential, that is posed by a consumer product during or as a result of its normal or foreseeable use and that may reasonably be expected to cause the death of an individual exposed to it or have an adverse effect on that individual's health, including an injury, whether or not the death or adverse effect occurs immediately after the exposure to the hazard, and includes any exposure to a consumer product that may reasonably be expected to have a chronic adverse effect on human health.

5.3.4.2.3 No one is permitted to package or label a consumer product in a manner that may create an erroneous impression regarding the fact that it is not a danger to human health or safety.

5.3.4.2.4 No manufacturer or importer shall manufacture, import, advertise or sell a consumer product that is a danger to human health or safety, is the subject of a recall order or a voluntary recall in Canada because the product is a danger to human health or safety, or is the subject of a measure that is required to be carried out and has not been carried out.

5.3.4.2.5 A person who manufactures, imports or sells a consumer product for commercial purposes has reporting obligations to the Minister and, if applicable, the person from whom they received the consumer product, regarding any incident related to the product within two days after the day on which they become aware of the incident.

An "incident" means: (i) an occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects on their health; (ii) a defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; (iii) incorrect or insufficient information on a label or instructions (or the lack of a label or instructions) that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or (iv) a recall or measure initiated for human health or safety reasons by a foreign entity, provincial government, provincial public body, aboriginal government or prescribed institution or entity.

5.3.4.2.6 The manufacturer of a consumer product (or if outside of Canada the importer) shall provide the Minister with a written report containing information about the incident, the product involved, any other products that could be involved in similar incidents and any measures they propose be taken within 10 days after they become aware of the incident (or other period specified by the Minister). The Minister may make an order for a recall if the Minister believes on reasonable grounds that a consumer product is a danger to human health.

5.3.4.3 Product liability is governed by common law principles in all provinces except Québec. Claims are typically framed as actions in tort, e.g. negligent design, negligent manufacture, and breach of duty to warn. If a contract governs the transaction, normally liability will be founded on contract and warranty law however independent liability in tort may exist. To succeed in a claim for negligence, plaintiff must establish that (i) the defendant owed a duty of care to the plaintiff (claimant), (ii) the defendant breached that duty, (iii) the plaintiff suffered damages and (iv) those damages were caused by the defendant's breach of duty of care to the plaintiff. A plaintiff alleging that a product was negligently manufactured must prove that (i) the product in question was defective in that it was not manufactured in accordance with the specifications that the manufacturer intended and (ii) the defect arose as a result of the manufacturer's failure to take reasonable care and (iii) the plaintiff sustained harm that was caused by the defective condition of the product.

In Québec, product liability in consumer agreement is government by the Consumer Protection Act. Plaintiff must demonstrate that (i) the defect renders the product unfit for its intended use or diminishes the product's usefulness to a point where the buyer would not have bought it or paid so high a price, (ii) the defect existed at the time of the sale, (iii) the defect was hidden and (iv) the parties in the supply chain were not aware of the defect at the time of the sale.

5.3.4.4 Each province (other than Québec where the sale of goods is regulated by the Civil Code) has enacted its own Sale of Goods Acts. Provincial Sale of Goods acts apply

to B2B and B2C transactions that are primarily for the purpose of selling goods and contain implied conditions as to quality or fitness.

For example, in Ontario, the supplier/seller of the goods has the obligation to provide a service or good that is of a reasonably accepted quality. Implied conditions and warranties under the Sales of Goods Act of Ontario include (i) where the buyer expressly or by implication makes known to the seller the particular purpose for which the goods are required, an implied condition that the goods will be reasonably fit for that purpose, and (ii) where goods are bought by description from a seller who deals in goods of that description (whether or not the seller is the manufacturer), an implied condition that the goods will be of merchantable quality. An implied warranty or condition as to quality or fitness for a particular purpose may be annexed by the usage of trade. Actions may be commenced on the basis of breaches of statutory warranty claims. The seller is liable for breaching the Act while the parties other than the seller may be liable due to negligence.

Historically, case law provides that "goods" would apply to tangible property and not intangible property such as software or digital files. It is likely that sale or supply of solely digital content would not be considered a "good" under provincial sale of goods acts.

However, there are two Ontario decisions which have been decided on the basis that the Ontario Sale of Goods Act did apply to software (*PCM Technologies Inc v O'Toole, 2012 ONSC 2534 at pars 26 and 31; Ronald Smith & Associates Inc. v. Intuit Canada, 2009 CanLII 10682* at para 5 (ON SC)) although in these decisions the definition of "goods" under the Ontario Sale of Goods Act was not considered.

At common law, generally the definition of "product" has been limited to tangible personal property.

5.3.4.5 There is no federal legislation applicable to services in general. Provincial regulation of consumer service contracts varies by jurisdiction in terms of whether it is regulated under legislation or common law but results in services requiring reasonable care or skill.

For example, the Ontario Consumer Protection Act has an expansive definition of services and consumer agreements to which it applies and provides that suppliers are deemed to warrant that the services they provide are of a "reasonably acceptable quality". British Columbia's common law provides that services are to be rendered with "reasonable care" or in a "proper workmanlike manner". Furthermore, under common law, where materials are supplied in the course of a contract to perform services, it is possible there is a warranty that materials supplied are subject to an implied warranty of good quality and fitness (*Ter Neuzen v Korn*, [1995] 3 SCR 674 at paras 73-84).

Any materials supplied in the course of a service contract may be subject to an implied warranty of good quality and fitness.

5.3.4.6 There are Federal and provincial acts that prohibit deception in relation to products.

5.3.4.6.1 The Competition Act is a Federal Act that, among other things, prohibits misleading advertising. False and misleading representations are prohibited.

5.3.4.6.2 Consumer protection legislation has also been enacted at the provincial level to prohibit deceptive acts or practices and deceptive representations and to regulate contracts. Consumer protection statutes in most provinces set out requirements for specific types of consumer agreements and prohibit a range of "unfair" practices such as misleading and unconscionable representation. Some provinces require contractual privity while others not (i.e. can bring claims even if there is no contract between the parties).

For example, under the Consumer Protection Act of Ontario, the supplier cannot make any false representation about the product, and misleading or deceptive representation. These provisions are interpreted to encompass a variety of claims against a manufacturer or seller. In *Richardson v Samsung*, the proposed class action respecting Samsung's allegedly defective smartphones, the plaintiff pleaded breach of the Consumer Protection Act for false, misleading or deceptive representations and unfair practice arising from (i) misrepresentation about the characteristics, benefits or qualities of the devices; misrepresentations respecting the devices standard quality; (ii) misrepresentation due to the use of exaggeration, innuendo or ambiguity as to a material of fact of failure to state a material fact leading to deception; (iii) misrepresentation respecting availability of and quality of replacement devices; (iv) breach of express warranty and (v) breach of implied condition as to quality and fitness for use. Proposed class action was dismissed by the Court. The Court stated that the defendant's compensation program was a preferable procedure than a class action.

5.3.4.6.3 The Consumer Packaging and Labelling Act and its regulations require that pre-packaged consumer products contain accurate and meaningful labelling information. No person shall package or label a consumer product in a manner, including one that is false, misleading or deceptive, that may reasonably be expected to create an erroneous impression regarding the fact that it is not a danger to human health or safety or regarding its certification.

5.3.5 JAPAN

The following rules apply under Japanese law:

- Product liability (see 5.3.5.2.1)
- Sale of goods or services (see 5.3.5.2.2, 5.3.5.2.3)
- Provision of information (see 5.3.5.3)

5.3.5.1 There is no legislation which specifically regulates 3D printing. Product safety requirements are only found in product-specific regulations. Therefore, safety of 3D printing machines, 3D printed parts or consumer appliances are regulated only to the extent they have the features to which product specific regulations apply.

For example, Electrical Appliances and Materials Safety Act ("**EAMSA**") applies if the consumer appliances are (i) the "Specified Electrical Appliances and Materials" under the EAMSA such as AC adaptors and (ii) "Other Electrical Appliances and Materials" listed in the EAMSA such as TV receivers and Air Conditioners. The EAMSA requires the manufacturer/importer of regulated consumer appliances to:

- notify the regulator within 30 days about the commencement of business (Article 3);

- conduct self-testing to meet the technical product standards specified by the relevant rules (Article 8) (for all regulated electrical appliances and materials);
- conduct third party testing to confirm compliance of the technical product standards (Article 9) (for Specified Electrical Appliances and Materials);
- put the "PSE Mark" on the consumer appliance which meet the technical product standards (Article 10 12); and
- not to sell the consumer appliance without "PSE Mark" (Article 27) (also applies to the seller).

If the regulator finds any breach of the EAMSA, the manufacturer/importer may be investigated and the regulator may request improvement of the operation, prohibit use of PSC Mark for a certain period or conduct a recall. Depending on the nature of breach, a director and/or employee of the manufacturer/importer may be punished by up to imprisonment with work for not more than one year or a fine of not more than one million yen, or both, and the company may be punished by a same fine or fine of not more than JPY 100 million.

Same obligations and sanctions apply to the manufacturer / importer of (i) "Specified Products" such as pressure cookers and autoclaves for home use, oil water eaters, oil bath boilers and oil heaters, and (ii) "Special Specified Products" such as portable laser application device and hot water circulator for bathtubs under Consumer Products Safety Act except that the mark that must be used for these products is "PSC Mark".

Certain regulated consumer appliances (such as air conditioners, televisions, electric heating blankets, rice cookers and microwaves) also have to comply with labelling requirements under the Household Goods Quality Labelling Act.

5.3.5.2 The safety of 3D printed parts and consumer appliances using 3D printed parts which are not subject to product specific regulations can be addressed under other rules if there is a defect (under product liability rules) or the goods lack conformity with the contract for the supply of such goods or services where such contract sets out any quality requirements or specifications to be met by those goods or services (as a matter of contract law).

5.3.5.2.1 The Product Liability Act ("**PL Act**") is a special law of the tort rules under the Civil Code and specifies strict liability for manufacturers where damage arises from a defective product. A "manufacturer" is defined to mean:

5.3.5.2.1.1 any person who manufactured, processed, or imported the product as its business;

5.3.5.2.1.2 any person who provides his/her name, trade name, trademark or other indication ("representation of name, etc.") on the product as the manufacturer of such product, or any person who provides the representation of name, etc. on the product which misleads the others into believing that he/she is the manufacturer; or

5.3.5.2.1.3 any person who provides any representation of name, etc. on the product which, in light of the manner concerning the manufacturing, processing, importation or

sales of the product, and other circumstances, holds himself/herself out as its substantial manufacturer.

Under the PL Act, a "defect" means a lack of safety that a product (movable products only) ordinarily should provide, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time at which a manufacturer delivered the product and other circumstances concerning the product (e.g. warning labels). Courts decide whether there was a defect on a case-by-case basis. The plaintiff has the burden of proof to establish the existence of a defect.

A manufacturer will not be held liable for damages caused by a product defect if:

- the manufacturer has established that the defect in a product could not have been discovered given the state of scientific or technical knowledge at the time when the manufacturer delivered the product; or
- the manufacturer has established that, where a product is used as a component or raw material of another product, the defect occurred primarily because of the compliance with the instructions concerning the design given by the other manufacturer of such other product, and that the manufacturer was not negligent in respect of the occurrence of such defect.

An alleged victim can make a claim under the PL Act within three years of becoming aware of the occurrence of damage and the identity of the liable party but the claim must be brought within up to ten years of delivery of a product.

5.3.5.2.2 Under the Civil Code, if the goods sold or services provided do not meet the quality requirements agreed in the relevant agreement, the purchaser can request the seller/service provider to repair, reduce fee, compensate damages or terminate the agreement. If a party does not perform the obligations under the agreement, that party must pay for damages incurred by the other party. However, there is no general quality requirement in the Civil Code which is implied or applies in the absence of any specific agreement in the supply contract.

5.3.5.2.3 Under tort rules of the Civil Code, a person can be liable if he intentionally or negligently provide a low quality product and thereby causes damages to another person.

5.3.5.3 As for the information on the goods / services supplied, the following misrepresentations are prohibited under the Act against Unjustifiable Premiums and Misleading Representations, which is a general advertising law:

5.3.5.3.1 Any representation where the quality, standard or any other particular relating to the content of goods or services is portrayed to general consumers as being much better than that of the actual goods or services, or are portrayed as being, contrary to fact, much better than those of other entrepreneurs (meaning businesses) who supply the same kind of or similar goods or services as those supplied by the relevant entrepreneur, thereby having a tendency to induce customers unjustly and to interfere with general consumers' voluntary and rational choice; and

5.3.5.3.2 Any representation by which price or any other trade terms of goods or services could be misunderstood by general consumers to be much more favourable than the actual goods or services or those of other entrepreneurs who supply the same kind of or similar goods or services as those supplied by the relevant entrepreneur,

thereby having a tendency to induce customers unjustly and to interfere with general consumers' voluntary and rational choice-making.

Misrepresentations are subject to a correction order by the regulator and/or administrative penalty (3% of sales for relevant period).

5.3.6 CHINA

The following rules apply under Chinese law:

- Product safety - Product Quality Law of the People's Republic of China (2018 Amendment) (see 5.3.6.2)
- Supply of goods and services
  - Product Quality Law of the People's Republic of China (2018 Amendment) (see 5.3.6.3)
  - Law of the People's Republic of China on the Protection of Consumer Rights and Interests (2013 Amendment) (if B2C) (see 5.3.6.4)
- Product liability / seller's liability
  - General Principles of the Civil Law of the People's Republic of China (2009 Amendment) (see 5.3.6.5)
  - Tort Law of the People's Republic of China (see 5.3.6.6)
- Provision of information - the Law of the People's Republic of China on the Protection of Consumer Rights and Interests (2013 Amendment) (see 5.3.6.7)

5.3.6.1 There is no legislation which specifically regulates 3D printed products. The safety of 3D printed parts and consumer appliances using 3D printed parts which are not subject to product specific regulations can be addressed under the following product quality law, consumer protection law or tort law.

5.3.6.2 A manufacturer must, under Product Quality Law of the People's Republic of China (2018 Amendment):

5.3.6.2.1 make the products which (i) are free from any unreasonable dangers threatening the safety of people and property, (ii) have the property they are due to have and (iii) conform to the standards prescribed or specified on the packages and have the quality specified in the instructions for use or indicated by the samples; and

5.3.6.2.2 compensate for damages caused to such other properties if defective products cause damage to other properties in addition to personal injury or damage to the product itself, unless (1) the products have not been put into circulation; (2) the defects causing the damage do not exist when the products are put in circulation; and (3) the defects cannot be found at the time of circulation of the products due to the scientific and technological level at the moment.

There is also a general labelling requirement under Product Quality Law of the People's Republic of China (2018 Amendment) under which the manufacturer must include on the product or the package a warning mark or statement in Chinese for a

product which, if improperly used, may cause damage to the product per se, or may endanger personal or property safety.

If a defective product causes personal injury or property damage, the affected party may claim for damages against the manufacturer or the seller.

5.3.6.3 Under Product Quality Law of the People's Republic of China (2018 Amendment), a seller must:

5.3.6.3.1 repair, replace, return or provide compensation (in case damage is caused to end-users or consumers) if the product sold by such seller does not (i) perform without prior warning, (ii) conform with the quality standard specified in such products or the packages; or (iii) conform with the quality description specified in the use instruction or the quality of samples; and

5.3.6.3.2 provide compensation if they cannot identify the manufacturer or supplier of the defective products duly sold by them, or if property damage or personal injury are caused by defects due to the seller's fault. "Defect" is defined under this law to mean an unreasonable risk that endangers the safety of human health or properties, or nonconformity with national or industrial standards applicable to that product (if any) for protection of human health and personal and property safety.

5.3.6.4 Under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests (2013 Amendment):

5.3.6.4.1 business operators must guarantee that the goods and services they supply meet the requirements concerning personal or property safety. Where the goods and services may endanger personal or property safety, business operators must give provide explicit and truthful warnings of this fact, and shall explain or indicate the correct way to use the goods or receive the services as well as the way to prevent the occurrence of damage;

5.3.6.4.2 business operators providing goods or services assume civil liability for (i) such goods or services being defective, and (ii) goods not having the required performance when in use with no explanation as to this fact having been provided at the time of sale, (iii) goods failing to comply with the standards indicated on them or their packaging, (iv) goods failing to reach the quality indicated by product instructions, real samples, and other means, (v) service is in breach of the agreement, (vii) business operators deliberately delaying or unreasonably refusing consumers' requests for repair, remanufacture, replacement, return of goods, refund or compensation for losses, or (viii) otherwise infringing consumer rights and interests under applicable laws and regulations;

5.3.6.4.3 where the goods or services provided by business operators have caused property damage to consumers, business operators have a civil liability under law (or under their agreement), including to repair, remanufacture, replace, accept return of goods, refund or compensate for the loss;

5.3.6.4.4 consumers may claim compensation from the seller and service provider if their lawful rights and interests are infringed when purchasing or using goods. Lawful rights include the right to be free from damage to their personal and property by consequence of their purchasing goods or receiving services;

5.3.6.4.5 consumers or other victims suffering personal injury or property damage due to the defects of goods may claim compensation from the seller or manufacturer;

5.3.6.4.6 business operators who committed fraud when providing goods or services, shall, as requested by the consumer, increase the amount of compensation offered to such consumer for its losses, and the amount of increased compensation shall be three times the payment made by a consumer in purchasing the goods or receiving the services. If this amount is less 500 yuan, the amount of the increased compensation would be capped at 500 yuan (unless provided otherwise by law);

5.3.6.4.7 if business operators knowingly provide consumers with defective goods or services causing death or serious health damage to consumers or third parties, such victims shall have the right to claim compensation for the loss from business operators and have the right to claim punitive compensation of less than twice the amount of the loss incurred;

5.3.6.4.8 in addition to attracting civil liability, business operators shall be punished pursuant to other applicable laws and regulations which provide for other forms of punishment and the involvement of relevant competent authorities (or in the absence of such provisions, the industry and commerce administrative departments or other relevant administrative departments shall make an order for correction, and may, according to the circumstances, issue a warning to the business operators, confiscate their illegal income, impose a fine of not less than the income derived by from illegal activity (but not more than ten times the illegal income) or, if there is no illegal income, impose a fine of not more than 500,000 yuan, or impose a combination of the above penalties on them, and in serious cases, order them to suspend business for rectification or revoke their business licenses if: (i) the goods or services provided do not comply with the requirements for the protection of personal and property safety, (ii) goods have been tampered with, passed off as genuine, superior or compliant when in fact counterfeited, inferior or non-compliant, (iii) the origin of the goods has been forged or certification or other quality marks have been falsely used, (iv) goods have been sold without inspection or quarantine as required, or such inspection or quarantine results have been forged, or (v) where consumers' rights and interests have been infringed in circumstances which are punishable in accordance with applicable laws and regulations; and

5.3.6.4.9 where business operators fall under any of the circumstances in the paragraph above, in addition to punishment in accordance with applicable laws and regulations, the relevant competent authorities shall enter the punishment record into their credit files and publish it.

5.3.6.5 Under the General Principles of the Civil Law of the People's Republic of China (2009 Amendment), if a substandard product causes property damage or physical injury to others, the manufacturer or seller of such product must bear civil liability.

5.3.6.6 Under the Tort Law of the People's Republic of China, if the defect of products caused by the seller's fault causes damage to others, the seller shall assume liability in tort. If the seller can neither specify the manufacturer nor the supplier of the defective product, the seller shall assume liability in tort. If there is any damage caused by the defect of the product, the victim may claim compensation from the manufacturer of the product and the seller of the product. If a product's defect endangers the personal safety or property of others, the victim shall have the right to request the manufacturer or seller to assume such liability in tort and remove or

eliminate the danger. If the defect in the product is found after such product has been put into circulation, the manufacturer or seller shall take timely measures to remedy the situation, such as issuing warnings and recalling the product in question. Any manufacturer or seller who fails to take such timely measures or take sufficient and effective measures and has caused damage shall assume liability in tort. If the manufacturer or seller knowingly manufactures or sells defective products, causing the death or serious health damage to others, the victim shall have the right to claim corresponding punitive compensation.

5.3.6.7 In terms of the information provided to consumers, under the Law of the People's Republic of China on the Protection of Consumer Rights and Interests (2013 Amendment), a consumer is entitled to know the true information of the goods he purchases or uses or the service he receives.

Consumers may claim compensation from business operators if their lawful rights and interests are infringed by business operators providing commodities or services due to false advertising or other means of false propaganda. If advertising agents or publishers engage in false advertising, consumers may request the competent administrative departments to punish such advertising agents or publishers. Advertising agents and publishers shall be liable to pay compensation if they cannot provide the true names, addresses and effective contact information of business operators. Paragraph 5.3.6.4.8 applies where business operators promote commodities or services in a false or misleading manner.

5.4 Legislative initiatives

See Annex 2.

6 Case studies

6.1 Approach taken

We have developed the case studies after taking the following steps:

6.1.1 identify a particular technical safety issue to illustrate;

6.1.2 specify the hazard represented by the technical safety issue;

6.1.3 specify the component or attribute which is presenting the hazard;

6.1.4 identify how the hazard is created by the component;

6.1.5 define the context in which the hazard presents a risk i.e. application of use with the domestic appliance; and

6.1.6 describe the scenario based on average consumer use and experience.

Three case studies have been developed based on the outcome of the literature review and stakeholder engagement to illustrate different aspects of the technology as well as different types of safety risks.

The legal considerations sections below set out at high level the stakeholders who could be liable towards the consumers affected by the relevant incident. They are not intended to be exhaustive, nor do they extend to the claims that traders might have towards other traders within the supply chain. In particular, the analysis does not discuss the relevant party's rights and obligations under their contracts except for B2C terms which are automatically included by statutes and cannot be contracted out.

6.2 Case study 1: bread maker

6.2.1 Scenario

6.2.1.1 The scenario is based in part on a "real-world" case which has been documented on a video posted on the internet[57]. A consumer found that a ceramic bobbin from their Panasonic SD-YD250 Bread Maker broke while moving house, Figure 10. The bobbin is used to separate the heating element from the metallic wall of the bread maker, Figure 11. Unfortunately for the consumer, the part was no longer in production and there were no spares available. Had a spare been available, it should have cost around $5 USD; without this part, the $200 bread maker was not safe to use.

[57] https://www.youtube.com/watch?v=6XC9-WNyMKQ (last accessed on 5 July 2019)

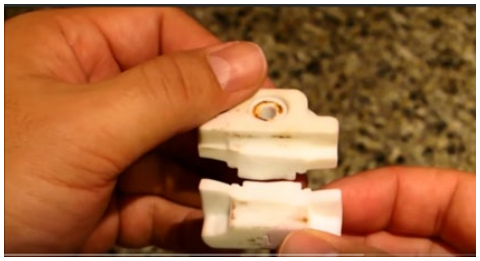

Figure 10: Damaged Ceramic Bobbin

Figure 11: Damaged Ceramic Bobbin in Unit

6.2.1.2 The consumer chose to attempt a repair on his own, which involved fabricating his own ceramic bobbin. As he did not have access to the original part geometric or performance specifications, he designed a similar component on his own based on the broken bobbin, Figure 12. He created his own 3D virtual model using a free computer aided design (CAD) program available online. The consumer chose to use an online 3D printing on demand service called Shapeways, where a customer chooses to upload their own design and select the material based on a selection of materials available via the website, and then the customer pays Shapeways for the service of 3D printing the item. The materials that Shapeways has available are based on the feedstocks that are suitable for the 3D printers that Shapeways uses. From the customer's perspective, it is unclear if Shapeways are printing the parts themselves, or if they subcontract the printing to a 3rd party.

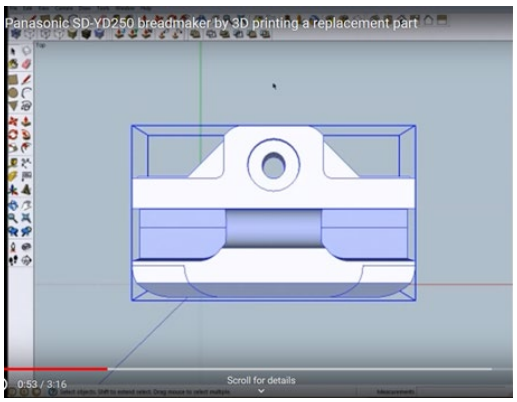

Figure 12: CAD Design of Bobbin

6.2.1.3 One limitation noted by the consumer when using the printing service was that there were dimensional limitations for the part which required that he redesign the bobbin to be wider than the original, but he did not believe this would affect the performance of the product. The customer had no way to verify how the dimensional change could affect the performance of the part until it was printed. He chose to upload his design to the Shapeways website to allow him and others to print from the design

that he created. Neither Shapeways nor any future users of his design will likely have any knowledge of the product performance or safety requirements.

6.2.1.4 The consumer knew that the part is ceramic, but he did not have any detailed information regarding the grade or quality of the ceramic, if it has any coatings, or any other specifications. He knew that it should resist heat and be an electrical insulator, and he selected a ceramic that was heatproof to 500°C. In order to have the part printed, Shapeways required only the CAD file and the material selection, and the consumer did not have any control over the way in which the part was printed. As the file was uploaded to the site and made publicly available, future customers would be able to "click" on the item to order it, without necessarily confirming the geometry or material. The cost for this part to be 3D printed was $14.12.

6.2.1.5 The customer received the part from Shapeways and was generally happy with it; however, it had a glaze applied to it that the customer was not expecting, Figure 13. As the screw hole was designed based on the original piece, the glaze resulted in the screw hole diameter being too small for the screw. The consumer drilled out the hole in order to make it the correct size, and subsequently amended the publicly available CAD file to account for the glaze in the hole, Figure 14. The amendment was made on a best-guess basis, as the consumer would not necessarily know the thickness of the glaze nor the consistency of application. After drilling out the hole, the consumer fitted the part and tested the breadmaker to find everything working as expected. The bread maker appeared to function properly, and he made a loaf of bread in the unit without incident. The consumer noted that it is best to bake bread during the day when someone is around, just in case there is an issue with the bread maker or the part.

Figure 13: Replacement Bobbin with Original Bobbin

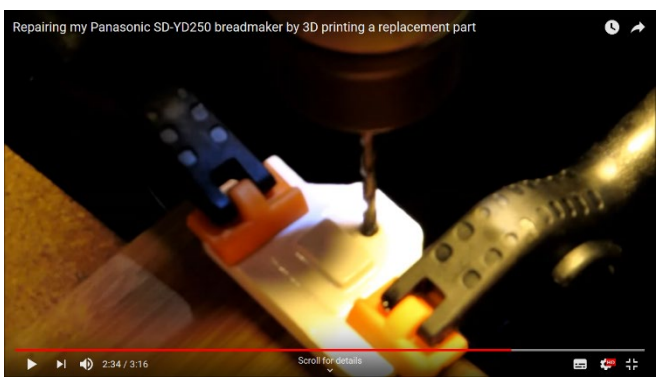

Figure 14: Drilling Out the Screw Hole

6.2.2 Safety issues under the scenario

6.2.2.1 Further to the scenario described in the real-world case, it is possible that the bread maker is used without issue to continue to make several loaves of bread. With each use, the consumer becomes more confident in the replacement part and comfortable with the performance of the product. This results in decreasing customer vigilance with each use of the product, such that he feels that he can eventually use the product overnight or when he is out of the house.

6.2.2.2 When the consumer drilled out the hole in the 3D printed spare, small cracks were introduced into the ceramic. After several uses, with repeated thermal cycling and mechanical impact caused by the bread tin knocking against the heating element when being removed and replaced in the machine, the cracks in the ceramic bobbin propagate. This ultimately leads to the bobbin failing and falling off during use. The heating element then comes into contact with the internal components of the bread maker, which results in the bread maker catching on fire. As the bread maker is on a kitchen counter, the fire spreads to the rest of the kitchen and house.

Failure of the ceramic bobbin led to the hazard of fire and extreme temperature, and could have also led to an electrical energy hazard. The issues contributing to the risks which are involved in this scenario are outlined below:

6.2.2.2.1 Limited material availability – Neither the consumer nor Shapeways have original material performance or safety requirements.

6.2.2.2.1.1 Not all materials are compatible with 3D printing

6.2.2.2.1.2 If a material is compatible, not all grades of that material may be compatible

6.2.2.2.1.3 Each printer and process will have unique compatibility issues

6.2.2.2.2 Material qualification and performance standards are less mature for 3D printed materials – *It is unknown how the ceramic material will perform during product use.*

6.2.2.2.3 3D printing materials may have different dimensional stability, mechanical, thermal, electrical, and aging properties than traditional materials – *It is unknown how the ceramic material will perform during product use.*

6.2.2.2.4 Designs for parts may not account for requirements of 3D printing – *Application of the glaze caused dimensional issues.*

6.2.2.2.5 Original part designs may not be available to the 3D printer – *The consumer had to design the part themselves.*

6.2.2.2.6 Motivation of the 3D printing machine operator – The printer operator has no knowledge of the final part application, so the operator may not be able to identify or use the best available printing method, nor do they have obligation to do so.

6.2.2.2.7 3D printing machine operator's understanding of the part’s performance requirements – The printer operator has no knowledge of the final part application, so the operator may not be able to identify or use the best available printing method, nor do they have obligation to do so.

6.2.2.2.8 Part quality issues – 3D printed part is unlikely to meet the original ceramic part's specifications

6.2.2.2.9 Part mechanical performance – 3D printed part is unlikely to meet the original ceramic part's specifications.

6.2.2.2.10 Repeatability – The design has been shared for free to anyone else that wants to make the part, but there is no guarantee that the outcome is repeatable. There may be variability in:

6.2.2.2.10.1 The supplier of material

6.2.2.2.10.2 Uniformity of material

6.2.2.2.10.3 Batch to batch variation

6.2.2.2.11 Post processing – The glaze coating was part of the post processing that resulted in dimensional changes.

6.2.2.2.11.1 Post-processing is not a standardized approach

6.2.2.2.12 Design may focus on aesthetics rather than function/performance

6.2.3 Legal considerations

6.2.3.1 Shapeway supplied a 3D printed part whose design and material were specified by the consumer who ordered the part. It is not clear if Shapeway supplied the 3D printed part or if Shapeway is merely a marketplace and a third party using this platform supplied the 3D printed part. In the paragraphs below, we refer to either of them (as applicable) as a "supplier".

6.2.3.2 The consumer does not seem to have informed the supplier that he is buying the 3D printed part for this bread maker. Therefore, the supplier is not responsible for supplying a 3D printed part that is suitable for this bread maker. If the supplier followed the instructions given by the consumer and supplied what the consumer had ordered, and the 3D printed part so supplied has no quality issue as a standalone item, the consumer is not likely to have a claim under the Consumer Rights Act 2015 against the supplier for any issue that this consumer may experience with the bread maker fitted with the 3D printed part.

6.2.3.3 The fact that the consumer has made an adjustment to the 3D printed part before use with the bread maker by enlarging a hole and fitting it onto the bread maker despite the part having a different size from the original part supports the position that the consumer will likely to be solely responsible for the consequences of using the bread maker adapted with this part.

6.2.3.4 The supplier has the general product safety obligation to place only safe products on the market under the General Product Safety Regulations 2005 as a producer (see 5.3.1.13). Whether the part is a safe product depends on (among other things) what is considered to be the normal or reasonably foreseeable condition of its use including when put into service and installed. If the supplier was a spare parts supplier, then the supplier is likely to have been aware that the part can be used for a product with a heating element although they would not necessarily have known that it was for a bread maker or any for specific bread maker. If the supplier was a

maker of ceramic parts based on designs submitted to them, as ceramic parts can be used for other applications, often for aesthetic decoration or functional decoration, the supplier is not likely to be aware that the part was going to be used to insulate a heating element or for use in a bread maker.

6.2.3.5 As the supplier did not know that this part will be used with this bread maker, it is unlikely that the part would be considered an unsafe product by consequence of the fact that it was not suitable for this particular model. However, if the normal or reasonable expectation would be for this part to be used with a bread maker and it has any safety issue that could materialise with any other bread maker, then there may well be a scope to argue that it is not a safe product, in which case the supplier is in breach of the General Product Safety Regulations 2005.

6.3 Case study 2: washing machine

6.3.1 Scenario

6.3.1.1 This case study is a hypothetical scenario. A consumer has purchased a washing machine of a well-known brand from an online retailer who can deliver the product but is unable to provide assistance with installation. The consumer is experienced with DIY and is confident with their installation skills, and the washing machine came with clear instructions for installation. During installation, the consumer connected the water inlet hose (Figure 15) as instructed at the back of the unit, however, during this process, the consumer accidentally broke the 90 degree-oriented water inlet pipe connector (Figure 16) which is used to attach the hose at the back of the washing machine. This connector is used to reduce strain where the hose meets the unit and minimizes the potential for the water inlet hose to become loose or damaged during installation and use. The injection-moulded connector is made of nylon and is a custom size and shape to fit with a particular washing machine model.

Figure 15: Example of Rear of a Washing Machine

The customer looked online at the washing machine manufacturer's website and finds a link for spare parts; however, the original equipment manufacturer (OEM) parts were on backorder and not expected for at least another two months. The customer then searched the retailer's website and finds a link for a 3rd party professional (non-consumer) site that offered spares for various appliances. The spare supplier had limited stock on hand, but were able to make certain parts to order using 3D printing. Listed on their website were various brands they have

agreements with to print certain components deemed as non-electrical-safety-critical, including pipe connectors. The customer found a page for their brand of washing machine and saw that the water inlet pipe connector is available for printing based on approved CAD designs and approved nylon feedstock. The parts supplier claims to use industry leading, professional grade, 3D printing equipment.

Figure 16: Example of a 90 Degree Pipe Connector

6.3.1.2 Most of the parts that the supplier prints are aesthetic plastic components. The parts must look like original parts on the outside, i.e. have the same dimensions, geometry, and surface finish, but are not typically required to be the same internally. The supplier has printers (from a leading printer brand) which are a few years old and are generally suitable for printing the aesthetic components. The appliance manufacturers who have approved the printer are aware of the equipment used, but have not audited their maintenance program. Due to both the age of the printer and the specific program used to operate it, inter-laminar adhesion issues along with a degree of material anisotropy are present within printed parts; however, these issues are undetectable from the outside and do not tend to immediately affect aesthetic parts.

6.3.1.3 The consumer placed the order for the connector, which he duly received one week later. To the customer, the connector looked and felt identical to the original and he was able to install it without any issue. He expects the connector to last the life of the washing machine, and does not suspect any issues with its future quality or performance. After the consumer finished installing the inlet water hose with the replacement 90 degree-oriented pipe connector, the washing machine was moved back into position and was operated without any detectable issues.

6.3.1.4 The washing machine and water inlet connector continued to function without issue for approximately one year. After one year, the internal layers of the 3D printed part began to fail, ultimately resulting in the connector failing around its circumference. The connector failed to provide sufficient pressure against the inlet hose to ensure a robust attachment. Over the following year, the water inlet hose began to loosen as a result of the subtle movement of the hose as water starts and stops flowing into the washing machine. Two years after the installation of the water inlet connector, the hose loosened sufficiently to allow water to leak out. The leak begins relatively minor but, after several runs of the washing machine, it presents a steady flow of water at the back of the unit. The customer returns home to find his kitchen has flooded

6.3.2 Safety issues under the scenario

6.3.2.1 Failure of the nylon water inlet pipe connector led to an operational hazard resulting property damage via flooding, and could have also led to an electrical energy and/or

microbiological contamination hazard. The issues contributing to risk which are involved in this scenario are outlined below:

6.3.2.1.1 Variability between brands and models of printer – The qualification process for the 3rd party to be approved to print specific replacement parts may not have taken into account different models of printer.

6.3.2.1.2 Variability due to the materials available for one printer compared to another – The qualification process for the 3rd party may not have taken into account feedstock available for one printer or another.

6.3.2.1.3 Limited material availability – The selected material was susceptible to processing issues:

6.3.2.1.3.1 Not all materials are compatible with 3D printing

6.3.2.1.3.2 If a material is compatible, not all grades of that material may be compatible

6.3.2.1.3.3 Each printer and process will have unique compatibility issues

6.3.2.1.4 Material qualification and performance standards are less mature for 3D printed materials – The selected material was susceptible to 3D printing processing issues which were not immediately apparent.

6.3.2.1.5 3D printing materials may have different dimensional stability, mechanical, thermal, electrical, and aging properties than traditional materials – The connector failed as a result of mechanical stress over time.

6.3.2.1.6 Designs for parts may not account for requirements of 3D printing – The connector was originally designed to be injection moulded, and neither inter-laminar adhesion nor anisotropic issues were applicable to the traditional manufacturing approach.

6.3.2.1.6.1 Requirements may be different for each type of 3D printing technology and printer

6.3.2.1.6.2 Designs may only be suitable for traditional manufacturing techniques

6.3.2.1.7 Printing paths may not be adequately defined, as they are related to the part geometry, performance specifications, printing material, and printer – The printing path was defined to optimize aesthetics rather than functional performance.

6.3.2.1.8 3D printing machine operator's experience with:

6.3.2.1.8.1 3D printing in general

6.3.2.1.8.2 With one particular method vs another method

6.3.2.1.8.3 With one particular printer vs other printers

6.3.2.1.8.4 Making modifications and hacking of the printing machine, design files, print path or print parameters

6.3.2.1.9 Setting up and maintenance of the printer

6.3.2.1.10 The printing operator might be more familiar with optimization with regard to aesthetic quality and minimizing post processing.

6.3.2.1.11 Operator's understanding of the part's performance requirements – The operator did not understand the functional requirements of the connector.

6.3.2.1.12 Part quality issues – These were present as a result of the 3D printer, print path, and feedstock.

6.3.2.1.12.1 Anisotropy

6.3.2.1.12.2 Interlayer adhesion

6.3.2.1.13 Part mechanical performance – These were affected by the part quality issues.

6.3.2.1.13.1 Tensile strength

6.3.2.1.13.2 Compressive strength

6.3.2.1.14 Differences in part failure modes for 3D printed parts vs traditionally manufactured parts - The connector was originally designed to be injection moulded, and neither inter-laminar adhesion nor anisotropic issues were applicable to the traditional manufacturing approach.

6.3.2.1.15 Repeatability – The internal part quality issues became more prevalent over time with the printer, but this was not identified or addressed as the issues did not affect the aesthetic quality of products which were printed. Whether a part can be replicated repeatedly can depend on:

6.3.2.1.15.1 Age of printer

6.3.2.1.15.2 Maintenance of equipment

6.3.2.1.16 Post processing - Parts were printed for aesthetic quality rather than function/performance.

6.3.2.1.16.1 Design may focus on aesthetics rather than function/performance

6.3.3 Legal considerations

6.3.3.1 If the pipe connector's quality does not meet the standard that a reasonable person would consider satisfactory for use with the washing machine, and if the consumer establishes that the connector was in such condition at the time of delivery, then the supplier of the connector would be liable as the seller of goods under the Consumer Rights Act 2015 (see 5.3.1.18.2). The consumer could ask for a repair or replacement, depending on the availability of these remedies and the costs involved, after which the right to reject for a price reduction or a refund, subject to a deduction to account for use since the goods were delivered. However, the fact that the consumer expected the connector to last the life of the washing machine does not mean that the connector had to have such durability, nor does it necessarily mean that the connector was not of satisfactory quality or unfit for purpose by virtue of the fact that it failed before the washing machine did.

6.3.3.2 If the consumer can establish that the flooding in the kitchen was caused by the connector and it was a foreseeable consequence of the connector not being of satisfactory quality, the consumer could seek damages from the connector supplier under common law for breach of contract (see 5.3.1.18.2).

6.3.3.3 If the consumer makes a successful claim against the connector supplier, (i) if the issue was caused by the 3D printing machine (which is not due to lack of maintenance or any other issue on the connector supplier's part), the connector supplier could bring a claim against the manufacturer and/or the supplier of the 3D printing machine, and (ii) if the issue was caused by the material used for 3D printing, the connector supplier could bring a claim against the material supplier, in each case to recover the loss suffered by the connector supplier (see 5.3.1.18.1).

6.3.3.4 If the issue was caused by a lack of sufficient instructions or details from the manufacturer of the washing machine which would have been necessary for the connector supplier to 3D print the connector, rather than the issue with the 3D printer itself or how it was used, then whether the manufacturer owes any liability towards the connector supplier would depend on the contract with the connector supplier operating as an approved or authorised 3D parts supplier of the connector.

6.3.3.5 If the 3D printed connector was described when sold as a connector which has the same characteristics as the original connector, and the consumer relied on such description in deciding to buy it, then this could amount to the supplier's misleading act which is prohibited under the Consumer Protection from Unfair Trading Regulations 2008. If the consumer is successful in his claim on this ground, all or part of the price paid for the connector could be repaid as a discount (see 5.3.1.22).

6.3.3.6 If the supplier of the connector presented itself as an approved or authorised 3D printed parts supplier of the connector used on the washing machine without meeting relevant criteria or conditions to present itself as such to do so, and the fact that the supplier was the approved or authorised 3D printed connector supplier was a significant factor in deciding to buy the connector, then the consumer could claim that the connector supplier has committed a misleading act which is prohibited under the Consumer Protection from Unfair Trading Regulations 2008. If successful, all or part of the price paid for the connector could be repayable as a discount (see 5.3.1.22).

6.3.3.7 The consumer has to establish the existence of the relevant facts and circumstances of the case in making a claim. Given the time that has elapsed between installation / supply of the connector and the incident, this is likely to be challenging from an evidential perspective.

6.4 Case study 3: tumble dryer

6.4.1 Scenario

6.4.1.1 This case study is a hypothetical scenario. A consumer was moving a tumble dryer (dryer) in order to clean behind it. While pulling the dryer out using the handle on the door, the door latch (Figure 17) broke. The customer understood this could be a serious issue and contacted the retailer where he had bought the dryer to find a replacement part.

Figure 17: Example of the Tumble Dryer

6.4.1.2 The plastic door latch was originally made from an engineering thermoplastic blend (polycarbonate-acrylonitrile butadiene styrene, or PC-ABS) in order to satisfy stringent performance and safety requirements. It was a tough and somewhat flexible UL V-0 rated fire resistant plastic. The consumer was unaware of the specific performance or safety requirements of the material. The retailer was aware that this could be a safety issue and suggested that one of their installers should come over to assess the damage and make the repair if possible. The retailer said that the installer should be able to locate an appropriate spare part, if it cannot be repaired onsite.

6.4.1.3 The installer came over in the morning and inspected the tumble dryer. He observed that the other components of the door latch mechanism were intact, and that only the plastic latch had cracked. He tried to locate an OEM replacement part, but there were none which were readily available; however, the installer had access to a 3D printer as well as a parts list for the dryer, and could make the replacement part himself. He was able to access OEM CAD design files for part.

6.4.1.4 The installer's 3D printer was a desktop model which had a limited range of polymer feedstock it could print. The installer understood that the part likely had to be fire resistant (due to its proximity to electrical components in the latch mechanism) and tough (due to its function as a latch), however, he was unaware of the specific grade required and was not immediately concerned as the other components of the latch mechanism were intact which he felt was sufficient. He identified a fire resistant polylactic acid (PLA) plastic which he had available; while looking for a suitable material, he was focusing more on finding a fire resistant material rather than one which had good fatigue resistance under humid operating conditions. He was not aware of the long term performance characteristics of the polymer, in particular, that its mechanical properties could degrade after cyclical loading and particularly when exposed to humid conditions (PLA degrades via hydrolysis).

6.4.1.5 The installer returned to the customer's residence in the early evening with the printed part. He found that it fit well and was able to install it without issue. The dryer door latch mechanism functioned well and the dryer was left to run as normal.

6.4.1.6 One and a half years following the replacement, the latch failed as a result of fatigue and exposure to a humid environment. Part of the latch remains inside of the catch inside of the dryer, which results in the dryer sensing that the door is still closed even when it is not. A child in the house finds the dryer running and is able to open the

door without the dryer stopping. The child climbs inside of the dryer and sustains a severe injury to his arm, which requires amputation.

6.4.2 Safety issues under the scenario

6.4.2.1 Failure of the latch led to a kinetic energy hazard resulting in an amputation of the child's arm. The issues contributing to risk which are involved in this scenario are outlined below:

6.4.2.1.1 Limited material availability – The required grade of plastic was not available for the printer.

6.4.2.1.1.1 Not all materials are compatible with 3D printing

6.4.2.1.1.2 If a material is compatible, not all grades of that material may be compatible

6.4.2.1.1.3 Each printer and process will have unique compatibility issues

6.4.2.1.2 Material qualification and performance standards are less mature for 3D printed materials – *The performance specification of the printed component was unknown.*

6.4.2.1.3 3D printing materials may have different dimensional stability, mechanical, thermal, electrical, and aging properties than traditional materials – *The mechanical properties of the 3D printed component did not meet the properties of the OEM part.*

6.4.2.1.4 Fewer options for additives – It was unclear if additives were available to improve the polymer's durability and resistance to humidity.

6.4.2.1.5 Designs for parts may not account for requirements of 3D printing – The CAD design files and specifications were for a traditionally manufactured part.

6.4.2.1.5.1 Requirements may be different for each type of 3D printing technology and printer

6.4.2.1.5.2 Designs may only be suitable for traditional manufacturing techniques

6.4.2.1.6 3D printing machine operator experience with: - The printer operator was familiar with 3D printing technology, but as a hobbyist; he was making decisions based on his limited experience and information about the requirements of the part.

6.4.2.1.6.1 3D printing in general

6.4.2.1.6.2 With one particular method versus another method

6.4.2.1.6.3 With one particular printer versus other printers

6.4.2.1.6.4 Making modifications and hacking of the printing machine, design files, print path or print parameters

6.4.2.1.6.5 Setting up and maintenance of the printer

6.4.2.1.7 Motivation of the 3D printing machine operator – The installer/printer operator saw an opportunity to quickly fix the dryer, and believed he was making all of the necessary decisions.

6.4.2.1.8 Environment in which the printer is stored and used – The printer was in the installer's home, which is suitable for making objects for personal use but not necessarily appropriate for professional printing.

6.4.2.1.9 Operator's understanding of the part's performance requirements - The installer did not fully understand the part's performance requirements

6.4.3 Legal considerations

6.4.3.1 It is not clear whether the retailer engaged the installer or the consumer himself engaged the installer. If the consumer engaged the installer and purchased the 3D printed door latch directly from him, the installer could be held responsible as seller of the latch under the Consumer Rights Act 2015, as the latch was not fit for a purpose made known to him (i.e. that it was for use on this specific tumble dryer). If successful in the claim, the consumer would be entitled to repair or replacement, depending on the availability of these remedies and the costs involved, after which the right to reject, a price reduction or a refund (subject to a deduction to account for the use which since the goods were delivered) (see 5.3.1.18.2). If the retailer engaged the installer and the consumer paid the retailer for the replacement latch to be installed, then the claim above would need to be made against the retailer as the seller of the item. In the paragraphs below, we refer to "installer / retailer" as the seller of the latch to the consumer.

6.4.3.2 If the consumer can establish that the child's injury was caused by the latch which was not fit for purpose and that this was a foreseeable consequence, the consumer could seek damages from the installer / retailer for breach of contract (see 5.3.1.18.2). In order to establish his case, the consumer would need to establish that a child getting injured in the way described in this scenario is a foreseeable consequence of the latch not being fit for purpose (i.e. the foreseeable consequence is not only the latch failing but consequently the door of the tumble dryer becoming capable of being opened while the tumble dryer is in operation as well as a child getting injured in the way described in the scenario).

6.4.3.3 The installer could also be liable for not using reasonable care and skill in deciding to use the 3D printed latch pursuant to the Consumer Rights Act 2015 (see 5.3.1.20.2)). Whether this claim is successful will depend on what the installer was expected to do for him to be considered to have used reasonable care and skill in supplying the replacement and installing it and whether the installer, in fact, can be considered to have applied such care and skill. Relevant considerations could include whether proceeding with the use of the 3D printed replacement latch without knowing the specific material used in the original product is an action reasonably expected from a professional installer, whether the installer was reasonably expected to check the specifications of the latch with the manufacturer before proceeding with the installation, whether use of UL V-0 rated plastics for this type of product is known to professional installers of this type of product, and any other information that the installer was not aware of but should have found out before proceeding with the use of the 3D printed latch.

6.4.3.4 If the consumer can establish that the safety of 3D printed latch had a defect, he can seek damages from the installer, as the manufacturer of the latch, under the Consumer Protection Act 1987 for damage caused by the replacement latch in excess of £275. If his claim is successful, and the issue was caused by the 3D printing machine (rather than due to lack of maintenance or any other oversight on

the installer's part including the choice of the 3D printing material), the installer could in turn bring a claim against the manufacturer and/or the supplier of the 3D printing machine (see 5.3.1.16).

6.4.3.5 The consumer has to establish the existence of the relevant facts and circumstances of the case in making a claim. Given the time that has passed between installation / supply of the latch and the incident, this is likely to be challenging from an evidential perspective.

Appendix 1: Liability of stakeholders - overview

Note:

- The table below gives an overview of the legal grounds on which stakeholders (a) to (g) below may be held liable under applicable law where the relevant conditions are met.
- It does **not** include the stakeholder's liability for breach of any contractual obligations to supply goods or services of certain quality or standards agreed under those contracts. It also does not include any product- or services-specific law. Therefore, entries marked "N/A" below may still have obligations to supply designs / goods / services which satisfy certain safety / quality requirements under their contracts with the purchaser of their designs / goods / services, and may be liable for breach of contract accordingly.
- The assumption is that the manufacturers are also the sellers of what they produce and therefore subject to the rules that apply to sellers of the relevant items.

	UK	EU[58]	US / California	Canada	Japan	China
(a) the non-consumer designer of the component design file	Where the component file is for incorporation or use in a 3D printing device or 3D printing machine for business use, Health and Safety at Work etc. Act 1974 ("HS Act") if B2B. Whether Sale of Goods Act 1979 applies	Directive 2006/123/EC ("Services Directive") if established within the EU.	Applicability of safety related regulations are not clear - there is no established rule on whether or not digital content is a product to which product safety or liability rules apply.	N/A unless the designer undertakes other roles (e.g. seller).	Could be liable under tort rules of the Civil Code (although unlikely in practice due to remoteness)	Could be liable under the Product Quality Law ("PQL") if the design causes an unreasonable safety risk in the product using the design.

[58] The legislation which actually applies in the Member State is the national legislation which transposed the relevant EU Directives.

	UK	EU[58]	US / California	Canada	Japan	China
	depends on case law.		Implied warranty against infringement under UCC.			
	Consumer Rights Act 2015 (**"CRA"**), The Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 (**"CCR"**) and The Consumer Protection from Unfair Trading Regulations 2008 (**"CPR"**) if B2C.					
(b) the non-consumer manufacturer of the device / machine which allows 3D printing	SGA and the Consumer Protection Act 1987 (**"CPA"**) if B2B. CRA, CPA, CCR and CPR if B2C. If the device is a consumer	Directive 85/374/EEC (Product Liability Directive) if B2B. Directive 1999/44/EC (**"Consumer Sales and Guarantees Directive"**),	Implied warranties under UCC, Restatement (Second) of Torts and, if the device is a consumer product, Consumer Product Safety	Canada Consumer Product Safety Act (**"CCPSA"**) if the device is a consumer product sold to consumers. Also, the Sale of Goods Acts	Safety obligations only apply if the consumer appliance is one of the regulated products. Product liability applies if the	PQL, General Principles of the Civil Law and Tort Law.

	UK	EU[58]	US / California	Canada	Japan	China
	product, General Product Safety Regulations 2005 (**"GPSR"**) also applies and, if not, Health and Safety at Work etc. Act 1974 (**"HS Act"**) applies.	Directive 2011/83/EU (**"CRD"**), Directive 2005/29/EC (**"UCPD"**) and Product Liability Directive if B2C. Directive 2001/95/EC (**"GPSD"**) also applies if the device is a consumer product. Services Directive also applies if established within the EU.	Act of 1972 (**"CPSA"**) (if there is a defect in the 3D printer itself).	(provincial acts) if they are a seller (both B2C and B2B).	product has a defect.	
(c) the non-consumer manufacturer of the material used for 3D printing	SGA and CPA if B2B. CRA, CPA, CCR and CPR if B2C. If the material is a consumer product, GPSR also applies and if not, HS Act applies.	Directive 85/374/EEC (Product Liability Directive) if B2B. Consumer Sales and Guarantees Directive, CRD, UCPD and Product Liability Directive if B2C.	Implied warranties under UCC, Restatement (Second) of Torts and, if the device is a consumer product, CPSA (if there is a defect in the material itself).	CCPSA. Also, the Sale of Goods Acts (provincial acts) if they are a seller (both B2C and B2B).	Product liability applies if the product has a defect.	PQL, General Principles of the Civil Law and Tort Law.

	UK	EU[58]	US / California	Canada	Japan	China
		GPSD also applies if the material is a consumer product. Services Directive if established within the EU.				
(d-1) a non-consumer installer of a 3D printed part / component which is made by an unauthorised manufacturer ("unauthorised 3D printed part") for installation, repair or maintenance of consumer appliances	Supply of Goods and Services Act 1982 and The Provision of Services Regulations 2009 if B2B. CRA, CCR and CPR if B2C.	CPR and UCPD if B2C. Services Directive if established within the EU.	Common law obligation to use appropriate and reasonable skill and care.	CCPSA and provincial laws on consumer protection would likely to apply if the 3D printed part is supplied by the installer. Certain provincial laws govern services contracts. Otherwise, common law applies requiring reasonable care in providing services and potential implied warranties of fitness for products supplied	N/A	Law on the Protection of Consumer Rights and Interests for installation services. (PQL, General Principles of the Civil Law, Tort Law and the Law on Consumer Rights and Interest for the parts if supplied by the installer.)

	UK	EU[58]	US / California	Canada	Japan	China
				as part of a services contract.		
(d-2) a consumer installer[59] of an unauthorised 3D printed part for installation, repair or maintenance of consumer appliances	N/A	N/A	Common law obligation to use appropriate and reasonable skill and care.	N/A	N/A	N/A
(e-1) the non-consumer manufacturer of unauthorised 3D printed parts	SGA and CPA if B2B. CRA,CPA, CCR and CPR if B2C. If a consumer product, GPSR also applies. If not, HS Act applies.	Product Liability Directive if B2B. Consumer Sales and Guarantees Directive, CRD, UCPD and Product Liability Directive if B2C. GPSD also applies if the 3D printed part is a consumer product. Services Directive if established within the EU.	CPSA, implied warranties under UCC, Restatement (Second) of Torts and Restatement (Third) of Torts.	CCPSA and, if selling to consumers provincial laws on consumer protection, and if *selling* to consumers or businesses, provincial law on sale of goods.	Safety obligations only apply if the consumer appliance is one of the regulated products. Product liability applies if the product has a defect.	PQL, General Principles of the Civil Law and Tort Law.

[59] e.g. a householder using such part / component to replace the original part / component made by the authorised manufacturer

	UK	EU[58]	US / California	Canada	Japan	China
(e-2) a consumer manufacturer of unauthorised 3D printed parts[60]	N/A	N/A	N/A	N/A	N/A	N/A
(f-1) a non-consumer manufacturer of consumer appliances who uses unauthorised 3D printed parts in producing consumer appliances	GPSR, SGA and CPA if B2B. GPSR, CRA, CPA and CCR and CPR if B2C.	GPSD and Product Liability Directive if B2B. GPSD, Consumer Sales and Guarantees Directive, CRD, UCPD and Product Liability Directive if B2C. Services Directive if established within the EU.	CPSA, implied warranties under UCC, Restatement (Second) of Torts and Restatement (Third) of Torts.	CCPSA and, if selling to consumers, provincial law on sale of goods.	Safety obligations only apply if the consumer appliance is one of the regulated products. Product liability applies if the product has a defect.	PQL, General Principles of the Civil Law and Tort Law.
(f-2) a consumer manufacturer of consumer appliances who uses unauthorised 3D printed parts in producing	N/A	N/A	N/A	N/A	N/A	N/A

[60] e.g. a householder producing the part for use in consumer appliances that they own by using a 3D printing device / machine

	UK	EU[58]	US / California	Canada	Japan	China
consumer appliances[61]						
(g-1) a distributor (B2B) / vendor of consumer appliances which use unauthorised 3D printed part(s) (other than (e)).[62]	GPSR and SGA. Also liable under CPA if asked to identify the producer and fail to do so within a reasonable time.	GPSR and Product Liability Directive. Services Directive also applies if established within the EU.	CPSA, implied warranties under UCC, Restatement (Second) of Torts and Restatement (Third) of Torts.	CCPSA , provincial laws on consumer protection, and provincial law on sale of goods.	Safety obligations apply only if the consumer appliance is one of the regulated products (as an importer / seller). Product liability applies if the product has a defect.	PQL, General Principles of the Civil Law and Tort Law.
(g-2) a retailer (i.e. B2C) / vendor of consumer appliances which use unauthorised 3D printed part(s) (other than (e)).[63]	GPSR, CRA, CCR and CPR. Also liable under CPA if asked to identify the producer and fail to do so within a reasonable time.	GPSD, Consumer Sales and Guarantees Directive, CRD, UCPD and Product Liability Directive. Services Directive also applies if established within the EU.	CPSA, implied warranties under UCC, Restatement (Second) of Torts and Restatement (Third) of Torts.	CCPSA and provincial law on sale of goods.	Safety obligations apply only if the consumer appliance is one of the regulated products (as a seller).	PQL, General Principles of the Civil Law, Tort Law and the Law on Consumer Rights and Interest.

[61] e.g. creating a new appliance out of unauthorised 3D printed parts
[62] The assumption is that the vendor does not know that the appliances they sell use unauthorised 3D printed parts.
[63] The assumption is that the vendor does not know that the appliances they sell use unauthorised 3D printed parts.

Appendix 2: Legislative initiatives

1. EU

1.1 Directive (EU) 2019/771 (Contracts for sale of goods)

1.1.1 This Directive will repeal Directive 1999/44/EC (see 1.2 above). The new rules under this Directive are due to apply from 1 January 2022 to B2C sale of goods including digital content or digital services which are incorporated into or inter-connected with goods in such a way that absence of that digital content or digital service would prevent the goods from performing their functions.

1.1.2 The changes from the current Directive 1999/44/EC include additional express requirements for the goods to be considered to be in conformity including:

(i) the goods to possess:

- the functionality, compatibility, interoperability and other features, as required by the sales contract;
- the qualities and other features, including in relation to durability, functionality, compatibility and security normal for the goods of the same type and which the consumer may reasonably expect given the nature of the goods and taking into account any public statement made by or on behalf of the seller or other persons in previous links of the chain of transactions including the producer;

(ii) the goods must be delivered with:

- all accessories and instructions, including on installation, as specified by the sales contract;
- such accessories, including packaging, installation instructions or other instructions, as the consumer may reasonably expect to receive;

(iii) the goods must be supplied with updates as specified in the sales contract;

(iv) in the case of goods with digital elements, inform the consumer and supply updates including security updates necessary to keep the goods in conformity for the period that the consumer may reasonably expect; and

(v) fitness for purpose for which goods of the same would normally be used, by taking into account, where applicable, any existing EU and national law, technical standards, or in the absence of such standards and applicable sector-specific industry codes of conduct.

1.1.3 Where the consumer fails to install within a reasonable time updates supplied, the seller is not liable for any lack of conformity resulting solely therefrom if (a) the seller informed the consumer about the availability of the updates and consequences of the failure and (b) the failure of the consumer to install or incorrect installation was not due to shortcomings in the installation instructions.

1.1.4 In terms of remedies, in addition to the rights under the current Directive, the consumer can also immediately rescind contract or make a proportionate reduction of the price where the

lack of conformity is such a serious nature as to justify an immediate price reduction or termination of the sales contract.

1.2 Directive (EU) 2019/770 (Contracts for the supply of digital content and digital services)

1.2.1 The rules under this new Directive are due to apply from 1 January 2022 to B2C supply of digital content (data which are produced and supplied in digital form) or digital service (a service allowing the consumer to create, process, store or access data in digital form or sharing of or any other interaction with data uploaded by the consumer or other users of the service).

1.2.2 The requirements for the supply contract to be considered as being in conformity are effectively same as Directive (EU) 2019/771 (see 1.1 above) except that reference to performance features is made as part of the quality requirement and that digital content or a digital service must be supplied in the most recent version available at the time of contract unless otherwise agreed.

1.2.3 If there is lack of conformity, the consumer can:

(i) seek the digital content or digital service to be brought into conformity;

(ii) if:

- the above would be impossible or would impose disproportionate costs on the trader or not provided by the trader within a reasonable time or significant inconvenience to the consumer; or
- a lack of conformity appears despite the trader's attempt or the lack of conformity is so serious in nature to justify an immediate price reduction or termination of the contract,

a proportionate reduction in the price or terminate the contract.

2. US / CALIFORNIA

The following bills have been submitted to the US Congress.

2.1 HR 2621: Homeland Security Assessment of Terrorists Use of Ghost Guns Act

A bill introduced to the United States Congress by U.S. Rep. Max Rose (D-NY) on 9 May 2019 to crack down on unregistered and untraceable "ghost guns" (including 3D printed guns) sponsored by U.S. On 7 May 2019, Rose spearheaded a student roundtable on gun violence at Fort Hamilton High School in Bay Ridge, New York. Rep.

Passed the House Committee on Homeland Security on 23 May 2019.

2.2 HR 6649: 3D Printed Gun Safety Act of 2018

A bill introduced to the United States Congress by Rep Theodore Deutch (D-FL). By way of background, a gun enthusiast Cody Wilson published an online instruction manual for how to print your own gun from a 3D printer. It was downloaded more than 100,000 times. The Obama State Department forced him to take it down, arguing that such open publication would violate the law. Wilson sued. The State Department switched sides under President Trump, settling the case in June and rendering "any form" of 3D printing instructions or tutorials legal for public release or "unlimited distribution".

The bill was referred to the House Judiciary Committee on 3 August 2018, but no further action has been taken.

2.3 HR 6643: Untraceable Firearms Act

A bill introduced to the United State Congress by Rep. David Cicilline (D-R.I.) on 31 July 2018. Members of Congress have expressed concern that undetectable, untraceable firearms could proliferate with the growing availability of 3D printer technology, allowing criminals to circumvent the law and possibly breach security systems.

The bill was referred to the House Judiciary Committee on 31 July 2018, but no further action has been taken.

2.4 S 3304: 3D Printed Gun Safety Act

A bill introduced to the United States Senate by Rep Theodore Deutch (D-FL) on 31 July 2018. See the background outlined in 2.2 above.

The bill was referred to the Senate Judiciary Committee on 7/31/2018, but no further action has been taken.

2.5 S 3300: Untraceable Firearms Act

A bill introduced to the United States Senate by Sen. Richard Blumenthal (D-Conn.) on 31 July 2018. Members of Congress have expressed concern that undetectable, untraceable firearms could proliferate with the growing availability of 3D printer technology, allowing criminals to circumvent the law and possibly breach security systems.

The bill was referred to the Senate Judiciary Committee on 31 July 2018, but no further action has been taken.

2.6 AB-857 Firearms: identifying information

An act to amend Sections 11106, 16520, 23910, and 30105 of, and to add Chapter 3 (commencing with Section 29180) to Division 7 of Title 4 of Part 6 of, the California Penal Code, relating to firearms.

Signed into law by California Governor Jerry Brown on 22 July 2016, and thus anyone making a homemade firearm would be required to obtain a serial number from the state's Department of Justice and engrave or embed that serial number into every 3D printed firearm.

3. CANADA

Health Canada has issued "*Guidance Document - Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing*" whose application is limited to medical devices.

4. CHINA

Whilst not a legislative initiative, there are two national strategy plans that have been published:

4.1 On May 8, 2015, the State Council issued the "Made in China 2025", according to which China will promote and develop additive manufacturing industry.

On November 31, 2017, the Ministry of Industry and Information Technology, the National Development and Reform Commission and various other ministries in China issued the Action

Plan for the Developing Additive Manufacturing Industry (2017-2020). According to this action plan: (i) China will strengthen supervision on additive manufacturing industry in respect of manufacturing, sale, application, practitioners and data management; and (ii) China will carry out studies to establish a basic information reporting system for equipment and a registration system for practitioner registration in connection with additive manufacturing.

This publication is available from: www.gov.uk/government/publications/3d-printing-of-spare-parts-for-consumer-domestic-appliances-safety-and-legal-implications