European Network of the Heads of Environment Protection Agencies (EPA Network) - Interest group on Plastics
– Working paper –

Biodegradable Plastics

Approaches and experiences from 16 Members of the EPA Network

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November 2018

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Biodegradable bags intended to be used for biowaste collection at a farmers market in Italy

This paper is supported by the following agencies:

Environment Agency Austria (Austria), German Environment Agency (Germany), The Environment Agency of Iceland (Iceland), Norwegian Environment Agency (Norway), Slovak Environmental Agency (Slovakia), Swedish Environmental Protection Agency (Sweden), Federal Office for the Environment - FOEN (Switzerland), PBL Netherlands Environmental Assessment Agency (The Netherlands), Environment Agency England (UK)

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List of abbreviations

µm	Mikrometer (10−6 m)
ASTM	International Standardisation organisation
CA	Cellulose-Acetate
CEN	European Committee for Standardisation
CIC	Consorzio Italiano Compostatori
CO_2	Kohlenstoffdioxid
DIN	German Institut for Standardisation
EN	European Standard
EU	European Union
EUBP	European Bioplastics
ISO	International Organisation for Standardisation
NF	Normes Françaises
PBAT	Polybutylenadipat-Terephthalate
PBS	Polybutylene succinate
PCL	Polycaprolactone
PE	Polyethylene
PET	Polyethylene terephthalate
PHA	Polyhydroxyalkanoate
PHB	Polyhydroxybutyrate
PLA	Polylactide
PP	Polypropylene
PS	Polystyrene
PUR	Polyurethane
PVC	Polyvinylchloride
t/a	Ton per annum
TPS	Thermoplastic Starch

1. Introduction

Currently, about 60 million tons of plastics are produced in Europe every year[1]. Thereof, about 100.000 tons are biodegradable plastics.[2] Compared to the relatively small market share, the attention biodegradable plastics receive in the public as well as the policy sphere is astonishing. But how could it be any different – the promise of degradability under biological conditions, which the word *biodegradability* seems to imply, sounds all the more tempting the more we know about the devastating impacts plastic waste can have when entering the environment. Biodegradable plastics could be no less than the solution to one of the biggest manmade environmental problems: marine litter.

It is therefore understandable that biodegradable plastics receive a lot of attention, that they have a rather positive image, and that research on and the increased use of biodegradable plastics is promoted. However, skeptical voices are also raised, questioning the degradation of these materials under natural conditions, and asking how biodegradable plastics, once reaching the end of their product life, fit in established waste streams and existing waste infrastructure. Flanked by distinct lobby activities from the industry and without thorough knowledge on the chemical aspects of biodegradable plastics, it can be challenging to properly understand different labels related to biodegradation and the standards some of them are referring to.

Last but not least, biodegradable plastics have an exposed position in the EU Plastics Strategy. Published in January 2018, it aims at addressing the whole lifecycle of plastics, and it draws a vision of the production, usage and waste management of plastics in 2030. Biodegradable plastics are perceived as opportunity and risk at the same time, especially pertaining to a potential increase in littering and to complicating mechanical recycling. The European Commission therefore advises better labeling of biodegradable materials, so that consumers understand how products made of biodegradable materials are properly disposed of.

The current report gives seven recommendations on the use of biodegradable plastics. These recommendations are based on a recent study carried out for the German Environment Agency[3] as well as on a questionnaire developed and distributed by the IG Plastics in the EPA Network. In total, 16 replies from Austria, Cyprus, Denmark, Estonia, Finland, France, Germany, Iceland, Ireland, Italy, The Netherlands, Norway, Scotland, Slovak Republic, Sweden and Switzerland have been received and analyzed. They show that the majority of respondents are rather skeptical towards biodegradable plastics. Most concerns circle around their actual degradability, the contamination of established waste streams, and the risk of increased littering. In light of the scientific literature and the factual experiences with biodegradable plastics, the IG Plastics discussed and developed the recommendations presented in this report.

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[1] Data for 2016 for EU28+NO/CH, www.plasticseurope.org/download_file/view/477/179.

[2] Burgstaller et al: Study on the treatment of biodegradable plastics (2018), available at www.umweltbundesamt.de/publikationen/gutachten-zur-behandlung-biologisch-abbaubarer, p. 37.

[3] Ibid.

The report has three main parts. It starts with the recommendations developed by the IG Plastics. Next, the results of the questionnaire are presented. For those who would like to know more about the specifics of biodegradation, the last part provides insights.

2. Recommendations of the IG Plastics on biodegradable plastics

a) Apply the precautionary principle

The IG Plastics recommends the precautionary principle to guide the use of biodegradable plastics. Currently, these materials should not be considered a solution to the problem of plastic pollution. The preferred options from an environmental perspective should always prioritize prevention and reuse, not switching from one single-use product to another.

b) Biodegradable plastics thwart circular economy

Biodegradable plastics are not part of the circular economy[4] and as such contradict the paradigm of circularity. The materials degrade as fast as possible by design, therefore preventing multiple use. In this sense, biodegradable plastics are not aligned with the waste hierarchy, which considers saving resources and reducing the environmental impact through reuse and recycling of products as pivotal[5]. Biodegradable plastics, on the other hand, are prevalently single-use[6].

c) Standards need to reflect natural conditions

As standards are the most important source of information on the degradability for consumers, the IG Plastics asks to remedy the following shortcomings:

First of all, current standards do not reflect the natural conditions in different environmental compartments or realistic conditions in relation to industrial compost or fermentation plants. Therefore, the IG Plastics calls for a revision of relevant standards in CEN TC 249 according to the range of natural conditions that can be found in Europe, from Portugal to Iceland.

Further, a requirement should be included that the whole product is subject to the certification process, not only parts of it, or powders, films or flakes.

In addition, the whole product including all additives, colors or fillers and their potential ecotoxicity should be subject to the certification tests. This is underlined by the fact that products may contain additives and metabolites which might additionally negatively impact the environment.

d) Need for clear, EU-wide labels

Product labeling of biodegradable plastics has to provide clear instructions to the consumer on how to dispose of an item that is no longer used. For many consumers, the correct disposal route is currently not always obvious. To avoid contamination of waste streams and littering, unambiguous EU-wide labeling is needed. The labels should be combined with clear explanations such as “Only degradable in industrial composting facilities”, “Degradable in-home composting”, etc. One option might also be color coding for an easy identification of the correct disposal route.

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[4] See http://ec.europa.eu/environment/circular-economy/index_en.htm.

[5] It should, however, be noted that the definition of recycling according to the directive on waste (2008/98/EC) includes the reprocessing of organic material.

[6] There is an exception for lightweight plastic carrier bags used for wrapping fresh produce at the point of sale which might also be used for biowaste collection.

e) Possible use of biodegradable bags for biowaste collection

Field trials have shown that the distribution of biodegradable bags can increase biowaste collection. Therefore, some recommend the use of biodegradable bags for this purpose.

However, complaints of operators of composting plants have been registered about the fact that either a) the material does not degrade in the established rotting cycles, or b) that all foreign materials are sorted out in order to prevent contamination of the compost and that biodegradable plastics cannot be distinguished from conventional plastics.

Therefore, the specifications of municipal disposal facilities should always be considered when deciding upon the use of biodegradable bags. If the use of biodegradable bags is not recommended, then alternatives, such as the direct disposal of organic waste into the respective waste bin, should be selected. Some members of the IG Plastics also pointed to other alternatives, such as paper bags.[7]

f) Use of biodegradable materials for non-collectibles

Because of the varying environmental conditions in different environmental compartments as well as in different climatic zones across Europe, the IG Plastics believes that the possible fields of applications for biodegradable plastics are limited. In general, prevention, re-use, collection and recycling should always be the first choice. The IG Plastics therefore suggests limiting the use of biodegradable plastics to *non-collectibles*, such as products

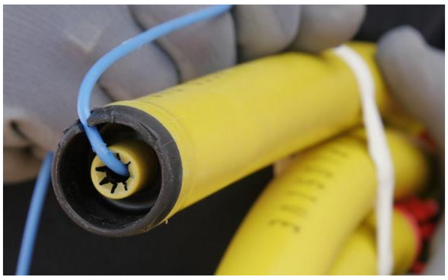
- for which there is currently no non-plastic alternative and
- for which it is currently very unlikely to be collected once turned into waste.

Examples include, but are not limited to:

- Shot bags
- Detonation cords
- Dolly ropes
- Cartridges of fireworks.

Shot bags

Cartridges of fireworks



Detonation cords

[7] Sweden and Denmark also report that in some municipalities, biowaste is collected in conventional plastic bags which are then sorted out in the composting plants. Other countries reject this option due to the risk of increased contamination of the compost with plastic particles.

Their common characteristic is that in the post-use phase, these products do not end up at a defined spot but are distributed across an undefined area for which a collection is not foreseen. This leads to frequent findings of these types of products in the environment, including on beaches.

g) Advise against use of biodegradable plastics for single-use applications

By contrast, the IG Plastics refrains from recommending biodegradable plastics for products which are liable to be littered - often, these are single-use plastics. This is due to the fact that their degradation cannot be guaranteed under the current circumstances and increased inputs of plastics are therefore feared.

In any case, none of the products made of biodegradable plastics should negatively impact the established waste streams.

3. Replies from 16 members of the EPA Network

The IG Plastics developed a questionnaire on biodegradable plastics which was distributed within the EPA Network. The questionnaire addresses three blocks of questions:

- first of all, legal requirements on biodegradable plastics and biodegradable products used in the respective countries,
- second, experiences with biodegradable plastics regarding consumer behavior and the treatment of biodegradables, and
- third, challenges occurring in the use and waste treatment phase with biodegradable plastics.

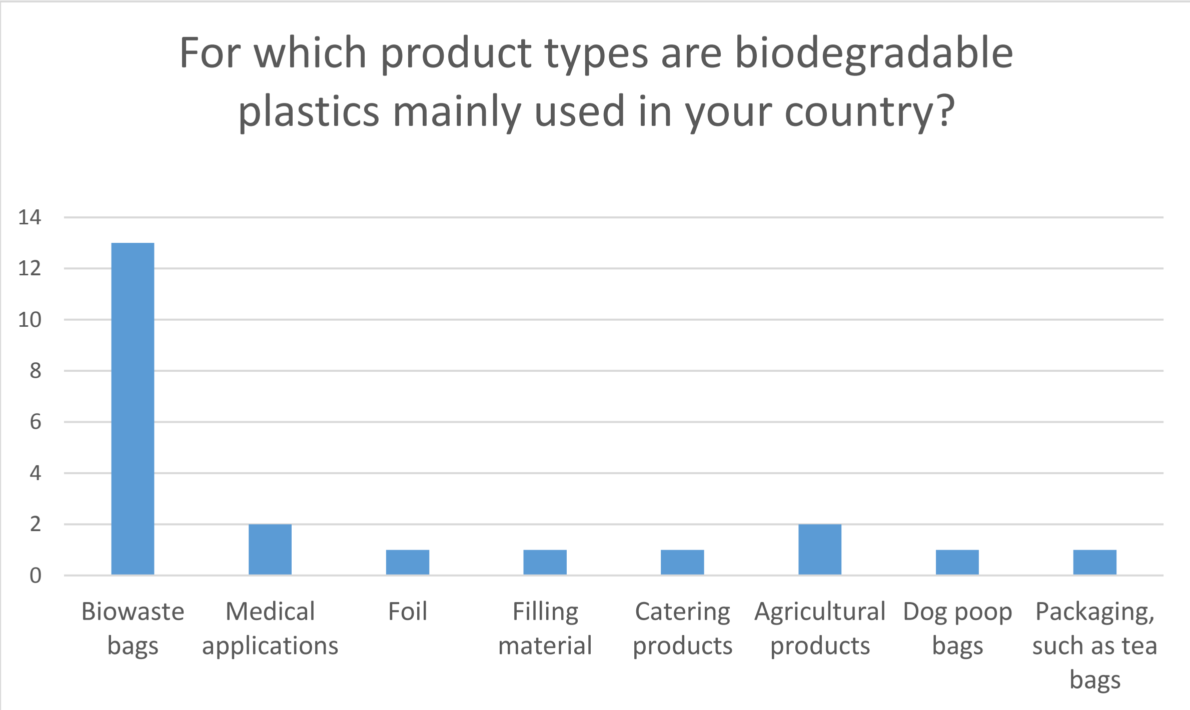
Part A: Biodegradable plastic – basics

A1 - The first question asked whether there are any regulations in place on the use of biodegradable plastics. Most countries denied this. However, two countries did introduce legislative measures, Italy and France.

Italy	Italy aims at the reduction of plastic bags of ultra-light material other than those meeting the following characteristics: biodegradability / compostability in accordance to EN 13432 and a minimum content of renewable raw material.
France	In France, plastics bags are banned since July 1 2016 as part of a 2015 energy bill. It bans plastic bags thinner than 50 micrometres from being distributed at cashiers regardless of volume, and regardless of whether or not the retailer charges customers for the bag. However, biodegradable bags are accepted as an exception to this ban. For plastics bags, disposable cutlery and magazine-"wrap": article 541-10-5 of the French Environment's Codex specifies that bags available in shops to wrap bulk vegetable or fresh food have to comply with the French standard NF T 51-800:2015 9/2015 or a similar foreign standard, for example «OK compost HOME», according to AIB-Vinçotte International specifications.

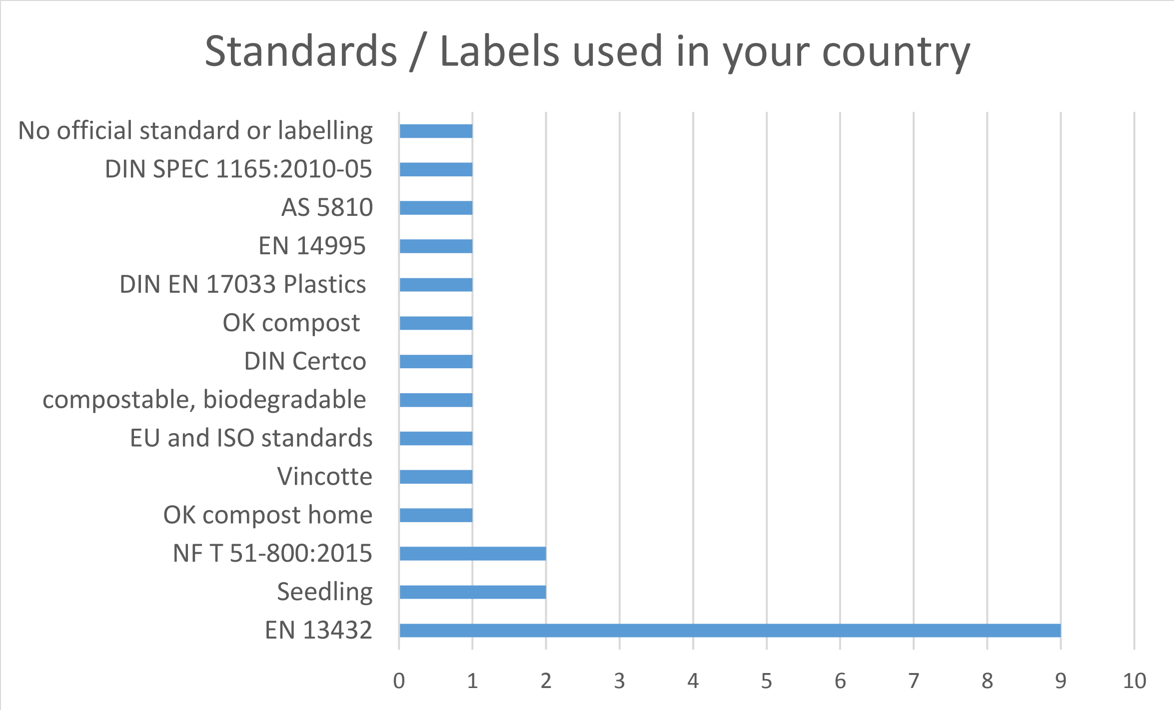
Cyprus reports that biodegradable waste bags are given priority under public procurement specifications, and Switzerland informs that the Federal Office for the Environment will, alongside different stakeholders, work on a list of waste suitable for composting and fermenting – this list will however not be legally binding, only provide informal guidance.

In Germany, there are no specific regulations on biodegradable plastics; however, there are two exceptions addressing biodegradable plastics: first of all, plastic bags certified according to EN 13432 may be used for collecting bio-waste. Similarly, films used in agriculture made of biodegradable plastics, also based on the certification according to EN 13432, are allowed as input streams in composting plants.



A 2- The second question of the first block asked "For which product types (e.g. (bio-) waste bags, agriculture films or mulches, medical products) are biodegradable plastics mainly used (in terms of quantity) in your country?". The most common application is (Bio) waste bags, either distributed in shops or sold on rolls for the use at home. Other applications are medical applications and agricultural applications (such as mulch foils). Single replies included cutlery and cups, filling material, and dog poop bags.

A 3 - The next question asked which standards/labels are used in the respective countries. Please note that the below table is a 1:1 reflection of the replies received and shows what experts understand under the terms "standards" and "labels". Apart from the specification of the norm, also descriptions are used or a logo, the "seedling". The best-known standard by far seems to be the standard EN 13432, which lays down the requirements for granting the "OK Compost" logo.



A 4 - Asked about whether financial incentives are granted for using biodegradable plastics, Austria indicated that there are lower tariffs in place for packaging material put on the market for biodegradable packaging material than for material made of conventional plastics. These are paid to the compliance schemes for the collection and recycling of packaging waste.

Cyprus replied that there is an indirect financial advantage due to the preference of biodegradable plastics under public procurement regulations. All other respondents said that there were no financial incentives in their countries.

Part B: Experiences with biodegradable plastics

B 1 - The next part started with a broad question about main advantages and disadvantages of biodegradable plastics.

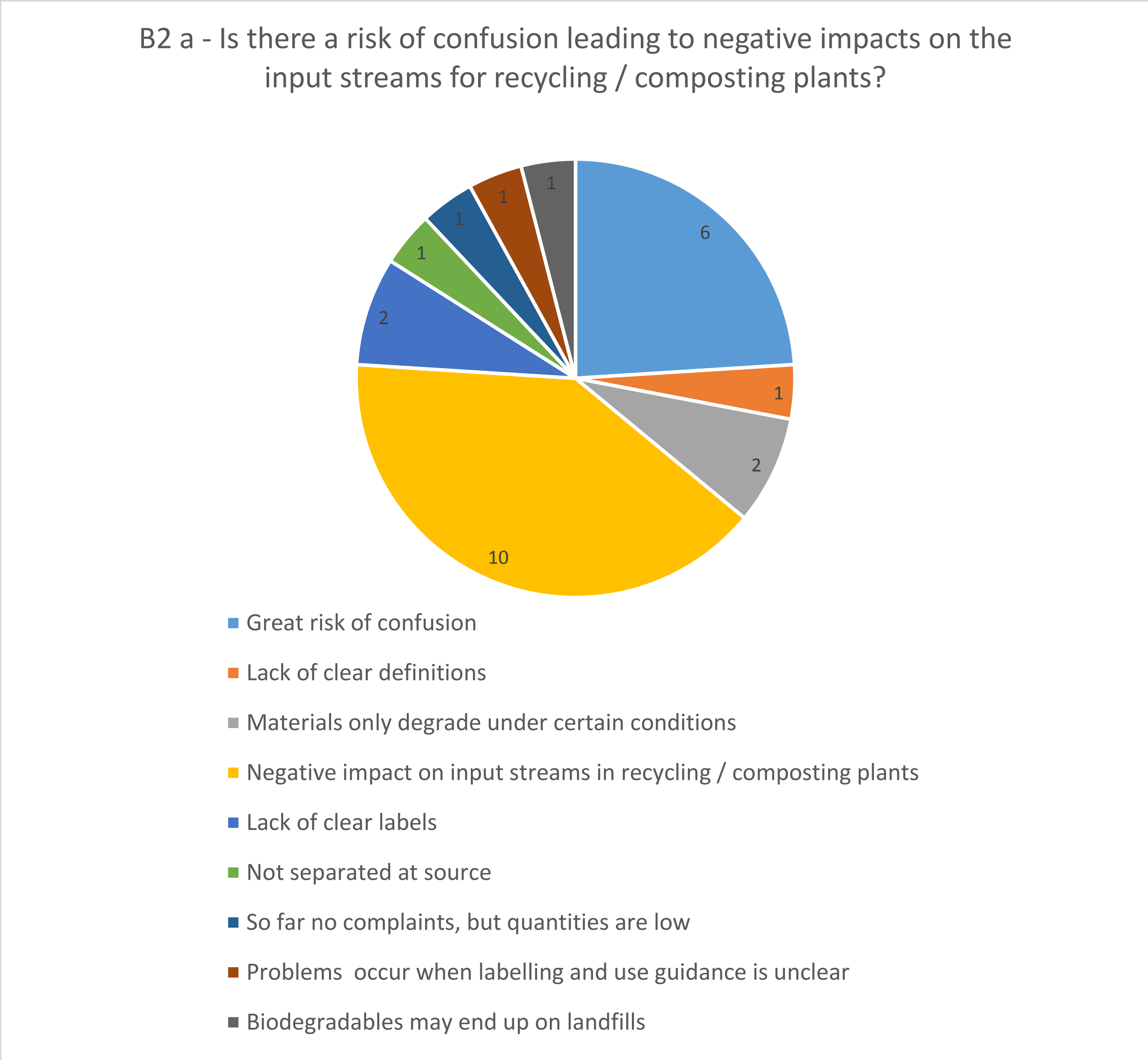
Respondents name different advantages. Please note that in none of the tables, the validity/correctness of the statements is assessed; they merely reflect the range of replies.

B1 Main advantages of biodegradable plastics	
There is an advantage if there is no closed loop alternative possible	1
Use of biodegradable plastics follows waste hierarchy	1
Helps to prevent waste	1
Supports resource conservation	1
Saves energy	1
Biodegradable plastics help reduce impacts of uncontrolled disposal of plastic waste at land and sea	1
Double use: wrap vegetables and use as biowaste bag	1
Help decrease the problem of marine litter	1
(Limited) degradability under certain conditions	1
Mainly made from renewable material, which reduces greenhouse gas emissions	1
Degradation time is lower than conventional plastics	1

In contrast to the advantages, there seems to be more consensus on the disadvantages. The disadvantage most frequently mentioned was that consumers might be confused because of ambiguous labeling of biodegradable products.

B1 Main disadvantages of biodegradable plastics	
Consumer confusion, need for correct labeling	7
Not readily degradable	6
Disturb established waste streams	4
Increased littering	4
Lack of clear definitions	2
Not recyclable	2
Costly	2
Composters need to turn it into compost	1
Questionable carbon footprint in production	1
Strength issues	1
Their wrong disposal can contribute to polluting water and soil and causing damage, even to wildlife	1
If disposed of in landfills: potential impact in terms of biogas production and leachate.	1
Biodegradable bags are designed as single-use packaging and the actual environmental advantage compared to other types of packaging, in particular reusable ones, should be subject to a deeper assessment, for example through a LCA study	1
Limited advantage in closed loop applications	1
No documented advantages	1
Breakdown products unknown	1
Conditions for complete degradation unknown	1
Remaining microplastic in environment unknown	1
Biodegradable plastics may lead to the impression that single use items with a short lifespan do have an ecological advantage, which is not the case. Instead, durability, reparability and a long lifetime of products help to protect resources and to reduce wastes	1
Plastic separation in recycling plants becomes more complex and expensive if biodegradable plastics contaminate the processes	1

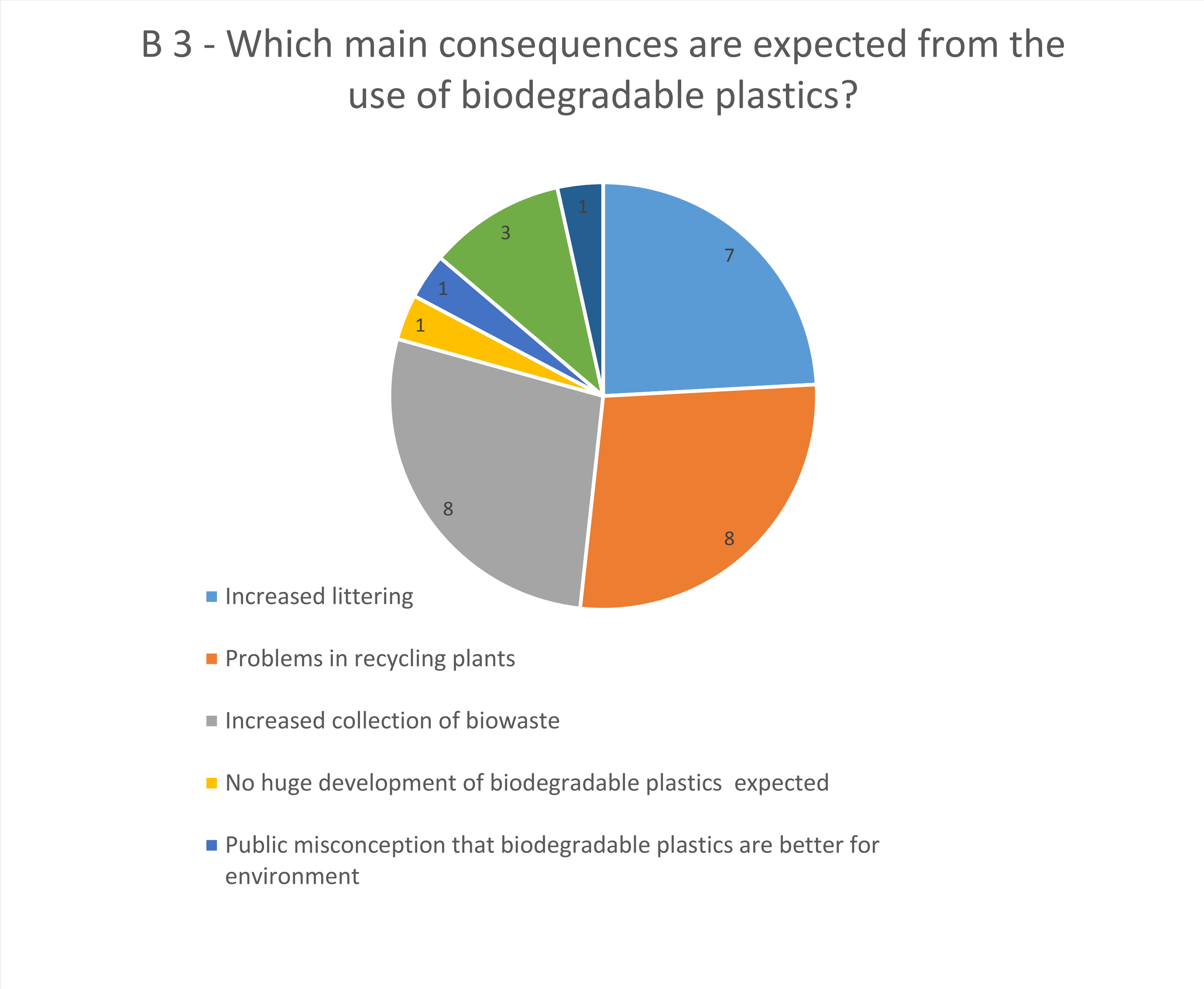
B 2a - Asked whether there is a risk of confusion between biodegradable and conventional plastic materials having a negative impact on the input streams for recycling or composting plants, most respondents replied with yes, albeit for different reasons. Again, confusion among consumers was a concern, followed by the lack of clear labels for biodegradable plastics.



B2 b - Most respondents are concerned about the risk of confusion for consumers between conventional and biodegradable plastics.

B2 b – Is there a risk of confusion for the consumer?	
Yes	12
Littering, also of conventional plastics	3
Educational campaigns should be promoted	2
Difference between different types of degradation and required conditions not clear	2
Public awareness is insufficient	2
No research yet on possible consequences	1
Probably	1
Home composting of materials intended for industrial composting is a potential source of micro plastic inputs	1
Biodegradable plastics may lead to the impression that products made thereof, especially single use items with a short lifespan, have an ecological advantage, which is not the case	1
More conventional plastics may end up in composting plants	1

B 3 – Asked about the expected main consequences from the use of biodegradable plastics, most respondents replied that they expect increased collection of bio-waste, but also increased problems in recycling / composting plants. An increase in littering was also a big concern.



Part C: Challenges with and recommendations on biodegradable plastics

C 1- “Do you have any recommendations regarding the waste management of biodegradable plastics?” was the first question of part C. Here is an overview on the results:

C1 Recommendations on waste management	
Clear communication with public and industry	2
Clear communication about technical possibilities	2
Need for requirements in labelling	2
Info campaigns on dis/advantages	2
No recommendations	2
More research should be conducted	1
Biodegradables should be collected separately from conventional plastics	1
Should fulfill home composting and therefore also requirements for industrial composting	1
Use of biodegradable bags more beneficial when industrial composting is in place, which only few municipalities have	1
Breakdown products must be well understood	1
Litter should be treated as a separate problem	1
Use biodegradables where degradability is functional	1
Use biodegradables where there is an increased risk of marine pollution	1
Better tests of degradation	1
Restriction on what kind of products should be biodegradable	1
Infrastructure for recycling of biodegradable plastics would be needed	1
Clear distinction needed btw biobased and biodegradable	1
Clear info needed whether BDPs degrade in industrial composting facilities	1
None official, but we do recommend if asked that people ask for documentation of micro plastic formation, breakdown products etc.	1
Collection of biowaste can be increased with certified bags	1
Many plant operators are against biodegradable bags for biowaste collection as they cause problems in the process and increase inputs of conventional plastics	1

C 2 - When asked what the main challenges on waste management are, separate collection and treatment of biodegradable plastics was perceived as a problem for three respondents.

C2 What are the main challenges regarding the waste management of biodegradable plastics?	
Separate collection and treatment	3
Biodegradable plastics do not degrade in standard periods in composting plants, which leads to the impression of an impure product (compost)	3
Impression that they are greener products but are not	3
Perceived easy degradability and short product lifecycles contradicts protecting resources and waste prevention	2
Consumers unable to tell difference btw different materials	2
Low public awareness	2
Do not degrade under natural conditions	2
Interfere with recycling systems (contaminate PET recycling streams)	2
Communication w industry, users, multipliers	1
How do these materials behave in the existing pre-treatment and recycling processes?	1
Harmonized definitions need at EU level	1
No	1
May lead to increased methane emissions in landfills	1
Insufficient recycling capacities	1
Sorting	1
Lack of knowledge of the potential for micro plastic formation	1

C 3 – When asked about the applications biodegradable plastics should be recommended for, two respondents said plastic bags, and two recommended the use for biowaste collection, should the use be in line with the conditions in composting plants. It is remarkable that also a number of negative replies were given.

C3 For which applications would you recommend the use of biodegradable plastics?	
Biowaste separate collection (if in line with composting plant)	3
Plastic bags	2
Medical applications	2
Open applications, agriculture and aquaculture, where post-consumer collection / treatment is not possible	1
Fruit and vegetables when also used for food waste collection	1
Currently no specific recommendations, maybe after LCA	1
Could be useful if more biowaste is collected	1
Some specific targeted applications in agriculture or medicine	1
No broad solution	1
Bin liner bags	1
Not recommended for use in agriculture	1
Not recommended for perishable foods	1
Not recommended for technical use	1
If degradable, then for litter-prone uses, such as candy wrappers, take away disposable packaging, and agricultural films	1
Not recommended: grocery /plastic bags	1
Not recommended: waste management bags in general	1
None right now as we haven't seen any valid scientific documentation on degradation etc.	1

Summary of the replies

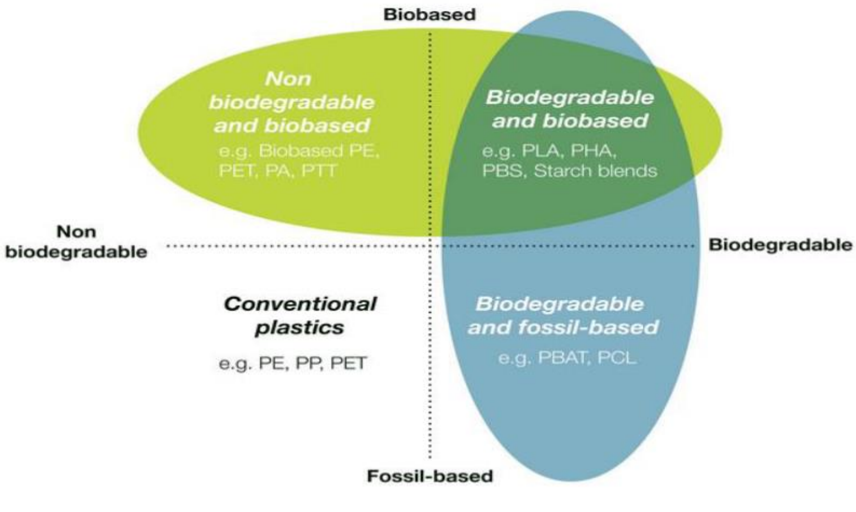
- Hardly any countries have regulations on biodegradables in place. Exceptions are France and Italy.
- The majority of the respondents seem to be skeptical towards biodegradable plastics.
- So far, the main application for biodegradable plastics are by far biowaste bags. Few respondents named additional applications, such as medical applications and agricultural products (mainly foils).
- The standard most commonly known and named by the majority of respondents is *EN 13432*. Follow ups, but with far less replies, are the seedling and NF T 51-800:2015, the French standard for home composting.
- There does not seem to be a clear picture on the advantages of biodegradable plastics.
- On the disadvantages, consumer confusion was the front runner, followed by doubts about the degradability of biodegradable plastics, concerns about the functioning of established waste streams and processes in recycling and composting facilities, and a potential increase of littering.
- Half of the respondents believe that the use of biodegradable biowaste bags will lead to increased collection of organic waste.
- In order to improve the waste management of biodegradable plastics, respondents recommend better information via labelling, and clear communication toward public and industry.
- As a possible application, some respondents recommend the use of biodegradable bags for biowaste collection.

4. The fundamentals of biodegradable plastics

Biodegradable plastics is a term which raises questions among a lot of consumers. For many, the prefix "bio" seems to suggest ecological advantages compared to conventional plastics; others interpret *bio-degradable* as a readiness of these materials to degrade in the open environment or in garden composting. In addition, distinguishing biodegradable plastics from bio-based plastics is challenging. While it can be confusing to find ones way in the world of these new materials, the severe consequence can be improper treatment of products made of biodegradable plastics, potentially leading to increased inputs into the environment. To avoid misunderstandings, it is necessary to properly define biodegradable plastics and distinguish them from other materials. This chapter will look at the material, the market situation and the regulatory side, as well as the standards used to certify biodegradation.

4.1. What are biodegradable plastics? Definition and demarcation to other materials

The term *biodegradable plastics* refers to materials which can potentially be transformed into naturally occurring metabolism end products through biological activity. Ideally, this chemical metabolism leads to mineralization of the products to inorganic matters such as oxygen, carbon and ammoniac. This process strongly depends on the environmental conditions. In order to be labeled as biodegradable, the material or the product made thereof needs to be certified as such.



Source: www.european-bioplastics.org

Biodegradable plastics and *bioplastics* are often used synonymously, and/or not distinctly distinguished. However, the umbrella term *bioplastics* may refer to biodegradable as well as bio-based plastics. The graphic shows that there are bio-based materials, which are not biodegradable, bio-based materials which are biodegradable, and fossil-based materials which are either biodegradable or non-biodegradable. Furthermore, end products can consist of mixtures of these plastics, e.g. a product certified as biodegradable can consist of biodegradable bio-based and biodegradable fossil-based materials. In order to avoid confusion among consumers, it is therefore strongly advisable to always communicate unambiguously which material characteristics are referred to.

Sometimes, oxo-plastics are also mentioned when talking about bioplastics. Based on either fossil-based material or biomass, these materials fragment trough the addition of certain additives through light, warmth, or mechanical load. However, the material does not fully degrade in this process, but only fragments in smaller pieces. There is no internationally accepted standard recognizing oxo-plastics as biodegradable.

4.2 Current situation on the European market

Currently, the global market share of biodegradable and bio-based plastics is rather small, conventional plastics clearly dominate the market with roughly 99%[8]. While the estimated annual use of biodegradable plastics lies at 290.000t, production capacities are believed to be about 850.000t per year[9]. In Europe, the share of biodegradable plastics is estimated to be around 100.000t per year[10]. The biggest quantities in terms of material composition are PLA, PLA blends, as well as starch-copolymer-blends.

At present, applications mainly include the packaging sector, but also agriculture and gardening. The top 5 bestsellers on the EU markets in 2015 are shopping bags, biowaste bags, rigid packaging, disposable tableware and flexible packaging.

Source: nova Institute

Big producers of biodegradable plastics in Europe are based in Italy, France, Germany, and the Netherlands.

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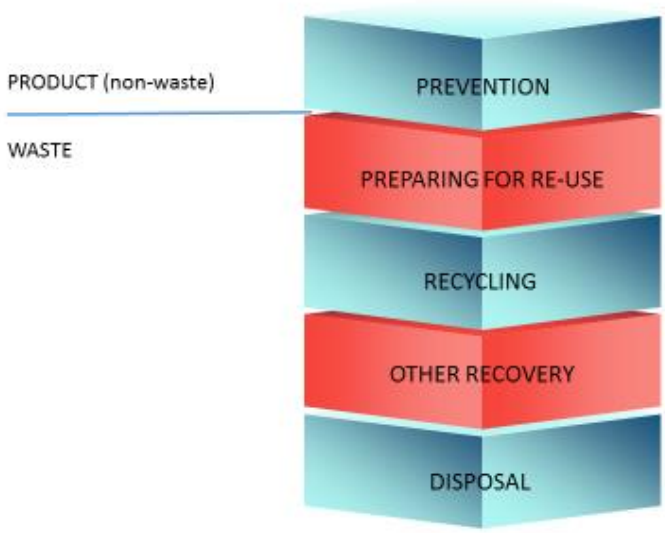
8 IfBB 2016; nova-Institut/EUBP 2017.
9 IfBB; nova-Institut/EUBP.
10 narocon/nova-Institut.

5. Regulations on biodegradable plastic waste in EU

5.1 Possible disposal routes along the waste hierarchy

EU Waste Hierarchy



In the EU, waste treatment is regulated under the Waste Directive (2008/98/EC), which is translated into national law by the member states. The core of the Waste Directive is the waste hierarchy as laid down in Art. 4. Prevention of waste is the key principle of the hierarchy, other treatment options are considered subordinate.

Biodegradable plastics can in theory be treated within most stages of the waste hierarchy.

- Preparing for re-use

Re-using products made of biodegradable plastics is possible under specific conditions.

- Material recycling

Currently not used extensively, material recycling is possible for biodegradable plastics, as several tests and projects have shown[11].

- Material recycling – industrial composting

Industrial composting usually comprises three steps: preparation, intensive rotting, and post-rotting. The material is shredded and homogenized in the preparation phase, then biowaste is degraded under controlled addition of oxygen and humidity. Post-rotting stabilizes the fresh compost

[11] Castro-Aguirre et al. 2016; Kreindl 2013.

and transforms it into finished compost. In different member states, different regulations exist on treating biodegradable plastics pertinent to composting.

- Material recycling – garden composting

Garden composting of biodegradable plastics should only be carried out when the products are labelled and certified as “home compostable”.

- Material recycling – other use / fermentation

In theory, fermentation of biodegradable materials is possible, whereas currently not used in waste treatment.

- Other Recovery – energy recovery
- Energy recovery of biodegradable plastics in co-incineration plants and incineration plants that fulfill the R 1 criteria of annex II of the waste framework directive 2008/98/EC is currently carried out extensively and without restrictions.Disposal – Landfilling and incineration without energy recovery

In the Waste Directive's Annex, there is a non-extensive list of disposal options for waste, which do not represent high quality recycling. Nonetheless, this is how many member states treat waste – among them possibly also biodegradable plastics.

5.2 Current certification schemes in the EU

In the EU, different standards exist on biodegradable plastics. These standards are tested and proven by certification companies. If all requirements of the standard are fulfilled, the products may be labelled accordingly. The acknowledged certifications companies include:

- DIN CERTCO - Germany
  - AfOR – United Kingdom; cooperates with DIN CERTCO
  - Keurmerkinstitut – The Netherlands; cooperates with DIN CERTCO in awarding the Seedling (label developed by EUBP for certifying EN 13432)
  - COBRO – Poland; cooperates with DIN CERTCO in awarding the Seedling (label developed by EUBP for certifying EN 13432)
- Vinçotte – Belgium, since December 2017 part of TÜV Austria Group (OK Compost Labels)
- Certiquality/Italian Composting Association CIC – Italy.

So far, biodegradation can be certified for the following processes / conditions:

- Industrial composting
- Home composting
- Biodegradable under room temperature
- Biodegradable in soil
- Biodegradable in the marine environment
- Biodegradable under freshwater conditions.

Products as well as materials can be subject to certification. The requirements on biodegradation as well as disintegration are important in this regard. *Biodegradation* means the transformation of the organic compounds into carbon dioxide, water and mineral salts (mineralization) as well as new biomass. *Disintegration* means the decomposition of plastics, defined by a quantified disintegration assessment via mass loss of a plastic material.

While the assessment of the biodegradability of a material can only be carried out under controlled lab conditions, the assessment of disintegration is carried out in semi-industrial to large scale industrial criteria under near-life conditions.

5.3 Biodegradable plastics in the EU Plastics Strategy

In the EU Plastics Strategy, published in January 2018, biodegradable plastics are quite prominently addressed. They are described as bearing risks and opportunities, as they might on the one hand play a role in certain applications, but might, on the other hand, complicate mechanical recycling.

The Commission underlines that plastics labelled as "biodegradable" are often only degradable under very specific conditions, which are not met in the natural environment; especially not in the marine environment. Furthermore, plastic products labelled as "compostable" are not necessarily fit for home composting, the Commission continues. Mixing compostable and conventional materials might also lower the quality of recyclates. The Strategy therefore envisages to establish a clear regulatory framework for biodegradable plastics.

One element of this framework the Commission deems necessary is consumers' access to clear and unambiguous information. Moreover, the impression should be avoided that biodegradable plastics could be a solution to the problem of littering. Therefore, clearly regulating which plastics are allowed to be labelled as "compostable" and "biodegradable" is foreseen, and how they should be treated after usage. Those applications with clear ecological benefits should be identified, for which the Commission will then develop measures in order to stimulate innovation and market developments into the right direction.

In order to enable separation and to prevent wrong environmental claims, the Commission aims at developing harmonized regulations for the definition and labelling of compostable and biodegradable plastics. In addition, a life cycle analysis is announced, in which the Commission will assess the conditions under which the use of biodegradable and compostable plastics is advantageous and lay down criteria for such applications.

5.4 Biodegradable plastics in the Proposal for a Directive on the reduction of the impact of certain plastic products in the environment

On May 28 2018, the European Commission published a legislative proposal for a Directive "on the reduction of the impact of certain plastic products on the environment" (COM(2018) 340 final). The proposal is the first document elaborated within the framework of the EU Plastics Strategy. The products addressed are mostly single-use products and are among the 10 products most often found at European beaches ("top litter items"). The proposal includes measures to limit the negative impact of these items on the environment. In this proposal, biodegradable plastics are mentioned in different instances. The proposal says:

> *"The evaluation should also consider whether scientific and technical progress that has taken place in the meantime, including the development of biodegradable materials and the development of criteria or a standard for biodegradability of plastics in the marine environment, as foreseen in the European Plastics Strategy, allows the setting of a standard for biodegradation of certain single-use plastic products in the marine environment. That standard would include a standard to test if, as a result of physical and biological decomposition in the marine environment, plastics would fully decompose into carbon dioxide (CO_2), biomass and water within a timescale short enough for the plastics not to be harmful for marine life and not lead to an accumulation of plastics in the environment. If that is the case, single-use plastic*

products that meet such a standard could be exempted from the prohibition on placing on the market."[12]

This leaves a backdoor for biodegradable plastics potentially replacing conventional plastics in single-use applications. However, it is also highlighted that taking into account different marine conditions is challenging. To date, there are no signs hinting at the Commission acting to promote the use of biodegradable plastics.

6. Biological degradation – fundamentals[13]

In natural environments, microorganisms play an essential role in decomposing organic matters. They are responsible for the degradation of biomass. This process is part of their energy metabolism, with which microorganisms gain energy for the production and synthesis of new biomass.

Under aerobic conditions, up to 40% of the organic substrate can be transformed into new biomass. Under anaerobic conditions, the decomposition happens gradually along a food chain with the combination of fermentation and the development of methane and carbon dioxide as end products. In comparison to aerobic metabolism reactions, anaerobic respiration leads to less energy production, and therefore, also less biomass production. Only about 10-20% are transformed into biomass, the majority is mineralized. The different reactions related to degradation and biomass production under aerobic / anaerobic conditions influence the degradation criteria of biodegradation tests.

The following factors mostly determine biodegradation:

- The amount of microorganisms and the composition of the microbial population;
- Environmental conditions influencing the reproduction, such as humidity, temperature, oxygen content, PH value and nutrient content;
- The bioavailability of organic substrate; for solid matters especially water solubility and hydrolyzability.

Biodegradation of polymers follows a two-step procedure. First, the polymer chain is hydrolyzed in smaller fragments. These are often water soluble and can be taken up by cells. Enzymes are involved in the hydrolysis; chemical-physical processes do also play a role with some polymers, such as PLA. The fragments are further degraded in the cells up to their mineralization / transformation into biomass.

6.1 Biodegradation of plastics under optimal conditions in different environments

In general, the analysis of biodegradability is conducted under lab conditions. This means that full control over parameters like temperature, moisture and ventilation is ensured at all times. In addition, assessing the biodegradation via assessing biological end products (carbon dioxide, methane) or via measuring oxygen uptake can best be carried out under lab conditions, as well as balancing carbon compounds. It is well understood that these controlled conditions cannot reproduce the conditions in all climatic zones and natural habitats or treatment plants.

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[12] See https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM%3A2018%3A0340%3AFIN, p. 23.

[13] This chapter is in large parts based on the „Study on the treatment of biodegradable plastics“, available at www.umweltbundesamt.de/publikationen/gutachten-zur-behandlung-biologisch-abbaubarer.

As assessing the biodegradation of plastics happens via using naturally occurring microorganisms, no definitive general statement can be made on the degradability in all naturally occurring habitats or treatment plants. Because degradation is always strongly dependent on the specific environmental conditions and the origin of the microorganisms used, and again, lab conditions cannot reproduce nature.

6.1.1 Testing methods to proof biodegradation

Laboratory methods assess the general biological degradation of materials. If the degradation process is successful, a naturally occurring enzymatic system is in a position to mineralize the testing material under specific artificial conditions. These lab tests do not allow concluding statements on the behavior of the materials under real-life conditions.

For assessing complete biodegradation of solid matters in aerobic conditions under standardized lab conditions, the production of carbon dioxide as the final product of mineralization is an acknowledged method. Under aerobic conditions, the $C0_2$ production correlates closely with oxygen consumption, which is used as a parameter in some test methods. The primary degradation measured via specific analyses of mass loss is not an unambiguous proof of a complete biodegradation, but only a parameter for assessing the fragmentation of the test material.

As the degradation depends on different environmental conditions, adapted test methods have been developed for different habitats such as composting, soil, and aqueous milieu. These are also available as standardized testing methods. The methods differ especially considering the matrix and incubation temperature. The degradation tests are usually two tests carried out in parallel: one with the test material itself, and a reference approach with a polymer which is known to biodegrade well. This allows to assess the degradation and also the functioning of the testing system.

For lab methods in anaerobic conditions, biogas production (CO_2 and CH_4) is the acknowledged indicator for complete biodegradation.

The criteria required for the degradation for biodegradable plastics, meaning the minimum degradation after a defined time, is laid down in test programs. They describe the requirements for specific testing goals and are also published as standards. The degree of degradation of 90% in all test programs can be understood as a rather restrictive criterion. Up to 40% of the test material is transformed into new biomass. A degradation degree of 90% can only be achieved if part of the newly built biomass is mineralized again. It should be noted that degradation of 90% in absolute terms can usually only be achieved after very long duration of the tests – also for the degradable reference material. Therefore, an alternative assessment criterion is the degree of degradation of the test material relative to the degree of degradation of the reference material. Here, a degree of degradation of at least 90% of the maximum value of the reference material has to be reached.

Testing methods of biological degradability

	Milieu	Temperature	Measuring parameter	Mass ratio test material/ Inoculum	Relevant standards
Aerobic	Compost	57 ±2 °C	CO_2-Production	14 % (TM)	ISO 14855-1
	Compost	25 ±5 °C	CO_2-Production	14 % (TM)	ISO 14855-1 at 25 ±5 °C
	Fresh water	20 – 25 °C[14]	O_2-Use CO_2-Production	min. 100 mg/L	ISO 14851 ISO 14852
	Soil	20 – 28 °C	O_2- Use or CO_2-Production	0,1 %	ISO 17556
	Marine water[15]	30 ±2 °C	CO_2-Production	min. 267 mg/L	ASTM D6691
Anaerobic	Sludge	35 °C	Production of CO_2 and CH_4 (Biogas)	200 mg/L 100 mg OC/g TM	ISO 14853
	High-Solid Digestate	52 ±2 °C	Production of CO_2 and CH_4 (Biogas)	1,5 – 2,0% 7,5 – 10 % (TM)	ISO 15985

Anaerobic degradation is only optionally required in test programs for composting (EN 13432, EN 14995, AS 4736). After two months at the longest, a degradation degree of at least 50% of the theoretical value is required. Additional standards for assessing the anaerobic degradation of plastics are under preparation.

In addition to biological degradation, disintegration tests are required for certifying biodegradable plastics. The disintegration of these plastics is tested under conditions close to reality. What is essential for assessing disintegration is the declaration of the layer thickness under which the material is assessed.

6.1.2 Plastics with proven biological degradation

Please note that in this paragraph, only results from tests in which the degradation was assessed via mineralization are referenced.

Literature only refers to degradation results under thermophile composting conditions. These are relevant for the test goal “industrial composting”. The test setup did not in all cases allow for reaching a plateau phase but ended relatively quickly. However, also in those cases, degradation of the respective polymer could be assessed. In case of TPS, PHA, PLA, PBAT, PBST and PBS, the maximum degradation time is significantly below the limit of six months. Regarding the timeframe of biological degradation, TPS and PHA show the fastest results (ca. 30-45 days), followed by PLA and PBAT / PBST (60-80 days). PBS takes the longest to degrade entirely, namely 160 days, mostly explained due to its high percentage of crystalline structure.

[14] It should be noted that the temperatures used in the standard do hardly reflect real life conditions, especially not broadly across Europe.
[15] Ibid.

An overview on biological degradation of biodegradable plastics in soil can be found in the annex (table 2).

There are almost no results on the biological degradation for home composting to be found in literature, which means at temperatures of up to 30 degrees Celsius. Under composting conditions with temperatures between 50 and 60 degrees Celsius, PLA degrades entirely within a few weeks. In compost and soil under environmental conditions, so less than 30 degrees Celsius, the degradation progresses only slowly. This is due to the fact that the hydrolysis of the polymer required for degradation happens under physical-chemical conditions at higher temperatures, contingent on the crystallinity of the material. If not composted in composting plants, but under natural conditions in soil and waters, the required temperatures cannot be reached.

An overview on biological degradation of biodegradable plastics under composting conditions can be found in the annex (table 3).

When compared to the reference material cellulose, it becomes clear that the degradation speed in soil at room temperatures is much slower than under hot rotting compositing conditions. In addition to that, the thickness of the material is a decisive factor for the degradation speed. For example, polymer films of below 100 µm are much faster mineralized than such films with >500 µm.

The below table gives an overview on the materials certified with Vinçotte and their respective thicknesses.

Certified materials and thicknesses

Thickness [µm]				
Brand name	**Polymer**	**OK Compost**	**OK Compost HOME**	**OK biodegradable MARINE**
Ecovio FT 2341	PBAT/PLA	249 µm	53 µm	
BIOPLAST 505	Starch-Blend	250 µm	37 µm	
BIOPLAST 500	Starch-Blend	172 µm	65 µm	
Mater-Bi NF 01U	Starch-Blend	100 µm	67 µm	
Mater-Bi EF 01A	Starch-Blend	100 µm	16 µm	
AONILEX X151A	PHA	130 µm	130 µm	47 µm
MIREL M2100	PHA	690 µm	1000 µm	45 µm
RWDC PHA Copolymer	PHA	390 µm	85 µm	85 µm
DaniMer 12291	PHA	90 µm	90 µm	
Meridian	PHA	430 µm	430 µm	19 µm
BioPBS FD 92	PBS	87 µm	85 µm	
GS Pla FD92	PBS	87 µm	85 µm	
BIONOLLE 5001 MD	PBS	126 µm	126 µm	
BIONOLLE STARCLA 1Xln	PBS	129 µm	79 µm	

Source: own after Vincotte 2017b, 2017c, 2017a

In aqueous milieus, some polymers show faster degradation rates than in soil. It should be noted that the temperatures for these tests lie at 20 degrees Celsius at the lower end, and up to 60 degrees Celsius. In these conditions, thermoplastic starch and PHA and PCL are mineralized within four to eight weeks. Other materials, such as PLA and PBAT, degrade much slower. In marine waters, starch-based materials and PHA and PCL show good degradation rates and are in some cases entirely degraded within 28 days. PLA, PBS and PBAT only degrade slowly. Here, temperatures of 20 degrees Celsius at the minimum, up to 28 degrees at the maximum are used. Please take a look at table 5 in the annex for an overview on different real-life trials.

The degradation characteristics of different polymers play an important role concerning the certification in the respective sphere of application. Certification for home and garden composting does not include PLA-based materials, or blends with only little PLA content. Starch-based materials dominate in this sphere, as they degrade well under the specific environmental conditions, such as PHA and PBS. Certificates for materials to be applied in aqueous milieus have so far been granted for PHA-based materials. Alongside the material, the thickness of the films plays an important role for each application.

6.2 Timeline of biodegradation in situ in soil, freshwater and marine waters under real world conditions

There is a number of publications on the degradation of biodegradable plastics in fresh water, marine waters and soil, with an emphasis on soils. It should be noted that for biodegradation assessments under natural conditions, the test procedures vary from those under laboratory conditions. This is due to the fact that natural environments are open systems, in which it is not possible to assess biodegradation through assessing the end product carbon in environmental compartments. The most important parameter is therefore assessing the degradation of the plastic material, mostly via weight loss and / or surface area analysis or visual assessment.

6.2.1 Degradation in soil

For degradation in soil, the environmental conditions are relatively good compared to other environmental compartments. The main reason is that in soil and compost, over 90 different types of microorganisms have been identified which are able to digest biodegradable plastics (Emadian et al. 2017). They consist of different bacteria, but mostly also fungi. Especially in soils, a bigger variety of microorganisms can be found than in aquatic environments.

For soil degradation, first assessments reach back to the 90ies. Tests in France showed that after 24 months, PHB, PCL, PCL/TPS and Cellophane were fully degraded (Calmon et al. 1999). For PLA, the results were far less clear – between 0 and 100% degradation was assessed. Similar to the tests conducted under controlled conditions, there was a clear correlation between the thickness of the material and the degradation rate – the thicker the material, the less degradation took place. In comparison, PE was not degraded at all.

In Italy, the degradation of starch-based polymer was tested (Mater-Bi®). Within three months in summer, less than 5% of the material degraded. The same material was also tested in Portugal, used as mulch film (Costa et al. 2014). Within five months, no degradation of the foils could be observed.

Tests in Greece with PLA films showed that during an eleven months period, only little degradation happened, if any at all. PLA fibers were not degraded at all (Rudnik und Briassoulis 2011).

Similar tests were also conducted in some Asian countries, in the US and Australia. All results show that the degradation of biodegradable plastics in soil strongly depends on the environmental conditions, mostly temperature, moisture and pH-value. Starch-based polymers are degraded after about 12 months in favorable conditions. For PLA-based materials, degrees of degradation vary considerably, from not at all up to completely degraded after 24 months. This also matches the test results on PLA under lab conditions at room temperature.

6.2.2 Degradation in freshwater

In freshwater as well as in marine waters, smaller concentrations of microorganisms can be found than in soil and compost. The microflora mostly encompasses bacteria, not fungi, which apparently account for the majority of the degradation process.

There are only few publications on biodegradable plastics under realistic freshwater conditions (Brandl und Püchner 1992; Gilmore et al. 1993; Volova et al. 2007; Showa Denko K.K. 2015; Accinelli et al. 2012). It should also be noted that the test designs varied strongly. Therefore, a summary is presented here. The results of the tests show that the defining parameters for degradation in fresh water are mostly temperature and oxygen content. Even after several months, the degradation rates in some cases only reached 1,5%, up to about 90% after 200 days in one case. As the case numbers are small and the results varied that much, a case-by-case assessment seems even more needed than for degradation in soil.

6.2.3 Degradation in marine waters

Tests with different biodegradable plastics in marine waters show that materials like PHA, PCL and starch-based materials degrade under natural conditions to varying degrees. Synthetic polyesters such as PBS and PBAT apparently degrade as well, but much slower within a timeframe of several years. In marine waters, apart from the microbial composition of the habitat, also physical-chemical conditions play an important role. Moreover, the temperature as well as the water depth in which the tests are conducted influence the results.

In the marine ecosystem, six different habitats are distinguished:

- Supralitoral: splash zone; salt meadows and beaches relatively high above sea level
- Eulitoral: tidal zone (wadden sea)
- Sublitoral: coastal zone always under water; tide-ways, seabed
- Deep sea zone
- Sediment: sublitoral and deep sea zone
- Pelagial: water body

For tests in marine waters, there is a standard to proof the degradation in the water body (pelagial). For other marine water habitats, no standardized methods have been developed.

Overall, the literature review shows that the actual degradation of biodegradable plastics depends on various factors, such as temperature, light, and microbial composition.

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Annex

Please note: All tables are based on the "Study on the treatment of biodegradable plastics"[16]. All errors remain the author's own.

Biological degradation (mineralization) of biodegradable plastics in soil

Material	Temperature	Degradation Degree	Time	Source
PBAT/PLA (Ecovio®M2351; PLA 9 %)	max. 28 °C	94 %	181 Days	(Künkel 2017)
PHB (Mirel™ P5001, 85 µm Film) PBSe* (25 µm Film) PBSeT** (25 µm Film) Cellulose paper	25 °C	90,2 % 91,7 % 76,7 % 92,5 %	120 Days 120 Days 318 Days 318 Days	(Wilde et al. 2016a)
PHB (Mirel™ P5001, 85 µm Film) PBSe* (25 µm Film) PBSeT** (25 µm Film) Cellulose paper	28 °C	82,6 % 87,4 % 90,5 % 83,5 %	210 Days	Novamont (Wilde et al. 2016a)
PHBV (60 µm Film) Starch (powder 20 µm) Cellulose (powder 20 µm)	25 °C	65 – 90 % >70 % >70 %	23,4 Weeks 8,4 Weeks 13,8 Weeks	(Arcos-Hernandez et al. 2012)
PHA (620 µm Film) Copolyester/Starch (Ecobras™, 720 µm Film) Cellulose-paper (350 µm)	20 °C	69,2 % 55,1 % 74,2 %	660 Days	(Gómez und Michel 2013)
PLA (powder 500 µm) Cellulose (powder 20 µm)	20 °C	<1 % 76 %	186 Days	Fraunhofer UMSICHT
As powder: PBS PBS/TPS PLA	25 °C	15 % 25 % 12 %	28 Days	(Adhikari et al. 2016)
PHB/HV PCL Mater-Bi Film Cellulose	20 – 25 °C	ca. 35 % ca. 20 % ca. 18 % ca. 48 %	125 Days	(Solaro et al. 1998)
PLA (30 µm Film) PLA (75 µm Film) Filter paper PE	20 – 25 °C	*Mass loss:* 0 % 0 % 100 %	11 Months 11 Months 3 Months	(Rudnik und Briassoulis 2011)
Test material for comparison 3 mm thickness: PCL/TPS (75/16), 9 % Additive	20 °C	*Mass loss:* ca. 37 %	9 Months	(Di Franco et al. 2004)

[16] www.umweltbundesamt.de/publikationen/gutachten-zur-behandlung-biologisch-abbaubarer

Biological degradation (mineralization) of biodegradable plastics under composting condition

Material	Temp.	Degradation Degree	Time	Source
Thermoplastic Starch-(TPS) TPS/PCL (Mater-Bi class Z)	55 °C	>80% >90 % based on reference	30 Days	(Catia Bastioli 1998)
TPS (Powder)	58 °C	73 % 99 % based on reference	56 Days	(Du et al. 2008)
TPS	58 °C	80 %	45 Days	(Shin et al. 2004)
PLA (extruded) PLA/PFF/Starch 80/5/15	58 °C	13 % 53 %	60 Days	(Ahn et al. 2011)
PLA Bottle	58 °C	84 % 98 % based on reference	58 Days	(Kale et al. 2007b)
PLA (amorph) PLA/PBAT (35 µm Film)	55 °C	ca. 70 % ca. 40 %	28 Days	(Tabasi und Ajji 2015)
PHA (Film)	58 °C	79,7 – 90,5 % 95,9 – 108,9 % based on reference	70 Days	(Weng et al. 2011)
PHA (AONILEX)	58 °C	>80 % ca. 60 % reference material	28 Days	(KANEKA Corporation 2014)
PHA PHA/PBAT PBAT (35 µm Film)	55 °C	ca. 80 % ca. 45 % ca. 35 % ca. 90 % reference material	28 Days	(Tabasi und Ajji 2015)
PBS PBS 75 % composit powder 100 µm	58 °C	90 % 90 %	160 Days 140 Days	(Anstey et al. 2014)
PBS (Bionolle 1001 MD, 70 µm film) PBSA (Bionolle 3001 MD, 70 µm film)	58 °C	ca. 90 % ca. 90 %	150 Days 50 Days	(Showa Denko K.K. 2015)
PBS/Starch (Film)	58 °C	100 %	45 Days	(Jayasekara et al. 2003)
PBAT (powder 500 µm)	58 °C	83 % >90 % based on reference	74 Days 64 Days	Fraunhofer UMSICHT
PBST (powder 500 µm)	58 °C	88,5 % >90 % based on reference	74 Days 64 Days	Fraunhofer UMSICHT
PBAT (Film)	58 °C	60 %	45 Days	(Kijchavengkul et al. 2010)
PCL (powder 63 – 250 µm)	50 °C	59 %	11 Days	(Ohtaki et al. 1998)
PCL (500 µm Film)	58 °C	40 %	45 Days	(Shin et al. 2004)
Cellulose-Acetate (CA) CA-1,7 CA-2,5 (powder: 300 – 400 µm)	53 °C	72 % 78 %	24 Days 60 Days	(Gu et al. 1993)

Biological degradation (mineralization) of biodegradable plastics in aqueous milieu

Material	Temperature	Degradation Degree	Time	Source
Freshwater environment				
TPS/PCL TPS/Cellulose >85 % TPS	20 – 25 °C	ca. 90% ca. 80% ca. 95%	55 Days	(Catia Bastioli 1998)
PBS (Bionolle 1001 MD, 70 µm Film) PBSA (Bionolle 3001 MD, 70 µm Film)	25° C	60% >70 % (60% reference material)	90 Days 50 Days	(Showa Denko K.K. 2015)
PHA (AONILEX)	25 °C	>80 % (ca. 75% reference material)	28 Days	(KANEKA Corporation 2014)
PLLA (PLA made of L-Lactid) (Gewebe, 45-50 % cristalline; Film, 30-35 % kristallin)	25 °C 37 °C 55 °C 60 °C	<10% 10% 80% 90%	180 Days 180 Days 210 Days 120 Days	(Itävaara et al. 2002)
PCL (Pulver) PLA (20 µm Film) TPS/PCL (Mater-Bi, 20 µm Film) PBAT (20 µm Film)	30 °C	37,7% 3,7% 42,8% 15,1% (17,3% reference material)	28 Days	(Massardier-Nageotte et al. 2006)
PLA (Powder 500 µm) Cellulose (Powder 20 µm)	20 °C	<10% >70%	118 Days 28 Days	Fraunhofer UMSICHT
Ecoflex® PBAT	20 °C	<10%	500 Days	(Eubeler 2010)
Ecovio® 55 %PBAT/45%PLA Ecovio® 20%PBAT/70%PLA/10%Cit-rofol	20 °C	ca. 35% <10%	350 Days	(Eubeler 2010)

Material	Temperature	Degradation Degree	Time	Source
Marine waters				
PHBH (Powder) PHBH (Film) PCL (Film) PBSA, PBAT, PBS, PLA (Film) (100 µm Film)	27 °C	ca. 52% ca. 23% ca. 14% < 4%	28 Days	(Lepoudre 2017)
Mater-Bi® (22 µm Film) Cellulose paper	20–25 °C sublitoral	68,9% 76 %	236 Days	(Tosin et al. 2012)
PCL (Pulver 500 µm)	20 °C	>90%	28 Days	Fraunhofer UMSICHT
Nylon 4 (25 µm Film) PHB	25 °C	ca. 80% ca. 80%	25 Days 14 Days	(Tachibana et al. 2013)
Ecoflex® PBAT	20 °C	<10%	500 Days	(Eubeler 2010)
Ecovio® 55 %PBAT/45%PLA Ecovio® 20%PBAT/70%PLA/10%Cit-rofol	20 °C	ca. 30% <15%	500 Days	(Eubeler 2010)
PHB PBSe PBSeT* LDPE	25–28 °C	69 – 97% 64 - 100% 18 – 92% <10%	120–180 Days	(Tosin et al. 2016a)