D5.6 INSTITUTIONS AND CREATIVE DIDIY

Project Acronym:	DiDIY
Project Name	Digital Do It Yourself
Grant Agreement no.	644344
Start date of the project	01/01/2015
End date of the project	30/06/2017
Work Package producing the document	WP5 – Exploring the impact of DiDIY on Creative Society
WP Lead Partner	UOW
Other Partner(s) involved	all
Deliverable identifier	D5.6
Deliverable lead beneficiary	AC
Due date	M26 (February 2017)
Date of delivery	28/02/2017
Version	1.0
Author(s)	AC
License	Creative Commons Attribution ShareAlike 4.0
Classification	PUBLIC
Document Status	APPROVED
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 644344.	
Disclaimer: The views expressed in this document do not necessarily reflect the views of the EC.	

Disclaimer

This document is provided “As Is”; it is a study introducing the main research topics in the presented context. We encourage you to further study other sources. Any feedback, suggestions and contributions to make this document better and more useful are very welcome. Please let us know through the contact page http://www.didiy.eu/contact. We will seek to incorporate relevant contributions in the document and add your name to the list of contributors.

Executive summary

DiDIY is, in many of its aspects, an avenue for creative expression. However, as mentioned in the Project's Grant Agreement, the practice of DiDIY in creative cultures can be expected to have an "indirect impact on the value of professionalism and the traditional institutions and regulatory mechanisms that professional work has generated". Following the mission statement presented in the Grant Agreement, the present deliverable carries out a critical investigation of the ethical issues raised by that expected impact. Section 2 reiterates some clarifications about the concept of DiDIY outlined in previous deliverables. It also specifies what we mean exactly by "creative DiDIY", as opposed to DiDIY *simpliciter*. With the help of illustrations, we distinguish several major categories of creative DiDIY. In section 3, which contains the bulk of our discussion, we then consider how some of those forms of creative DiDIY present a challenge to existing institutions and regulatory mechanisms. In that context, we pursue further the discussion, started in D6.1, on how to deal with the potential risks that DiDIY products might present in terms of safety and liability, and describe and evaluate a few additional solutions that have been proposed in the existing literature. We particularly note the merits of the proposal to institute a clearninghouse that would sell digital blueprints for creative DiDIY products certified as safe. We conclude our analysis by emphasizing the need for further reflection and discussion on these issues, and the importance of avoiding exaggerating the regulatory challenges presented by creative DiDIY in light of the current evidence.

Revision history			
Version	**Date**	**Created / modified by**	**Comments**
0.0	04/07/16	AC	First, rough draft.
0.1	14/02/17	AC	Second draft, revised in accordance with D6.1 and shared with all Project partners.
0.2	20/02/17	AC	Third draft, containing some revisions and additions (including the conclusion).
0.3	22/02/17	AC, LIUC	Fourth draft, including comments from LIUC
0.4	26/02/17	AC, LIUC, FKI	Fifth draft, including comments from FKI
1.0	28/02/17	LIUC	Approved version, submitted to the EC Participant Portal.

Table of Contents

1. Introduction

DiDIY is, in many of its aspects, an avenue for creative expression – whether one is talking about artworks or consumer goods. This is without doubt very exciting. However, as mentioned in the Project's Grant Agreement, the practice of DiDIY in creative cultures can be expected to have an "indirect impact on the value of professionalism and the traditional institutions and regulatory mechanisms that professional work has generated" (Annex 1, part A, p. 26). Following the mission statement presented in the Grant Agreement, the present deliverable carries out a critical investigation of the ethical issues raised by that expected impact. Section 2 reiterates some clarifications about the concept of DiDIY outlined in previous deliverables. It also specifies what we mean exactly by "creative DiDIY", as opposed to DiDIY *simpliciter*. With the help of illustrations, we distinguish several major categories of creative DiDIY. In section 3, which contains the bulk of our discussion, we then consider how some of those forms of creative DiDIY (namely what we call DiDIY consumer goods, DiDIY food, and DiDIY drugs) present a challenge to existing institutions and regulatory mechanisms. In that context, we pursue further the discussion, started in D6.1, on how to deal with the potential risks that DiDIY products might present in terms of safety and liability, and describe and evaluate a few additional solutions that have been proposed in the existing literature. We particularly note the merits of the proposal to institute a clearinghouse that would sell digital blueprints for creative DiDIY products certified as safe. We conclude our analysis by emphasizing the need for further reflection and discussion on these issues, informed by the latest empirical evidence, and the importance of avoiding exaggerating the regulatory challenges presented by creative DiDIY in light of the current evidence.

2. Some basic conceptual clarifications

2.1 Technical terms and acronyms

(including definitions from the Project's Shared Vocabulary)

Term	Meaning
Atoms-Bits Convergence, ABC	socio-technical scenario where physical and informational components of entities are progressively integrated making it increasingly easy to swap from representation to physical instantiation and back
CAD	Computer-Aided Design
CLIP	Continuous Liquid Interface Production
CNC	Computer Numerical Control
Do-It-Yourself, DIY	social phenomenon of personally building or customizing physical or informational objects or services not as one's main professional activity
DIYer	individual or organisation (formal or informal) that engages in DIY
Digital Do-It-Yourself, DiDIY	DIY enabled by digital tools and developing objectively as an activity and subjectively as a mindset, where the production of the outcomes is often facilitated by the access to online resources
DiDIYer	DIYer that engage in DiDIY
DiDIY product	product created by a DiDIYer using one or more DiDIY tools
DiDIY tool	DiDIY resource as physical or virtual tool or machine directly used in physical or design work for the purpose of engaging in DiDIY
Do It Together, DIT	DIY where the activity is performed in a collaborative way by a group of individuals
Fab Lab	makerspace structured according to a specific model of DIY, as proposed by the MIT's Center for Bits and Atoms
GA	Grant Agreement
KF	Knowledge Framework
Maker culture	culture that promotes the idea that anyone is capable of performing a variety of design, manufacturing, and service tasks rather than relying on professionals
Makerspace	community-operated physical place that affords sharing of tools, resources and knowledge motivated by maker culture, revealing specific ways of creation, collaboration and learning

Prosumer	a person who combines the roles of producer and consumer with regard to one and the same product
SV	Shared Vocabulary

2.2 DiDIY and "creative DiDIY"

Our perspective on DiDIY in this deliverable is reflected in the preliminary remarks we made in subsection 2.2 of deliverable D3.3. Let us just mention that in this document, we will overall be focusing on the narrower understanding of DiDIY that includes ABC (based on the contrast introduced in section LW7 of the KF, which states that "in a narrower view DiDIY is aimed at producing physical artefacts, while in a broader view it is also aimed at creating intangibles and performing services"). That is because forms of DiDIY that do not involve ABC seem less likely to present important challenges to existing institutions and regulatory mechanisms, even though they can certainly provide great examples of creativity, as illustrated for instance by the contemporary YouTube phenomenon.

An additional aspect that needs to be clarified for the sake of this deliverable concerns the idea, mentioned in its title, of "creative DiDIY". The phrase "creative DiDIY" suggests that this type of DiDIY, by contrast with simple DiDIY, must by definition demonstrate a certain degree of creativity or originality. What is specifically creativity and what exact degree is required is clearly a debatable question. In this document, we will adopt an inclusive understanding of the idea of creative DiDIY, only ruling out from that category DiDIY products that are copies of existing artefacts (such as DiDIY counterfeits, which were discussed in D3.3), or that are entirely dictated by functional considerations leaving no room for a personal, creative touch. To present this by reference to the framework of everyday creativity elaborated by Elizabeth Sanders, our proposed conception of creativity covers what Sanders calls the "creating" mode (which involves paradigmatic instances of creativity such as composing a song or inventing a new game), but also the less demanding "adapting" mode, which still requires a certain level of ingeniousness – such as when one modifies an existing object to better suit one's unique needs (Sanders, 2012). The difference between Sanders's framework and the conception of creative DiDIY proposed here lies in the fact that our core criterion for classification is the degree of actual creativity exhibited by a DiDIYer through the things she makes, whereas Sanders focuses on how the act of producing those things makes that person *feel* (a correlate of this is that we are focusing here more on DiDIY as activity than as mindset, and therefore as objective rather than subjective phenomenon).

In the following subsubsections we will offer a few paradigmatic examples of creative DiDIY as it is encountered today.

2.2.1 Creative DiDIY consumer (or prosumer) products

We begin with the broad category of consumer products that fall under the label of creative DiDIY. We understand this category to include all non-edible DiDIY products that serve a functional purpose, yet are also made in a manner that demonstrates at least a minimum amount of creativity. Given that such products can in principle be designed or manufactured (or both) by their end user, rather than a third party, it might sometimes be appropriate to speak of "prosumer" goods or products. For the sake of convenience, we will stick to the more familiar phrase "consumer goods" or products in the following discussion, bearing in mind nevertheless that we intend it to cover prosumer goods as well.

The project-sharing website Thingiverse (https://www.thingiverse.com), popular among the Maker community, provides various examples of creative DiDIY consumer products. Consider for instance this lampshade, suitable for 3D printing:

Figure 1 – "Voronoi lamp" by Thingiverse user Markellov (accessed 20 January 2017 <http://www.thingiverse.com/thing:584714>).

While this lampshade, just like virtually any other, is fundamentally an item performing a useful function (softening and/or directing the light from a lamp), this particular one – assuming its design is indeed an original one, not copied from anywhere – clearly demonstrates creativity, over and above its purely functional features.

Another example is the "footwear" section on Thingiverse, which features a variety of highly original shoes that can be made with a 3D printer (with some assembly required), such as the following noteworthy models:

Figure 2 – "Recreus Sneaker II – Gyrobot Remix" by Thingiverse user Gyrobot (accessed 20 January 2017 <http://www.thingiverse.com/thing:289292>).

Figure 3 – "Shoe", by Thingiverse user gej216 (accessed 20 January 2017 <http://www.thingiverse.com/thing:811118>).

Again, at the most basic level, these shoes are – like all others – functional items, meant to allow users to walk around more comfortably. Nonetheless, these particular DiDIY models stand out in

terms of their level of originality, which would be sure to get their wearers noticed in public settings. The model on the right, in particular, is actually intended more as a fanciful fashion item than as footwear for everyday use. It is therefore a borderline case between standard "creative" DiDIY consumer products, and DiDIY art, or at least decoration – the two categories we will consider next.

2.2.2 DiDIY art

Examples of DiDIY art have already been presented on other occasions within the framework of this Project – we provide a reminder of these examples here. The first one is a new form of 3D printed ceramics created by a German design student named Steffen Hartwig, as presented on the DiDIY blog:[1]

Figure 4 – Ceramic by S. Hartwig, from the DiDIY blog
(accessed 20 January 2017 <http://www.didiy.eu/blogs/digital-diy-helps-artisans-produce-better-products>).

In the words of website www.3ders.org, Hartwig

> has created a series of beautifully organic and functional 3D printed ceramics using a self-designed ceramic 3D printer, extruder, and software system... Though functional and machine-made, the 3D printed pieces are imbued with intentional imperfections, resulting in ambiguous yet alluring artifacts that carry the trace of ceramic's handcrafted roots. (Quoted in Fioretti, 2016)

Another example, this time in the realm of pictorial art (but also sculpture), is provided by the work of animation student Michael Lainé, who used a Microsoft Kinect scanner to create 3D scanned pictures of himself, such as the one featured below. He then used those 3D scans to create both a music video of himself lip-syncing to a popular song, and individual prints (created with the help of a Makerbot replicator 2 3D printer) of the various scans (Hipolite, 2014). As suggested in D4.1, this may well be an indication of what the art of the future will look like.

1 There is admittedly room for debate as to whether Hartwig's creations should be categorized as DiDIY art or decoration (the category we discuss next). Whichever stance one happens to take on this issue, it is not crucial from the perspective of the present discussion.

Figure 5 – "Zoetrope" by student Michael Lainé
(accessed 21 January 2017 <https://3dprint.com/18520/3d-printed-cinema>).

2.2.3 DiDIY decorative items

Closely related to DiDIY art, we have the category of items that, while also considered interesting because of their aesthetic properties, are nevertheless classified as "decoration" rather than "art" proper, because of the additional function they serve as furniture, tableware, or toys, for instance. DiDIY tools like 3D printers have greatly facilitated the production of such items, most often made of plastic, as illustrated by the following example of toys that can be painted by the consumer herself.

Figure 6 – Articulated Christmas Toys, by Thingiverse user bqLabs
(accessed 21 January 2017 <https://www.thingiverse.com/thing:1168292>).

2.2.4 DiDIY food

The prospect of DiDIY food was alluded to in D3.3, which described the Foodini food printer by Natural Machines, a 3D printer working with capsules that users fill with their own ingredients. Assuming that this kind of tool can become both effective (in terms of printing speed and texture of the resulting food; see Ledford, 2015) and affordable enough to be used by many people, it would allow amateur chefs to create sophisticated and original dishes that could not be made using traditional culinary techniques. Examples of what such a dish might look like are provided by the chocolate globes and letter-shaped noodles pictured below, both of which were created using 3D printing technology (even though the former were created by a professional food designer, Marijn Roovers). On the question whether food printing technology will improve enough to find its way

into most households over the next decade or two, there is currently disagreement among experts (contrast for instance Lipson and Kurman, 2013 who believe that it will, with Barnatt, 2014, who is sceptical). In what follows, we will take seriously the possibility that this might come to happen, while acknowledging the degree of uncertainty associated with that outcome.

Figure 8 – 3D printed chocolate globes by food designer Marijn Roovers (taken from Ledford, 2015).

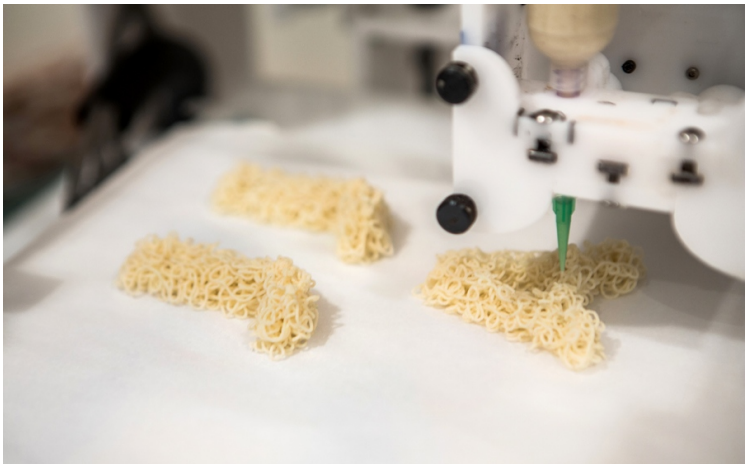

Figure 9 – 3D printed minestrone noodles (taken from Ledford, 2015).

2.2.5 DiDIY drugs

D3.3 also mentioned the idea of 3D printing one's own drugs, using a digital blueprint together with a special "ink". This might be relevant to the issue of creative DiDIY if such procedures were to allow private individuals to experiment with combining different substances, using DiDIY tools, to create new chemical compounds. Whether or not this is a likely prospect is a matter of controversy. Expert Lee Cronin has argued that the production of unauthorized DiDIY drugs could be forestalled by relying on authorized apps to drive the DiDIY tools used to make the drugs, and on an ink that could not be modified (Holmes, 2012). Others have expressed scepticism about the prospect of successfully implementing such solutions, given for instance the track record of hackers when it comes to successfully breaking into various supposedly secure systems (Tuccille, 2016).

This sceptical point about the prospect of creating secure apps seems well taken, as already suggested in D8.11, p. 13. On the other hand, D3.3 already mentioned the fact that the need to create the right type of ink for the drugs one wanted to make might raise a technical obstacle to

experimental DiDIY drugs, whether recreational or nootropic in nature.[2] There seems to be no straightforward path from the basic components needed to make a particular drug (say, poppy plants, in the case of heroin) to the specific ink to be used to print the drug. It is unclear that the move from the former to the latter would be any less challenging than making an illegal drug from scratch using more traditional DIY methods, involving no DiDIY tools. Alternatively, we can imagine a scenario in which someone got hold of cartridges for drug printing in a legal manner, opened them, and mixed their contents, thereby producing a new type of ink, and ultimately a new chemical compound – again, of either the recreational or nootropic kind. Whether or not one could, using this procedure, obtain a satisfactory type of compound at the end is an open question at this point. What is certain is that there would be reason to worry about the safety of the compounds that might get created in this way.

2.2.6 DiDIY and collective creativity: Do It Together

The various examples of creative DiDIY that we have described so far are all, we are assuming, produced by single individual makers. However, as pointed out by Sanders (e.g., 2012), creativity can also be demonstrated at the *collective* level (in the production of artefacts belonging to any of the categories previously distinguished). An example of this, already featured in D3.3, is provided by FirstBuild, a co-creation community that allows its members to get involved in the creation of a new product from the very beginning. Most of the items created at FirstBuild tend to fall under the category of DiDIY consumer products, such as the Opal Nugget Ice Maker (pictured below), an innovative machine that makes chewable nugget ice, and costs less than the home nugget ice makers that had been available on the market so far. To be precise, we may note that an item like the Opal Nugget Ice Maker is a product of Do It Together (DIT), since a number of different people collaborated in its conception. Nonetheless, insofar as the people involved were engaging in DiDIY (they provided feedback via the FirstBuild website), and as the position adopted in the context of this Project has been that the "yourself" in DiDIY can be collective and therefore that DiDIY can include DIT, then the Nugget Ice Maker does seem to fit the definition of DiDIY product stated in the SV.

Figure 10 – Opal Nugget Ice Maker, the product of a Co-Create collaboration at FirstBuild (accessed 29 January 2017 <https://nuggetice.com>).

2 Nootropic drugs, such as amphetamine or modafinil, are used with the aim of improving characteristics such as wakefulness, energy, and cognitive function in healthy individuals.

2.2.7 Creative DiDIY and entrepreneurship

Finally, as mentioned for example in D5.2, DiDIY tools are also used in a creative manner by budding entrepreneurs who are launching start-ups. 3D printing technology, for instance, makes it easier for them to create prototypes in order to showcase their ideas and attract investors. In their case, what starts out as creative DiDIY eventually becomes – if they are successful – a full-fledged business venture.

3. DiDIY and the issues of safety and liability

3.1 Safety and liability issues raised by DiDIY products

With the rise of the DiDIY phenomenon, we are already witnessing a new flourishing of creativity, as non-professionals engage in the design of new artefacts such as those described in the previous section, which they then share with the rest of the world using platforms like Thingiverse, allowing anyone with access to the required equipment (whether at home or via a Fab Lab) to make the relevant artefacts themselves. However, as discussed in D6.1, parallel to this growth of creativity, a growing number of people are raising concerns about the safety of DiDIY products and the challenge they raise for product liability (see for instance Engstrom, 2013; Berkowitz, 2015; De Clercq Advocaten Notarissen, 2015; Harris, 2015; Nielson, 2015; Van Eecke and De Bruyn, 2015).

As Lucas Osborn puts it in a discussion of the rise of 3D printing, “pessimists will be apt to worry about millions of amateurs unintentionally making shoddy and outright dangerous products” (Osborn, 2014, p. 566). Such products could for instance result in injury, either to the user herself, or to someone else (take again the example, given in D6.1, of a chandelier – which could be of a highly original and decorative nature – containing a flaw that causes it to fall on someone). Or in the case of homemade drugs or food, inadequate quality control could result in health problems for the user(s). Even though items sold by business sellers can also, of course, occasionally raise such concerns, they are more salient in the context of DiDIY, because products from commercial sellers are required to undergo certain tests for purposes of quality control, whereas this mostly does not apply to DiDIY products (though we will consider an exception to that rule in subsubsection 3.3.2). In what follows, we will push further the analysis already offered in D6.1 of some of the ethical issues surrounding safety and liability in relation to DiDIY products that are plausibly included into the category of creative DiDIY. In particular, in line in the goals outlined for the present deliverable in the GA, we will be focusing on the ways in which creative DiDIY manufacturing of physical artefacts might present a challenge for oversight by existing regulatory bodies.

As explained in D6.1, safety issues related to DiDIY can arise at three main levels: design, manufacturing, and warning. At the level of design, the digital blueprint for the good to be manufactured could contain flaws – that is to say, design flaws that would result in the production of an unsafe good, rather than, say, flaws that would simply prevent the good from being produced at all by the device, as happens relatively frequently (Allen, 2013). Reliance on 3D scanning, insofar as it only captures the surface properties of an object, might also contribute to design defects, if the internal design of the object is completed by someone without the relevant professional skills (or, of course, if the scanning process reproduces a design defect that was already present in the original object). Besides people’s concerns about such risks, it would be useful to be able to estimate the actual extent of such risks on the basis of solid empirical data. We are not yet aware of any reports about waves of injuries caused by objects the blueprints for which were downloaded from Thingiverse or any other similar website. That said, it might be retorted that this is not enough to dismiss the potential risks presented by the spread of DiDIY products, given that DiDIY is still a relatively new phenomenon. We will therefore take the possibility of such risks seriously in our following discussion, while bearing in mind that the reality of those risks remains a contentious matter and has to our knowledge not yet been demonstrated in real-life cases.

At the manufacturing level, a DiDIY product could end up being of substandard quality because of the use of cheap or inappropriate basic materials, or inadequate handling of the relevant device. According to Eric Lindenfeld, compatibility issues between digital blueprints and hardware might

also yield unpredictable results: “complications can arise when a 3D printer utilizes a CAD file that was intended for a different type of 3D printer. In other words, a design created for production on one 3D printer can produce a product on a different 3D printer which alters significantly from the intended product” (Lindenfeld, Forthcoming, p. 7). Even assuming that such issues do not arise, it has been argued that a technology like 3D printing will generally tend to yield products of lesser quality (particularly in terms of mechanical features) than more traditional procedures like injection moulding, because it involves building objects in layers (Allen, 2013). The limitations of this remark (besides the fact that it does not apply to other forms of digital manufacturing) are that it ignores the latest techniques developed for 3D printing, such as CLIP, which do not involve layer-by-layer manufacturing, as well as the arrival of new filaments that allow us to build stronger objects. Nevertheless, it may retain some relevance to the extent that affordable methods of 3D printing might remain the less reliable ones, at least for some time.

It is also worth noting that there are risks associated with the actual process of using certain DiDIY tools. Concerns have been raised, for instance, that 3D printers in operation might emit ultrafine particles that could potentially be harmful when the devices are used in unfiltered indoor environments (Stephens et al., 2013). Moreover, a fire hazard is not out of the question, for instance in the case of a malfunction of the temperature sensor (Stevenson, 2015). There is also some degree of risk to the user associated with the use of devices such as laser cutters, even though such risks are arguably lower in the context of a Fab Lab (where they are most likely to be used), given the presence of staff with the relevant expertise who can assist visitors, and the use of safety induction sessions. Furthermore, there are also examples where the use of DiDIY tools can, on the contrary, improve safety in comparison to more traditional manufacturing methods. The use of a CNC mill to finalize the main component of a rifle (called the “lower receiver”), for instance, reduces the risk of injury compared with the use of gunsmithing tools like a drill press. Of course, DiDIY guns can also raise questions of responsibility and liability – an issue discussed in deliverable D6.2.

Finally, as discussed in D6.1, harm could also result from inadequate instructions and warnings, on the part of the agent distributing a DiDIY product (whether by sharing the CAD design for it, or by selling or giving the product to others, as long as one does not do so as part of a business activity), about how to use the product in question.

3.2 DiDIY challenges traditional oversight by existing regulatory bodies

As we have previously alluded to, while DiDIY opens up various new channels for creativity and innovation, it also presents a challenge to the institutions that have so far been in charge of monitoring and regulating the production and distribution of the kind of items that creative DiDIY allows non-professionals to manufacture. We will now review the categories of items that seem to present special challenges in this context: these include ordinary consumer (and prosumer) products from car seats to chairs; food; and drugs. We will argue that they do not all pose the same kind of challenges when it comes to safety and oversight by existing regulatory bodies. DiDIY artworks and decorative items arguably raise an even lesser level of concern than the three former categories, given their primarily aesthetic rather than functional nature, though they are not entirely irrelevant either. As for products resulting from creative DiDIY at the prototyping level that are then sold commercially, and co-creation initiatives like FirstBuild, they also seem of lesser relevance for the sake of the present discussion. Indeed, even though such products might be manufactured and sold in relatively small quantities, the companies that offer them will still typically count as business sellers, in which case they will be subject to existing regulations governing safety and liability in

relation to such sellers, such as – in the European Union – the Product Liability Directive (85/374/EEC, already mentioned in D6.1, p. 55).[3]

3.2.1 Ordinary consumer products

Let us now review the three categories of greatest relevance to our research topic, beginning with ordinary consumer products. In the European Union, such products are subject to monitoring both (1) during the design and production phase, a process referred to as "conformity assessment" (European Commission, 2016, p. 62); and (2) after they have been put on the market, what is then called "market surveillance" (ibid.). These two avenues of monitoring are governed by different legal documents: the former, by Decision No 768/2008/EC, titled "A common framework for the marketing of products in the EU" (European Parliament and Council of the European Union, 2008); and the latter, by Directive 2001/95/EC, which lays out general safety requirements that any consumer product has to meet if it is to be fit for the EU market (European Parliament and Council of the European Union, 2001).[4] As the European Commission itself puts it, "both techniques are complementary and equally necessary to ensure the protection of the public interests at stake and the smooth functioning of the internal market" (European Commission, 2016, p. 62). The rise of DiDIY, including creative DiDIY, allows consumer products to be made that are no longer subject to these traditional channels of safety monitoring, since they either go directly to the consumer as soon as they have been made, or they are sold by someone who does not count as a "business seller", i.e., this person does not sell the items in the course of her business. As a result of this, there are grounds for fearing that, if the manufacture and sale (by hobbyists) of DiDIY products becomes popular, this might result in a wave of injuries, and that in cases where someone gets injured by a DiDIY product because of someone else's mistake, they might not be able to claim compensation for their injuries. This concern is reinforced by the fact that websites like Thingiverse use their terms of use to disclaim in advance any liability,[5] both for themselves and their "suppliers", i.e., the people who upload their digital blueprints to their platforms (see articles 7 and 8 of the terms of use of Thingiverse, reproduced in Annex 1).

This leads us to the expected impact of DiDIY on the legal area called product liability, an issue already addressed in subsubsection 4.1.2 of D6.1 and in subsubsection 2.11.6 of D8.11. That deliverable emphasized that, in the European context, the makers of defective DiDIY products that do not create such products as part of their business can be expected to be held liable for harm only if negligence on their part (breach of their duty of care) can be demonstrated, rather than under strict liability rules.[6] It also stressed the desirability for the designers and/or sellers of those products to include an adequate set of warnings when making CAD files or completed DiDIY products available to others, and to subscribe to some form of collective liability insurance to ensure that they would be able to compensate victims in the case of a successful lawsuit. In subsection 3.3., we will pursue this reflection further and consider other potential solutions that

3 Furthermore, companies like FirstBuild, which makes the Opal Nugget Ice Maker described above, also seek to protect consumers through the provision of appropriate warnings and a one-year warranty, as described for instance in the Use and Care Guide for the Ice Maker (available at ; accessed 21 February 2017). It seeks to exclude liability for incidental or consequential damages, but also acknowledges that this might not be permitted by some local regulations. The European Product Liability Directive would precisely be an example of a document that rules out such limitations of liability (see Council of the European Communities, 1985, article 12).

4 This directive, however, is scheduled to be replaced soon: a draft of a new regulation on product safety has already been proposed (Wiesbrock, 2015, p. 87).

5 At least any liability above the sum of $50, in the case of Thingiverse.

6 As a reminder, under strict liability, the manufacturer of a defective product is liable for the harm caused even if there was no negligence or fault on their part.

might help minimize the risk of a wave of uncompensated injuries from defective DiDIY consumer products.

3.2.2 DiDIY Food

When it comes to regulations regarding food safety, the EU parliament is informed on food safety matters by the European Food Safety Authority, but the monitoring on the ground is usually done at the local level. In Germany, for example, as explained by the website of the Federal Ministry of Food and Agriculture,

> the responsibility for official food control and inspection rests with the federal states (Länder). The competent Länder ministries draw up monitoring programmes that are carried out by the food inspection and veterinary offices in the urban and rural districts. The Federal Office of Consumer Protection and Food Safety (BVL) provides assistance in this regard by acting in a coordinating and advisory capacity … The controls are carried out at production and processing establishments for foodstuffs, commodities or cosmetics, at retail outlets and at border inspection posts. Restaurants and communal catering facilities also undergo regular checks. (Federal Ministry of Food and Agriculture, 2014)

In the case of food production, however, DiDIY might be less likely to allow people to circumvent such monitoring. Indeed, 3D printed food has to be made from appropriate basic materials: in the case of meat printing, for instance, one could imagine "meat" cartridges containing animal cells (developed in a cell culture). It seems reasonable to expect that these basic materials will typically be purchased commercially, rather than produced by consumers themselves. This means that it should be possible for the relevant authorities to monitor and regulate their quality and safety. If so, food printing may not raise the same sort of challenges as DiDIY consumer products.

We could of course imagine people experimenting and trying out various combinations of basic materials when printing their food, but it is unclear that this would be any riskier than existing methods of culinary experimentation. In fact, some are suggesting that food printing could on the contrary help optimize the nutritional content of what we eat. Lynette Kucsma, CMO and co-founder of Natural Machines, is thus quoted by Digital Trends as claiming that "printers like the Foodini can help people cut down on the amount of chemical additives in their food and reduce overconsumption. The food printers of tomorrow could even allow customization at the macronutritional level, allowing users individualize the amounts of calcium, protein, omega-3, and carbohydrates in their meals" (Wiggers, 2015). Furthermore, besides offering chefs a new avenue for creative experimentation, food printing is said to have the potential to reduce the environmental impact of cooking (ibid.), as well as the need to raise and kill animals for food. All of this suggests that there is more promise than peril in this technology.

3.2.3 DiDIY drugs

Experimental DiDIY drugs are arguably a greater source of concern. For our purposes here, it is worth distinguishing between prescription drugs (including controlled substances, which are subject to stricter legal controls than other prescription drugs) and illegal drugs. The first category includes substances like antidepressants and psychostimulants, which are basically designed to treat medical conditions (even though some people might seek them for other purposes, e.g., to try and enhance their mental or athletic abilities). It is legal to obtain such drugs, though one needs a doctor's prescription to do so. The second category includes drugs, like heroin or cocaine, that have been judged harmful enough to impose an outright ban on their possession and distribution (sometimes

with special exceptions for medical and scientific research). To differentiate between these various kinds of drugs, EU member states rely on a classification based on three UN conventions: the Single Convention on Narcotic Drugs from 1961, the Convention on Psychotropic Substances from 1971, and the Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances from 1988 (European Monitoring Centre for Drugs and Drug Addiction, 2012). These documents distinguish different types of drugs based on their estimated harmfulness. Drugs judged too harmful to the public are prohibited by law, and those found contravening those laws are punished (though the stringency of such punishment varies significantly between European countries). As for prescription drugs, they need to be authorized before they can be put on the EU market. There are various procedures for getting such authorization, some involving the European Medicines Agency (EMA), others being regulated by national competent authorities in the member states (European Medicines Agency, 2014).

Here again, DiDIY is a potentially disruptive force, which some might fear will allow people to produce such substances while completely circumventing existing regulations. First, it means that the rate at which amateurs create new chemical compounds might reach unprecedented levels, making it even more challenging for drug regulation to keep up. Already today, European regulators are facing the challenge of what has been called “legal highs”: private individuals with the relevant skills devise new drugs that they then have synthesized in laboratories outside Europe, and finally legally imported (Power, 2013).[7] Secondly, even once a compound has been added to the list of banned or controlled substances, enforcing any prohibition on its manufacture and possession might be next to impossible if private individuals can make it at home using DiDIY tools. This, however, will depend on how easy it will be to get hold of the basic ingredients needed to make DiDIY drugs, compared with more traditional DIY methods. As previously suggested, if it were necessary to secure substances that were illegal or somehow difficult to obtain, this would help law enforcement thwart such endeavours. By contrast, if one could simply use legally available “cartridges” for drug printing (if necessary, by first getting hold a prescription) and mix their contents in various ways, attempts at regulation might become futile (unless we were prepared to resort to highly problematic surveillance methods).

On that basis, while it seems important not to exaggerate the risks presented by the prospect of experimental DiDIY drugs, it is therefore reasonable to view them as a greater cause for concern than DiDIY food. The example of Portugal, which as we mentioned previously in a footnote has some of the most liberal drug laws in Europe, shows that such an approach to drug regulation need not automatically lead to any significant increase in drug use (no such increase was observed in the country after it decriminalized all drugs in 2001; see Ingraham, 2015). Nevertheless, the threat of punishment is clearly not the only factor that determines ease of access to illegal drugs. We can therefore not rule out the possibility that a spread of DiDIY drug manufacturing techniques would result in a rise in the availability and consumption of potentially dangerous compounds – though as we have mentioned, digital manufacturing techniques are not the only ones to raise that concern. Besides the current phenomenon of legal highs, it has been suggested that drugs like heroin could be made at home, using genetically engineered yeast and a home-brewing kit, with no need for DiDIY tools (LePage, 2015).

On a more positive note, it might be suggested that creative DiDIYers could, through their own experiments, happen to create new compounds that might hold significant therapeutic or enhancing promise. While such a possibility cannot be ruled out, the safety concerns associated with such an

7 If the drug in question were designed using a computer, then it might already constitute an example of a DiDIY drug – even though it would presumably not count as involving DiDIY manufacturing, unlike experimental drugs printed at home.

unregulated method of drug discovery make it look rather unappealing. That said, creative DiDIY drugs can be described as having clear beneficial potential if, under that concept, we include the type of custom-made, printable drugs that many expect to help advance personalized medicine in the coming years. It is thus reported that many patients nowadays face transportation and customization issues when it comes to the prescription drugs they need. To address such issues, MIT researchers have recently unveiled an "on-demand pharmacy" that would allow patients to print custom-made drugs in their home. A journalist describes it as follows:

> The project [uses] small tubes with continuous flow while developing the chemical reactions needed to make modern medicines...As of March 2016 the device is ready to deliver four medications: Benadryl, lidocaine, Valium and Prozac. Though not all drugs can be produced via the tube method, it is theoretically ready to handle recipes for as many other drugs as are possible. It's especially useful for so-called "orphan drugs" – those with low demand, which are made artificially expensive under the current methods. (Brick, 2016).

While it is still unclear whether such a system will eventually be released commercially, there is growing interest among researchers in developing devices of this kind. Insofar as the basic ink that would need to be purchased to make such drugs would be subject to strict standards of quality control, and as the printing procedure could be expected to be reasonably straightforward (not leaving much room for missteps that would result in the production of a dangerous substance), the safety risk that such custom-made DiDIY drugs might pose would seem rather limited. Perhaps we cannot rule out a scenario in which a malfunctioning printer ended up producing a dangerous chemical – just as we can conceive of a non-DiDIY tool, such as a bread maker, malfunctioning in a way (say, spilling lubricant) that ended up yielding an unsafe product. However, if the printer was purchased commercially (as will at least often be the case), and if it can be shown that malfunction was responsible for its printing of a dangerous compound, then the printer manufacturer will be held liable on the basis of EU law. True, it remains conceivable that cases of uncompensated harm could occur if the manufacturing device used were itself the product of DIY (as with the RepRap 3D printer, designed to be built by the users themselves), or if demonstrating the causal role of the malfunction were to prove challenging for the victim. Still, while such possibilities should not be ignored, it remains unclear at the present stage to what extent they are really more than mere thought experiments.

In light of all of this, creative DiDIY drugs do carry perils, but also potential benefits that should not be neglected – and make a policy of blanket prohibition on such drugs inappropriate. Still, this leaves us with the vexing question of how to regulate the potential dangerous compounds that DiDIYers might create in the future. Depending on one's ethical perspective, different stances might be taken on this issue. For instance, libertarians, who hold that no one should be prevented from engaging in any activity that does not involve a serious risk of harm to others (no matter how harmful it might be to oneself), are likely to consider it less urgent to stop people from acquiring the ability to make their own DiDIY drugs than those who believe that we should aim to eradicate drug use from society altogether, regardless of the restrictions this might entail for individual freedom. Furthermore, even if we agree about the social harms from drug use that we wish to prevent, it is still debatable what regulatory measures (whether prohibition, or alternatives) are most likely to guarantee such protection.

Nonetheless, regardless of the particular position one happens to take on this issue, we have mentioned that, depending on the details of the procedures that might become available for making DiDIY drugs, discussions about how to regulate such drugs might become moot, if the proposed regulations turn out to be impossible to enforce. Furthermore, we have also highlighted the various

unknowns about the potential of DiDIY tools to increase drug availability: what particular ingredients will be required, and how easy will it be to get hold of them? And even assuming this becomes a viable avenue for drug creation, how broad will the appeal of DiDIY be, compared for instance with the existing market for illegal drugs? At the present stage, it therefore seems premature to recommend any specific policy regarding DiDIY drugs. Still, as general guidelines, we can say, first, that radical solutions such as a complete ban on DiDIY drugs appear indefensible, and secondly, that it seems reasonable to apply similar policies to DIY and DiDIY drugs, at least in the absence of evidence justifying differential treatment. Beyond this, we would suggest monitoring closely future developments pertaining to DiDIY tools and their ability to create new chemical compounds. As more evidence becomes available, we will get a clearer idea of whether new policies are needed to deal with DiDIY drugs, and if so, which ones.

3.3 Managing the impact of DiDIY on product liability: further possible avenues

At the regulatory level, there are various possible ways of addressing the concerns we have described so far about ensuring that the rights of the users of DiDIY products (especially DiDIY consumer goods) are adequately protected. We have already mentioned, following D6.1, the suggestions that adequate warnings should be provided by those distributing CAD files and DiDIY products, and that these people might want to subscribe to some form of collective liability insurance scheme.[8] A variety of further positions on this issue have already been advocated in the literature. We will now review the most relevant ones, starting with the least stringent ones from a legal perspective.

3.3.1 No need for any new regulation: “user beware”

Libertarians, who – as we mentioned previously – endorse a philosophy that gives pre-eminence to the values of freedom and autonomy, might take issue with the suggestion that the risk of harm from DiDIY products calls for any new regulatory measures to protect prospective users. At most, they might argue, children under a certain age deserve such extra protection, and we should ensure that they cannot access the websites where CAD files are shared, or the devices that would allow them to make actual objects based on those designs. But when it comes to grown-up adults, libertarians would typically argue, a minimalist “user beware” policy is perfectly appropriate. That is, as long as the websites in question make it clear in their terms of use that they offer no guarantee regarding the quality and safety of the designs they host, and that people thus use these files at their own risk, the sites have done all that could reasonably be required of them. After all, the argument would continue, it is appropriate to expect adult users to acquaint themselves with such terms of use and to assume responsibility for the consequences of their use of such sites. To introduce special measures destined to protect them from their own autonomous choices would be inappropriate paternalism, libertarians might argue, and would unjustifiably introduce regulatory burdens that might hamper the activities that such websites make possible.

Arguably, the plausibility of this line of argument depends on the actual risks presented by DiDIY products. If it were to turn out that these risks have been overestimated, then the libertarian line might be persuasive: many potential regulatory measures will look like unnecessary complications. However, if the risks in question happen to be real (even if they apply only to a minority of cases), then the libertarian argument becomes less appealing. Yes, people should acquaint themselves with the websites’ terms of use, and can be held responsible for the choice to use a design that might, for

8 The insurance scheme in question would have to be a collective one to ensure that DiDIYers, who typically do not have the kind of financial resources available to commercial sellers, could afford participating in it (see Berkowitz, 2015). How exactly such a scheme might be implemented is a matter for further discussion.

all they know, contain some dangerous flaws – especially considering that they already have various alternatives at their disposal that have been certified as safe. Yet we can acknowledge this and still hold that it is preferable to have a system that minimizes people's risk of getting harmed by such files, both out of concern for their well-being and to avoid increasing the costs of medical care. Furthermore, the "minimalist" libertarian proposal under consideration does nothing to help people make informed decisions regarding which files, and which procedures to use in order to avoid unpleasant surprises. But clearly, most people want to be able to avoid unsafe files and procedures, and it is not paternalistic to help them do so. Therefore, we will now consider an alternative proposal that would create a special structure designed to offer people guarantees of safety and quality, while at the same time leaving them free to take risks with unmonitored files if they so wish, and avoiding interference in the management of existing project-sharing sites like Thingiverse.

3.3.2 Creating a special structure ("clearinghouse") guaranteeing the safety of CAD files

Such a solution is proposed by Allison Harris in relation specifically to files for 3D printing, but it might be extended to CAD files for the manufacture of DiDIY products more generally. Harris thus proposes to institute "a clearinghouse for the distribution and sale of authorized 3D printer CAD files" (Harris, 2015). Such a structure (Harris does not specify whether it should emerge from the public or private sector) could even be subject to strict liability, as it would have the resources necessary to "spread the cost of product risk to the masses through use of insurance" (ibid.). At the same time, Harris's solution would still allow the maker movement to operate as it already does, and for websites to distribute CAD files freely and based on the principle of "user beware". To sum up, "consumers will have the choice to either pay for an authorized design or download a free, but potentially dangerous file". While Harris does not hold that her proposed solution would completely solve the challenges for courts of assigning liability, she nevertheless suggests that it would "restore a degree of balance between innovation and consumer safety and protect the foundation of product liability law for the future" (*ibid*.).

Harris's solution holds much appeal. While allowing, just like the libertarian view, the free dissemination of CAD files via existing channels, thereby promoting innovation, creativity, and global sustainability, it has the advantage of securing a trusted source of digital blueprints for users. Also, insofar as her proposed clearinghouse would contract liability insurance, it would guarantee that consumers would get compensated for any harm resulting from a defective file, if getting hobbyist providers of CAD files or DiDIY products to subscribe to collective insurance were to prove unfeasible. A possible reservation that Harris's proposal might elicit is that, since the authorized files available through the clearinghouse would need to be purchased, designs available for free on project-sharing websites like Thingiverse would be economically more attractive, which would give people an incentive to run the risk of using potentially unsafe files. It is debatable, however, whether this is really a drawback of Harris's proposal: after all, perhaps a libertarian would be right to interject here that if people are willing to take extra risks in order to save money, then they should be free to do so, while at the same time bearing the consequences of their choices.

A distinct though somewhat analogous risk would be the threat of piracy: one might worry that the designs sold by the clearinghouse would, shortly after having been put on sale, become available for free on illegal file-sharing websites. However, while it does seem reasonable to expect a certain degree of piracy to occur, it is unclear that it must necessarily reach such a magnitude as to undermine the viability of the clearinghouse. After all, online services selling digital files like the iTunes Store are still viable despite competition from pirates (and the associated loss of revenue). Furthermore, it might prove challenging for pirates to gain the trust of consumers who are risk-

averse enough to only want to use files that have been certified as safe by such as clearinghouse – especially as unsafe designs would not simply threaten to harm one's computer, but could result in actual physical harm to the user.

It is worth noting here that something very close to Harris's solution seems about to be implemented in the real world. Consider Fab Market, a new online shop for locally made products. Their website, which is still in beta mode as of February 2017, invites anyone who so wishes to submit a design to them. If someone's creation is approved, that person will then be invited to their local Fab Lab[9] for prototyping and testing. Once all those procedures have been successfully completed, both the design and the product can then go on sale on the Fab Market website: products are sold as either "ready for fabrication" (i.e., in the form of an open source file) at the modest cost of 5 €, "ready for assembly", or "ready for use", the latter two options involving higher prices than the first one (often significantly higher).[10] This is arguably a very welcome initiative with significant affinities to Harris's idea, plus the added advantage of offering open source designs. Nevertheless, two issues remain. First, Fab Market does not appear to have liability insurance to ensure compensation for those who might get harmed by products purchased from their site. Contracting such insurance, if possible, would be highly desirable, as argued in D6.1. One way in which this might be done would be to give consumers the option, if they so wished, of benefiting from liability insurance for an extra fee, somewhat in the way a number of airlines give their customers the option of purchasing travel insurance for their trip. The question would be whether the relevant fee could be low enough to allow the designs and products in question to remain competitive in the marketplace. Secondly, one might wonder whether the testing procedures carried out for the products to be sold by Fab Market are adequate. Indeed, as long as an initiative of this kind has not grown enough in size to count as a business seller, it will not be legally required to comply with the EU regulations on product safety that we have previously outlined. It therefore seems important that the Fab Labs in charge of product testing should collectively agree upon an adequate set of standards to guarantee safety – even though the fact that the Fab Market initiative is co-funded by the Creative Europe Programme of the European Union can be expected to promote rigour and accountability on this issue.

Granting that the Fab Market model has much to recommend itself, let us now consider whether it might be desirable to introduce measures that would improve the safety of the files on offer on free project-sharing platforms as well.

3.3.3 Monitoring file quality on project-sharing platforms through online word-of-mouth

One option that has been suggested (e.g., by Osborn, 2014, pp. 596-7) to ensure some form of quality control of the CAD blueprints made available online would be to have a system analogous to what we see on websites like Amazon or TripAdvisor. Namely, this system would involve users of the relevant project-sharing website, like Thingiverse, rating either the files available for download on the site, or the users who uploaded them. Now while such a ratings system might be a useful source of feedback for both designers and users (e.g., regarding the practicality of a particular object), it seems to us that in the case of unsafe artefacts, it might be enough to have a system allowing users to report such artefacts to the website that hosted them. In fact, such a system already exists on websites like Thingiverse, which has a "report thing" function for each item the design of which they make available. The question is, what exact action does such a website take when a design gets reported to them for being unsafe. Presumably, the incriminated design should be removed from the website, if it could be established that the complaint made about it was

9 Provided that it is part of the FabShop Network associated with Fab Market.
10 See http://market.fablabs.io/#fabshop [accessed 14 February 2017].

warranted. Perhaps the user who uploaded it should also get banned, at least if caught repeatedly uploading such designs and after they had received appropriate warnings. To ensure that the websites in question would indeed take such action in circumstances of this kind, regulators could either engage in dialogue with them to encourage them to adopt such a policy, or, if necessary, pass laws requiring them to implement it.

Such a solution would not seem to require meddling significantly with the activities of the project-sharing websites concerned (beyond requiring them to evaluate the occasional report of an unsafe design and to take appropriate action in response).[11] On the other hand, it would only offer limited protection to prospective users of the designs. First, the system would involve taking down an unsafe design only after it had been reported as such by someone, which in at least some cases will mean after someone had already been harmed by the artefact in question. Some users might need to serve as "guinea pigs" in order to protect others, which would clearly be less than ideal. Secondly, it might not be too difficult for a user who had been banned from a site to sign up again using a different username and/or personal details, or for someone to re-upload an unsafe file under a different name.[12] Thus while the proposed banning system would still have a protective effect for users, this effect would necessarily be limited. Still, would it not be enough? Perhaps it would be, especially if combined with Harris's proposal outlined in the previous section, yet let us now consider an alternative that seeks to offer better protection to prospective users by monitoring file quality at an earlier stage.

3.3.4 Monitoring file quality *before* allowing them to be made available online

An optimal scenario would arguably be one in which we could completely prevent dangerous files from being made available online – at least on popular project-sharing sites. Heidi Nielson argues in favour of such a scenario when she writes that "policymakers could seek cooperation from Thingiverse to ensure that CAD-file designers are identifiable or to require testing the reliability of CAD files before allowing files to be posted on the site" (Nielson, 2015, p. 619 n63).

While such a solution would seem ideal, it would also seem to impose a much greater burden on the relevant websites, since it would require checking all files prior to allowing them to get uploaded, as opposed to a select few that had been reported as unsafe by users after being uploaded. This would be impractical, at least in the present state of things, as well as undesirable if we wish to help such sites remain hubs of creativity and innovation. However, this could change in the future if new technology became available that would greatly facilitate such prior testing of files. Already today, software exists that can automatically repair certain defects in CAD files, defects that would for instance result in a file not getting read by a 3D printer.[13] To the best of our knowledge, such software is not yet able to correct design defects that would make the final object dangerous – or, perhaps more plausibly, at least identify and flag, or automatically remove, such defective designs. Nonetheless, it does not seem crazy to think that such a capacity might be developed in the relatively near future. If this happens, we will then have an ideal tool that policy makers could reasonably require all the major project-sharing websites to use. For the moment, however, such a solution still lies in the future.

11 Though one might conjecture that such meddling would already be resented by the people running those websites. Somewhat encouragingly, however, Nielson writes that "the industry has already proven to be engaged and willing to cooperate with various government agencies, including the Patent and Trademark Office and the Food and Drug Administration" (Nielson, 2015, p. 619 n63).

12 Admittedly, this problem could be addressed by requiring that people who upload CAD designs online remain identifiable (Nielson, 2015, p. 619 n63). This more intrusive solution, however, would still not resolve the first problem just described.

13 Staples, for instance, provides such a software as part of their 3D printing service: .

3.3.5 Extending strict liability to hobbyist sellers of DiDIY products

A final option we will consider, the most legally constraining of all those listed here, would involve changing existing European law by extending strict liability to hobbyist sellers of DiDIY products. This would mean amending the EU's Product Liability Directive to remove the exemption clause for those who are manufacturing or distributing items in a way that does not represent their "business". Clearly, the main drawback of such a stringent solution is that it would force such sellers to face potential liability costs that they might not be in a position to absorb. This would rapidly lead them to end their activities, together with any benefits these might have brought to users.

In the American context, Nicole Berkowitz has proposed a more nuanced solution that would help avoid such undesirable consequences. Namely, she proposes "to create a separate category and legal standard for 'micro-sellers'", whom she describes as "the sellers that are not in the best position to spread or absorb the losses and do not have superior bargaining power over their customers" (Berkowitz, 2015, p. 1049). Micro-sellers, on Berkowitz's proposal, would get the chance to avoid strict liability in accordance with the following guidelines:

> under my proposed "micro-seller" affirmative defense, once the plaintiff establishes that the product was defective and caused his or her injury, the seller will have the opportunity to avoid strict liability by establishing that strict liability, in fairness, should not apply. In its fairness analysis, the court should consider factors such as (1) the seller's experience in manufacturing, selling, or designing products, (2) the scale of the seller's business in units and dollars, (3) the seller's ability to spread costs or buy insurance, (4) the societal desirability of the specific product at issue, and (5) the seller's good faith" (*ibid*.).

Perhaps such a flexible proposal could be adapted to the European context. It would have the advantage of avoiding the drawbacks of a wholesale extension of strict liability to all hobbyist sellers, while still allowing to assess each case on its own merits. Nevertheless, implementing something like Berkowitz's proposal would, first, still mean that some victims of injuries from DiDIY products would be unable to claim compensation from their injuries; and secondly, it would not introduce any additional quality control for CAD files that were being distributed for free (i.e., not by sellers). It thus seems that, while a straightforward extension of strict liability to all seller of DiDIY products (and perhaps also CAD files) would be indefensible, a more nuanced proposal like Berkowitz's might be worth considering. Even if adopted, however, it would still need to be coupled with one or more of the other solutions we have examined so far.

4. Conclusion

The potential of DiDIY to help promote creativity, and its many further benefits, is very much to be welcomed and encouraged. While emphasizing that fact, this deliverable has also considered some of the challenges that products of creative DiDIY might raise for existing regulations and institutions, in particular when it comes to product safety and liability. We identified creative DiDIY consumer goods as the category most likely to raise such challenges, and surveyed possible solutions, pushing further the discussion initiated in D6.1. We saw particular promise in the proposal to create a clearinghouse guaranteeing the safety of the CAD files it made available for purchase (ideally on the model of Fab Market, which uses open source designs), and in technological solutions (provided that these can be developed in the near future) that would allow to, if not automatically repair, at least identify and remove, defective designs distributed online.

We fully acknowledge that further reflection and discussion will be needed on these matters in the future, informed by the latest evidence about the state of development of DiDIY tools, and about the degree to which creative DiDIY products will been disseminated through society. For the time being, however, we would suggest that it is preferable not to overemphasize the regulatory challenges that creative DiDIY might present. In addition to the empirical uncertainties associated with this issue, we have also mentioned that several forms of creative DiDIY can be expected to ultimately produce items (e.g. custom-made DiDIY drugs, commercial products from co-creation initiatives like FirstBuild) that will be covered by existing European regulations on safety and liability. Although this might initially sound like a paradox, DiDIY – including creative DiDIY – need not necessarily be divorced from professional work.

5. References

ALLEN, N. 2013. Why 3D Printing Is Overhyped (I Should Know, I Do It For a Living). Gizmodo [Online]. Available: http://gizmodo.com/why-3d-printing-is-overhyped-i-should-know-i-do-it-fo-508176750 [Accessed 13/2/2016].

BARNATT, C. 2014. *3D Printing: Second Edition*, CreateSpace Independent Publishing Platform.

BERKOWITZ, N. D. 2015. Strict Liability for Individuals? The Impact of 3-D Printing on Products Liability Law. *Washington University Law Review,* 92**,** 1019-53.

BRICK, J. 2016. A 3D Printer For Pills Brings The Pharmacy To Your Home. *PSFK* [Online]. Available: [Accessed 27/6/2016].

COUNCIL OF THE EUROPEAN COMMUNITIES 1985. Council Directive of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products. *In:* EUROPEAN COMMUNITIES (ed.). Brussels: Official Journal of the European Communities.

DE CLERCQ ADVOCATEN NOTARISSEN 2015. The Legal Aspects of 3D Printing from a European Perspective. Leiden/Den Haag: De Clercq Advocaten Notarissen.

EUROPEAN COMMISSION 2016. Commission Notice of 5.4.2016: The 'Blue Guide' on the Implementation of EU Product Rules 2016. *In:* COMMISSION, E. (ed.). Brussels: European Commision.

EUROPEAN MEDICINES AGENCY 2014. The European Regulatory System for Medicines and the European Medicines Agency. London, UK: European Medicines Agency.

EUROPEAN MONITORING CENTRE FOR DRUGS AND DRUG ADDICTION. 2012. *Legal Topics Overviews: Classification of Controlled Drugs* [Online]. Available: [Accessed 26/6/2016 2016].

EUROPEAN PARLIAMENT & COUNCIL OF THE EUROPEAN UNION 2001. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety. *In:* UNION, E. (ed.). Brussels: Official Journal of the European Union.

EUROPEAN PARLIAMENT & COUNCIL OF THE EUROPEAN UNION 2008. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the Marketing of Products, and Repealing Council Decision 93/465/EEC. *In:* UNION, E. (ed.).

FEDERAL MINISTRY OF FOOD AND AGRICULTURE. 2014. *Food Control and Inspection in Germany* [Online]. Available: https:// [Accessed 27/6/2016 2016].

FIORETTI, M. 24 March 2016 2016. Digital DIY Helps Artisans to Produce Better Products. *DiDIY Blog* [Online]. Available from: 2017].

HARRIS, A. 2015. The Effects of In-home 3D Printing on Product Liability Law. *Journal of Science Policy & Governance* [Online], 6. Available: [Accessed 02/02/2016].

HIPOLITE, W. 2014. Master's Student Uses 3D Printing & Scanning to Create Extraordinary Cinema Presentations. *3DPrint.com* [Online]. Available: https://3dprint.com/18520/3d-printed-cinema/ [Accessed 21/01/2017].

HOLMES, K. 2012. In the Future, Your Drug Dealer Will Be a Printer. *Vice* [Online]. Available: https:// [Accessed 27/6/2016].

INGRAHAM, C. 2015. Portugal Decriminalised Drugs 14 Years Ago – and Now Hardly Anyone Dies from Overdosing. *The Independent* [Online]. Available: [Accessed 27/6/2016].

LEDFORD, H. 2015. Foodies Embrace 3D-Printed Cuisine. *Nature* [Online]. Available: [Accessed 23/01/2017].

LEPAGE, M. 2015. Home-brew heroin: soon anyone will be able to make illegal drugs. *New Scientist* [Online]. Available: https:// [Accessed 28/6/2016].

LINDENFELD, E. Forthcoming. 3D Printing of Medical Devices: CAD Designers as the Most Realistic Target for Strict, Product Liability Lawsuits. *University of Missouri-Kansas City Law Review,* 85.

LIPSON, H. & KURMAN, M. 2013. *Fabricated : the New World of 3D Printing,* Indianapolis, Indiana, John Wiley & Sons.

NIELSON, H. 2015. Manufacturing Consumer Protection for 3-D Printed Products. *Arizona Law Review,* 57**,** 609-22.

OSBORN, L. S. 2014. Regulating Three-Dimensional Printing: The Converging Worlds Of Bits And Atoms. *San Diego L. Rev.,* 51**,** 553-622.

POWER, M. 2013. Drugs Unlimited: How I Created my Very Own Legal High. *The Guardian* [Online]. Available: https:// [Accessed 10/02/2017].

SANDERS, E. B.-N. 2012. Creativity in Strategic Thinking. *In:* WOLTERS, H., GROME, A. & HINDS, R. (eds.) *Enhancing the Army's Strategic Thinking Capability: Insights to Assess, Develop, and Retain Strategic Thinkers.* Progressive Management.

STEPHENS, B., AZIMI, P., EL ORCH, Z. & RAMOS, T. 2013. Ultrafine Particle Emissions from Desktop 3D Printers. *Atmospheric Environment,* 79**,** 334-39.

STEVENSON, K. 2015. Do You Need a Smoke Alarm for your 3D Printer? *Fabbaloo* [Online]. Available: [Accessed 11/3/2016].
TUCCILLE, J. D. 2016. Print Your Own Drugs, For Health and Fun. *Reason.com* [Online]. Available: [Accessed 26/01/2017].
VAN EECKE, P. & DE BRUYN, J. 2015. 3D Printing 101: Atypical Challenges. *DLA Piper* [Online]. Available: https:// [Accessed 29/02/2016].
WIESBROCK, A. 2015. Disabiity as a Form of Vulnerability Under EU and CoE Law: Embracing the 'Social Model'? *In:* IPPOLITO, F. & IGLESIAS SANCHEZ, S. (eds.) *Protecting Vulnerable Groups : the European Human Rights Framework.* Oxford and Portland, Oregon: Hart Publishing.
WIGGERS, K. 2015. Why 3D Food Printing Is More Than Just a Novelty - It's the Future of Food. *Digital Trends* [Online]. Available: [Accessed 27/6/2016].

Annex 1 – Extract from the Makerbot Terms of Use

[Governing the "Thingiverse" website, last updated 28 April 2016; see https://www.thingiverse.com/legal/terms]

Section 7 ("Disclaimers"):

THE SITES AND SERVICES ARE PROVIDED "ASIS" AND "AS AVAILABLE" AND WE (AND OUR SUPPLIERS) EXPRESSLY DISCLAIM ANY WARRANTIES AND CONDITIONS OF ANY KIND, WHETHER EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, QUIET ENJOYMENT, ACCURACY, OR NON INFRINGEMENT. WE (AND OUR SUPPLIERS) MAKE NO WARRANTY THAT THE SITES: (A) WILL MEET YOUR REQUIREMENTS; (B) WILL BE AVAILABLE ON AN UNINTERRUPTED, TIMELY, SECURE, OR ERRORFREE BASIS; OR (C) WILL BE ACCURATE, RELIABLE, FREE OF VIRUSES OR OTHER HARMFUL CODE, COMPLETE, LEGAL, OR SAFE.

TO THE FULLEST EXTENT PERMISSIBLE BY THE APPLICABLE LAW, WE HEREBY DISCLAIM ALL LIABILITY FOR PRODUCT DEFECT OR FAILURE, CLAIMS THAT ARE DUE TO NORMAL WEAR, PRODUCT MISUSE, ABUSE, PRODUCT MODIFICATION, IMPROPER PRODUCT SELECTION, NONCOMPLIANCE WITH ANY CODES, OR MISAPPROPRIATION.

TO THE FULLEST EXTENT PERMISSIBLE BY THE APPLICABLE LAW, WE HEREBY DISCLAIM ANY AND ALL RESPONSIBILITY, RISK, LIABILITY, AND DAMAGES ARISING OUT OF DEATH OR PERSONAL INJURY RESULTING FROM ASSEMBLY OR OPERATION OF OUR PRODUCTS.

MAKERBOT ASSUMES NO RESPONSIBILITY, NOR WILL BE LIABLE, FOR ANY DAMAGES TO, OR ANY VIRUSES OR MALWARE THAT MAY INFECT YOUR COMPUTER, TELECOMMUNICATION EQUIPMENT, OR OTHER PROPERTY CAUSED BY OR ARISING FROM YOUR ACCESS TO, USE OF, OR BROWSING THIS WEBSITES, OR YOUR DOWNLOADING OF ANY INFORMATION OR MATERIALS FROM THE SITES.

SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES, SO THE ABOVE EXCLUSION MAY NOT APPLY TO YOU.

Section 8 ("Limitation on liability"):

IN NO EVENT SHALL MAKERBOT (AND OUR SUPPLIERS) BE LIABLE TO YOU OR ANY THIRD PARTY FOR ANY LOST PROFIT OR ANY INDIRECT, CONSEQUENTIAL, EXEMPLARY, INCIDENTAL, SPECIAL, OR PUNITIVE DAMAGES ARISING FROM OR RELATING TO THESE TERMS OF USE OR YOUR USE OF, OR INABILITY TO USE, THE SITES OR SERVICES OR THIRD PARTY SITES & ADS OR APIS EVEN IF MAKERBOT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. ACCESS TO, AND USE OF, THE SITES AND SERVICES AND APIS AND OTHER CONTENT ARE AT YOUR OWN DISCRETION AND RISK, AND YOU WILL BE SOLELY RESPONSIBLE FOR ANY DAMAGE TO YOUR COMPUTER SYSTEM OR LOSS OF DATA RESULTING THEREFROM.

NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, OUR LIABILITY TO YOU FOR ANY DAMAGES ARISING FROM OR RELATED TO THESE

TERMS OF USE (FOR ANY CAUSE WHATSOEVER AND REGARDLESS OF THE FORM OF THE ACTION), WILL AT ALL TIMES BE LIMITED TO THE GREATER OF (A) FIFTY US DOLLARS ($50); OR (B) AMOUNTS YOU'VE PAID US IN THE PRIOR 12 MONTHS (IF ANY). THE EXISTENCE OF MORE THAN ONE CLAIM WILL NOT ENLARGE THIS LIMIT. YOU AGREE THAT OUR SUPPLIERS WILL HAVE NO LIABILITY OF ANY KIND ARISING FROM OR RELATING TO THESE TERMS OF USE.

SOME JURISDICTIONS DO NOT ALLOW THE LIMITATION OR EXCLUSION OF LIABILITY FOR INCIDENTAL OF CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.