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Risk assessments for quality-assured, source-segregated composts and anaerobic digestates for a circular bioeconomy in the UK

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ABSTRACT

A circular economy relies on demonstrating the quality and environmental safety of wastes that are recovered and reused as products. Policy-level risk assessments, using generalised exposure scenarios, and informed by stakeholder communities have been used to appraise the acceptability of necessary changes to legislation, allowing wastes to be valued, reused and marketed. Through an extensive risk assessment exercise, summarised in this paper, we explore the burden of proof required to offer safety assurance to consumer and brand-sensitive food sectors in light of attempts to declassify, as wastes, quality-assured, source-segregated compost and anaerobic digestate products in the United Kingdom. We report the residual microbiological and chemical risks estimated for both products in land application scenarios and discuss these in the context of an emerging UK bioeconomy worth £52bn per annum. Using plausible worst case assumptions, as demanded by the quality food sector, risk estimates and hazard quotients were estimated to be low or negligible. For example, the human health risk of *E. coli* 0157 illness from exposure to microbial residuals in quality-assured composts, through a ready-to-eat vegetable consumption exposure route, was estimated at $\sim 10^{-8}$ per person per annum. For anaerobic digestion residues, 7×10^{-3} *cases of E. coli 0157* were estimated per annum, a potential contribution of 0.0007% of total UK cases. Hazard quotients for potential chemical contaminants in both products were insufficient in magnitude to merit detailed quantitative risk assessments. Stakeholder engagement and expert review was also a substantive feature of this study. We conclude that quality-assured, source-segregated products applied to land, under UK quality protocols and waste processing standards, pose negligible risks to human, animal, environmental and crop receptors, providing that risk management controls set within the standards and protocols are adhered to.

1. Introduction

1.1. Products from wastes for a circular economy

This paper is a synthesis of 10 years' risk research (Waste and Resources Action Programme, WRAP, 2016a, 2016b, 2016c, 2017a, 2017b) commissioned to inform decisions on declassifying quality-assured, composts and anaerobic digestion (AD) digestates prepared from source-segregated biodegradable materials as wastes; a legal prerequisite for positioning these products within a bioeconomy (Capital Economics et al., 2016). It reveals the burden-of-proof required to examine whether these process residues could re-enter the economy by exploring issues of potential human, animal and environmental risk; and highlights the considerable weight of evidence required to appraise stakeholders of the safety of these products. The authors believe this burden of proof has been underestimated by commentators on the circular economy and that this research has significance for all countries, and certain materials within their economies, making this

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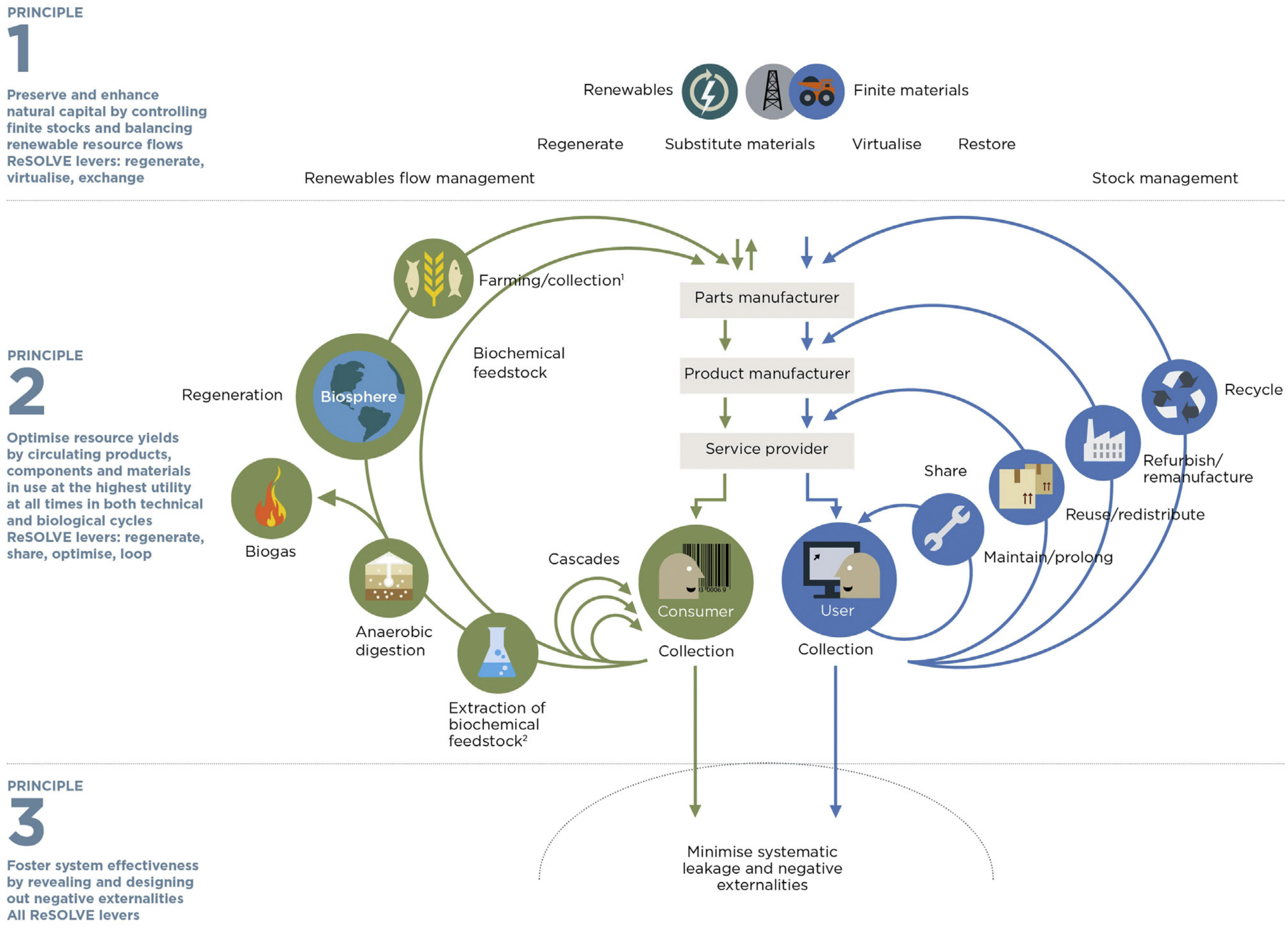


1. Hunting and fishing
2. Can take both post-harvest and post-consumer waste as an input

Fig. 1. A circular economy, illustrating the principal components of the bioeconomy on the left hand side (with permission; EMF, 2012).

transition.

In a circular economy (Stahel and Reday, 1976; Webster et al., 2013; Ellen MacArthur Foundation, EMF, 2012), a US$4.5 trillion global opportunity to improve resource efficiency (Lacy and Rutqvist, 2015), a sequential cascade of industrial processes (maintenance, reuse, remanufacture, refurbish and recycle) ensures that consumer products and constituent materials are recovered for remanufacture and reuse as products with renewed value (Fig. 1, right hand side; EMF, 2012). Waste biological materials (Fig. 1, left hand side) can be considered similarly (EMF, 2012; Webster et al., 2013; Webster, 2015), being reused in sequence either as biochemical feedstocks; or as precursors for biogas; or as composts and digestates for soil improvement and nutrient addition, which is the focus of this study. Biological cascades (Fig. 1) encompass primary agriculture, food processing and bioenergy production and, in concert, constitute the so-called ‘bioeconomy’ (Sillanpää and Ncibi, 2017).

Wastes are extensively heterogeneous materials containing useful materials for reuse but also contaminants that can render them unsafe; and so it is not appropriate to assume recovery for reuse without attention to the standard of re-processing, the quality of the products that emerge from it and the suitability of onward use. Furthermore, and because of the possibility of onward harm, most outputs from waste processing remain classified as ‘wastes’ in a legal sense, with their reuse frequently held back by a continuing stigma that impairs their economic position as products with renewed value (WRAP, 2012). In the UK, for example, before the introduction of standards and quality protocols referenced in this study, uncertainty over the point at which wastes were deemed ‘fully recovered’, and therefore ceased to become waste as defined by the European Waste Framework Directive 2008/98/EC (European Council, 2008), inhibited the production and marketing of beneficial products; impeding the diversion of wastes from landfill. At a Government level, changes to waste legislation were therefore required, so to allow beneficial wastes to re-enter the value chain as products; providing they did so without harming human health or the environment (WRAP, 2012, 2014). The conventional approach to examining this, impartially, has been through an independent risk assessment.

For a bioeconomy, the outputs from composting (fibre, organic carbon, and nitrogen and phosphorus nutrients) and AD (mainly nitrogen and phosphorus nutrients) are used as soil conditioners and fertilizers to improve soil quality, soil tilth and complete carbon and nutrient cycles. For users of these products (whether in agriculture, horticulture, forestry or land restoration) confidence in their safety requires a full understanding of the materials, of their benefits in use and how any perceived risks can be addressed. Composts and AD digestates have been applied widely for land improvement, as growth media in horticulture, and as a fertilizer replacement in agriculture and forestry; and over the years, trade bodies, consumers and regulators have expressed concerns about the potential for onward contamination of food chains, the degradation of receiving environments or the perceived losses in brand value, and thus revenue, for high value products grown on land where these products have been applied (Gillett, 1992; WRAP, 2016a, 2016b).

Given these concerns, key questions arise, as to: (a) how products derived from composting and AD can be made technically safe by adopting engineering controls during waste processing; (b) whether the products that emerge are inherently safe in their new uses, as evaluated by risk assessment; (c) what level of confidence citizens can have in claims for safety made by waste processors and the users of products, such as farmers; and (d) whether these residues can be declassified as wastes so their value can be secured and products marketed. In response, policy-level risk assessments (see for example, USEPA, 1995) have been used to inform these decisions that seek to balance resource efficiency with environmental safety (see Gillett, 1992; Chaney et al., 1996; Gale, 2002; Kinney et al., 2006; Brooks et al., 2012); assessments that deploy generalised scenarios for a range of end uses so to independently evaluate, albeit at a high level (i) the potential for harms to human health and the environment that might materialise from a change to legislation or from products in use; and (ii) the management controls required to maintain a reduction in any residual risk to acceptable levels.

1.2. Policy context

There is merit in summarising the chronology of approach to this study. The origins of the risk assessment and stakeholder engagement adopted in this paper lie in the UK desire to divert biological wastes from landfill, in line with Council Directive 1999/31/EC (European Council, 1999); a European directive seeking to prevent, or to reduce as far as possible, negative effects on the environment from landfill; in particular for surface waters, groundwaters, soil, air and human health. The reuse of biological wastes maximises the opportunity for their application to land and exploits their agronomic benefits, providing it can be achieved safely. The approach adopted was first assembled for the 'safe sludge matrix' (ADAS, 2001), devised for the safe application of sewage sludge to land in England and Wales. Following its acceptance, risk-based and stakeholder engagement approaches for other biological wastes gained traction in the UK policy landscape. For example, during the bovine spongiform encephalopathy (Comer and Huntly, 2003), foot and mouth and avian influenza outbreaks (Pollard et al., 2008; Delgado et al., 2010) in the UK and elsewhere (Berge et al., 2009), where mandatory composting of animal by-products was required, quantitative microbiological risk assessment methods were devised with stakeholder input (Gale, 2004; Berge et al., 2009). Then, as resource management in the UK shifted away from landfill, the processing of biological wastes grew rapidly; first through development of the composting sector (ca. 6.5 m tonnes of input processed in 2014) and then with AD technology (ca. 4.96 m tonnes of digestate produced in 2014). Both developments prompted demands for public confidence in the safety of waste processing and of the resulting soil improvement and replacement fertilizer products; calls that intensified as source-segregated composts and AD digestates became notable replacements for conventional fertilizers (see Cundill et al., 2012).

In response, the composting industry developed its own standard (The Composting Association, 2005); subsequently the basis for a publically available standard (PAS) referencing global initiatives on standards for composts that were achievable and safe. This became the foundation for policy-driven actions: (i) to standardise compost quality for different markets; and (ii) to develop a quality 'protocol' (WRAP, 2012), whereby composts that complied with the quality protocol for a secure market could be declassified as waste and not subject to waste regulations, thereby fostering market confidence and boosting compost production. A similar approach was then applied to source-segregated AD digestates.

Quality protocols set out 'end of waste' criteria for producing quality compost and AD digestates from source-segregated biodegradable waste destined for use in designated market sectors (WRAP, 2012). Source-segregated biodegradable wastes are materials or biodegradable wastes that are stored, collected and not subsequently combined with any other non-biodegradable wastes, or any potentially polluting or toxic materials or products, during treatment or storage (WRAP, 2012). For composts, processing standards were first developed in 2002 (PAS 100) and revised in 2005 and 2011 (British Standards Institution, 2011), with the quality protocol issued in 2012 (WRAP, 2012); and for AD digestates (PAS 110) processing standards were developed in 2010 and revised in 2014 (British Standards Institution, 2014), with the quality protocol being issued in 2014 (WRAP, 2014). In this paper we use the term 'source-segregated composts' and 'source-segregated AD digestates' to refer to those products produced under their respective quality protocols, the criteria for which are specified in the Annexes for each quality protocol.

In brief, the two quality protocols set out the criteria for the production of quality-assured composts and AD digestates from source-segregated biodegradable waste destined for use in specific market sectors. Providing criteria were met (WRAP, 2012, 2014; as an example, for AD, PAS110 compliant processing, quality protocol permitted feedstocks only, whole digestates only with a dry matter content of $< 15\%$ dry wt., batch pasteurisation at 70 °C for 1 h), the outputs (products) of the two processes were deemed to have been fully recovered from the waste stream and they ceased to be classified as waste. Waste processors were not obliged to follow quality protocols, but not doing so meant that their process outputs remained classified as waste. Further, the protocols did not detract from waste processors' continuing legal obligations on the receipt, storage or processing of wastes as inputs to composting or AD products that met the quality protocols.

Throughout these developments, heightened awareness raised the burden of proof on UK Governments to independently assess the human and environmental safety of composts and AD products being put to land. Central to this was a requirement to quantify whether risks to human health, animal health, to the environment and to crops were acceptable or not and whether they were being actively managed. Only with these risks independently characterised, it was argued, would the Government feel able to decide whether or not the new products, processed under quality protocols to publically available specifications for defined UK markets, could be declassified from the Environmental Permitting Regulations (2010) that required regulators to control activities that could harm the environment or human health. In all this, multiple environmental and economic policy objectives were at play; including supporting new markets and jobs for source-segregated compost and digestate production; and promoting biogas utilisation within a lower carbon fuel mix for the UK.

Running through the debate was a fundamental research need to risk assess quality-assured, source segregated products from composting and AD in their secondary use settings, while viewing them as additions to an emerging UK bioeconomy estimated to be worth £52bn in 2013 rising to £58bn in 2030 (Capital Economics et al., 2016). This paper addresses this primary objective by summarising the assessments of risks (WRAP, 2016a, 2016b, 2017a, 2017b) conducted independently and in advance of the decision to declassify quality-assured, source-segregated composts and AD digestates as wastes. The authors contend that the assessments and the attending deliberative processes serve as an important consideration for all contentious wastes being recovered for a circular economy.

2. Materials and methods

2.1. Scope

The risk assessments and consultations that followed, were conducted between 2008–09 and 2010–11. Their eventual publication in 2016 and 2017 (WRAP, 2016a, 2016b, 2016c, 2017a, 2017b) reflects the probing evidence and methodological reviews (Committee on Toxicity, 2011a, 2011b, 2013; Advisory Committee on the Microbiological Safety of Food, 2009, 2013) they were subject to subsequent to assembly of the core results. The core reports (WRAP, 2016a, 2016b, 2016c, 2017a, 2017b; see links within references) detail the engineering process parameters and processing conditions that were assumed for compost and AD technology; the prioritisation of residual contaminants and exposure pathways for subsequent quantitative risk analysis; and the assumptions used based on extensive literature reviews in each case.

2.2. Stakeholder input, expert review and critique

A significant feature of this research was the deep stakeholder engagement to inform exposure scenarios and expert committee review of the risk assessments. The reuse of even quality-assured, source-segregated compost and AD residues has been contentious; with concerns expressed about the perceptions of tainted foods and individual company (even market sector) 'collapse' from a loss of consumer confidence.

Two stakeholder communities informed the risk assessments: (i) a technical advisory group for compost (TAG; n = 46 members); and (ii) a sector steering group for AD digestate (SSG; n = 140). Both the TAG and SSG had a similar constituency of members dependent on their expertise or interests in compost or AD-derived products; comprising influential members of trade bodies, retail consortia, landowner associations, multinational companies, Government ministries, regulators, farmers, technology providers and scientific specialists from across the UK. Generalised exposure scenarios were generated in TAG and SSG workshops, where the basis for 'worst case plausible scenarios' was agreed for the risk assessments. Risk assessments were presented to the TAG and SSG: (a) at the conceptual model development stage; (b) following risk estimation; and (c) at the final reporting stage. Three regional meetings in England, Wales and Scotland ensured stakeholders contributed under a mechanism of open consultation.

Two advisory committees of the Government's Food Standards Agency: (i) the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT, 2019); and (ii) the Advisory Committee on the Microbiological Safety of Food (ACMSF, 2019) critiqued the risk assessment methods and risk characterisation findings. COT and ACMSF are independent, scientific and non-statutory committees providing expert advice to Government. Meetings were held 'in camera', with formal deliberations made public (see ACSMF, 2009, 2013; COT, 2011a, 2011b, 2013). Committee reviews resulted in revisions to the risk assessments, with each committee stating confidence in the methods adopted, as revised, and with recommendations offered. The formal endorsement of risk estimates, however, is not standard practice for UK Government and is outside the remit of expert committees.

2.3. Risk assessment

A tiered approach to risk assessment used Government guidance, accepted frameworks (Fig. 2a) and published methods (DETR et al., 2000; Defra, 2011) to screen, and quantify where appropriate, risks to human health, animal health, the environment and crops from the application of quality-assured, source-segregated composts and AD digestates to land. Using a risk assessment schema (Fig. 2a; DETR et al., 2000), problem definition, hazard identification and Tier 1 risk screening/prioritisation preceded a Tier 2 generic quantification of risk estimates and hazard quotients using stakeholder-informed exposure scenarios. The overall conceptual model was highly complex with multiple hazards, exposure pathways and receptors generating millions of possible combinations, and so a prioritisation of key hazards and exposure pathways was necessary to avoid what would have otherwise been a misplaced effort on a multitude of trivial pathways. Hence, in sequence:

- problem formulation and Tier 1 risk screening and prioritisation (Fig. 2a) was used to identify and prioritise hazards (Fig. 2b) into two hazard lists using treatable wastes from the European Waste Catalogue (European Commission, 2000) that could be subject to compost or AD processing by reference to the accepted performance of these technologies to these wastes and the requirements of the quality protocols;
- potentially hazardous agents were included in the hazard lists if they had been identified or measured in source-segregated compost or source-segregated AD digestates, or where there was evidence available that specific agents could enter the respective process under 'typical practice', defined as PAS100/PAS110 compliant, with activities outside of this specification, including unauthorized contamination of feedstocks not being considered;
- the two hazard lists were condensed using supportable assumptions (Fig. 2c) on residual toxicity, potential survivability during treatment; environmental fate and transport characteristics; and the likely scale of doses that could be expected for human, animal, environmental and crop receptors, resulting in two master hazard lists (Tables 1a and 1b);
- next, conceptual exposure models were constructed and 26 exposure pathways identified through which residual contaminants in quality-assured, source-segregated composts and AD digestates could reach human, animal, environmental and crop receptors at likely doses to be of potential concern;
- a semi-quantitative ranking of these pathways (not shown for brevity; see WRAP, 2016a), with a focus on direct exposures of high availability (e.g. surface water run-off) and plausible pathways with evidence for onward transmission (e.g. residual pathogen exposure) was used to inform:
- the prioritisation of *significant* exposure pathways for hazardous residuals, considering the total number of opportunities for exposure and the more likely routes of transmission to human, animal, environmental and crop receptors (Fig. 3);
- hence, for quality-assured, source segregated composts for example, exposure assessment was performed for: (i) surface application to grazing land; (ii) incorporation into soil for growing grain crops for animal consumption; (iii) incorporation into soil for growing root crops for animal consumption; (iv) incorporation into soil for growing leaf crops for animal consumption; with scenarios ii to iv being combined into a single approach for estimating the uptake of potentially toxic agents by various crop types.

These steps delivered a prioritised list of significant exposure pathways for hazardous residual contaminants in quality-assured, source-segregated compost and AD digestates. Exposure models were sense-checked with the TAG and SSG. The assessment of microbial and chemical risks using UK-accepted risk assessment methods for human, animal environmental and crop receptors then progressed, adopting conceptual models of exposure and deterministic exposure assumptions derived from the prior art and from practice, as required by the TAG and SSG. Chemical risk assessment also drew on published data on organic chemicals in various sludges (Chambers et al., 2010; COT, 2011a). For the Tier 2 generic (i.e. policy-level) quantitative risk assessments (Fig. 4):

- event trees (illustrative example in Fig. 4a) for pathogen reduction during composting and AD processing were constructed, adopting Gale (2002, 2005a, 2005b) to estimate residual pathogen loads in quality-assured products that were subject to onward assumptions on re-growth and decay in soil to provide a potential dose on vegetable crops for human consumption;
- dose-response and infectivity models were used (illustrative example in Fig. 4b) to estimate incremental risks of infection to humans and animals from ingesting specific pathogens and viruses; and
- for chemical risks, hazard quotients (HQ) for a range of exposure scenarios (illustrative example in Fig. 4c) adopted using the approach described by McKone (1994); here adopting a deterministic

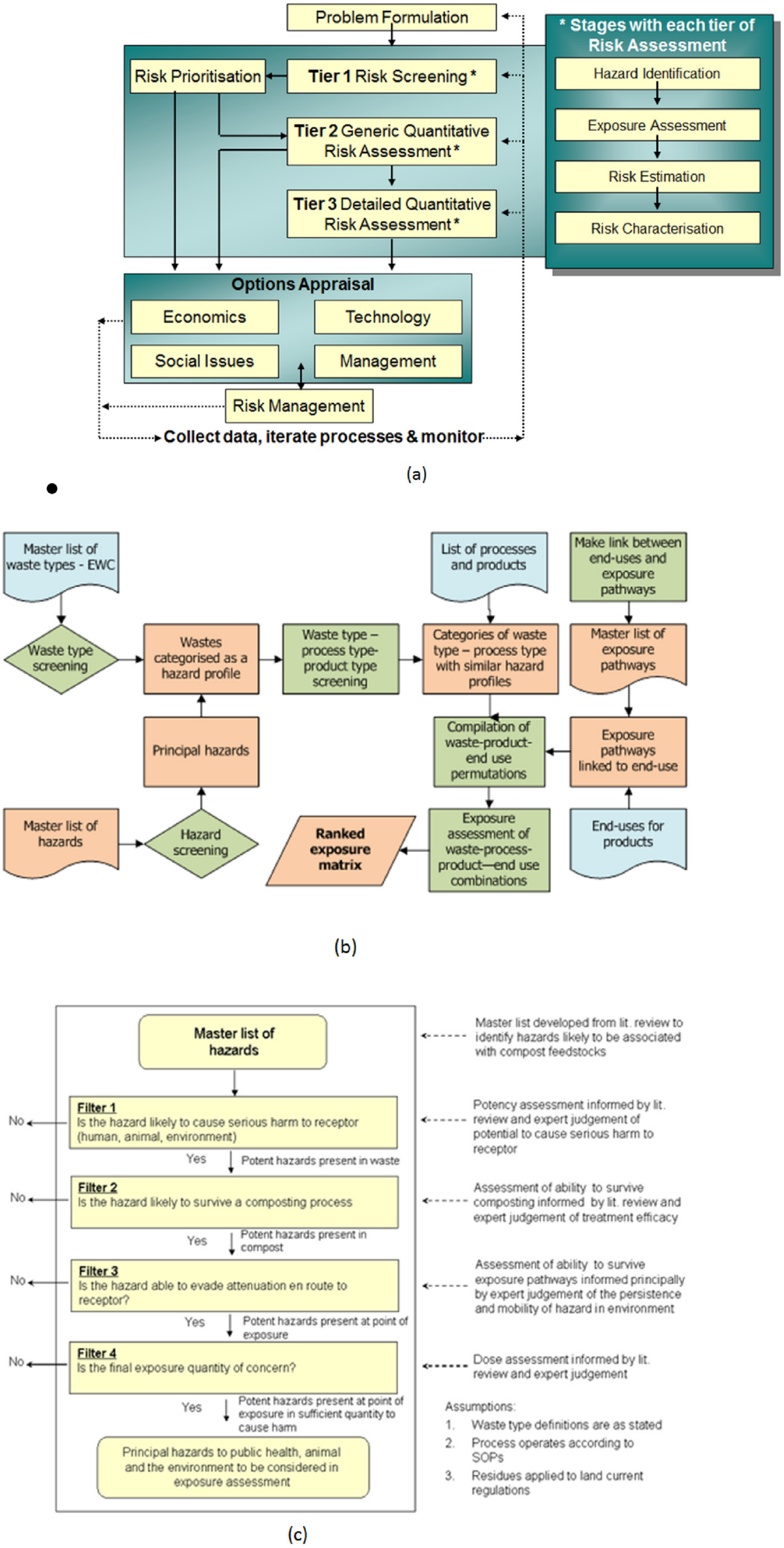


Fig. 2. Sequence of Problem Formulation (Fig. 2a; DETR et al., 2000), Hazard Identification (Fig. 2b) and Tier 1 Risk Screening and Prioritisation (Fig. 2c) tasks.

Table 1a
Master hazard list for PAS 100 quality-assured composts.

Hazards category	List of hazards cited in the research evidence
Potentially toxic elements (PTEs)	Cd, Cr, Pb, Hg, Ni, As, Ba, Zn, Cu; herbicide residues; marine biotoxins.
Nutrients & organic pollutants	NO_3^-, NH_4^+, P, K, micronutrients, degradable organics expressing a biochemical oxygen demand.
Persistent organic pollutants	polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs); polychlorinated biphenyls (PCBs) including dioxin-like PCBs; polycyclic aromatic hydrocarbons (PAHs).
Animal & human pathogens	*Salmonella* sp., *Streptococcus* sp., *E. coli* sp., *E. coli* O157, enteric virus, *Bacillus* sp., *Cryptosporidium* sp., Q-Fever (*Coxiella burnetii*), ringworm, *Leptospira* sp. (leptospirosis), *Mycobacterium bovis* (bovine tuberculosis), *Chlamydophila psittaci* (psittacosis), *Giardia entamoeba*, *Staphylococcus aureus*, *Campylobacter* sp., *M. avium* ssp. *paratuberculosis* (MAP), *Clostridium perfringens*, *C.botulinium*, *Ascaris suum*, bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), classical swine fever (CSF), *Pasteurella* spp. (pasteurellosis), tapeworm (*Taenia* sp., *Dipylidium Caninum*, *Echinococcus* sp., *Mesocestoides* spp.), *Toxocara* ssp.roundworms (toxocariasis), *Toxoplasma gondii* (toxoplasmosis), *Trichinella* spp. (trichinosis), *Yersinia enterocolitica* (yersiniosis), *Listeria monocytogenes* (listeriosis), *Brucella abortus* (brucellosis)
Invasive weed and exotic species and plant toxins	Pyrrolizidine alkaloids (PA) in *Senecio jacobaea* (ragwort), taxine alkaloid in *Taxus baccata* (yew)
Plant pathogens	*Fusarium oxysporum* spp., *Phytophtora* spp., *Pythium* spp., *Plasmodiophora brassicae*, *Rhizoctonia solani*, *Thielaviopsos basicola*, *Verticillium dahliae*, *Xanthomonas* spp., *Microdochium nivale*, *Armillaria melia*, pepino mosaic virus, tobacco mosaic virus, *Sclerotium cepivorum*, nematodes (*Globodera*), *Streptomyces* spp., *Pseudomonas* spp.
Physical contaminants	glass, stones, plastics, metal
Gases/bioaerosols	CH_4, SO_x, ammonia, NO_x, bioaerosols

Table 1b
Master hazard list for PAS 110 quality-assured AD digestates.

Generic quantitative risk assessment	Evidence-based discussion
Hazard – pathogen	
For human receptors:	**For human and animal receptors:**
E. coli O157	*Mycobacterium paratuberculosis*
Campylobacter sp.	Liver and rumen fluke (*Fasciola hepatica*, *Calicophoron daubneyi*, *Paramphistomum cervi*)
Salmonella spp.	*Taenia saginata* (tapeworm - bovine cysticercosis)
Listeria monocytogenes	*Neospora* spp.
Cryptosporidium parvum	*Sarcocystis* spp.
For animal receptors:	*Legionella* spp. (legionellosis)
Scrapie	*Aspergillus* spp.
Foot and mouth disease (FMD) Classical swine fever (CSF)	*Toxoplasma gondii* (toxoplasmosis)
	For plant receptors:
	Potato cyst nematodes (*Globodera rostochiensis and Globodera pallida*); free-living nematodes (*Trichodorus* spp., *Tylenchorynchus* spp.); Powdery scab (*Spongospora subterranea*); Common scab (*Streptomyces spp.*); Brown rot (*Ralstonia solanacearum*); Ring rot (*Clavibacter michiganensis sub.sp. sepedonicus*); Late blight (*Phytophthora infestans*); Black scurf (*Rhizoctonia solani*); Clubroot (*Plasmodiophora brassicae*); *Fusarium oxysporum* spp.; Mycotoxins.
Hazards – chemical	
Potentially toxic elements (PTEs)	Zn, Cu, Cd, Ni, Pb, Cr, Hg
Persistent organic pollutants	Polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs); polychlorinated biphenyls (PCBs) including dioxin-like PCBs; polycyclic aromatic hydrocarbons (PAHs).
Invasive weed and exotic species and plant toxins	Pyrrolizidine alkaloids (PA) in *Senecio jacobaea* (ragwort).

ratio of the exposure (Average Daily Dose, ADD, $mg\,kg^{-1}\,dg^{-1}$) to the appropriate reference dose (RfD, $mg\,kg^{-1}\,d^{-1}$) with a ratio less than or equal to 1 being regarded as ‘safe’ or of negligible risk, unless otherwise specified.

In this assessment, dioxins and dioxin-like PCBs were assessed on an individual basis, and collectively using Toxic Equivalency Factors (TEFs) and Toxic Equivalents (TEQs). While TEQs are the standard approach, it was deemed appropriate to also assess each congener separately because data on the levels of all congeners in quality-assured, source segregated composts and digestates were not available and there are differences in the environmental fate and transport of different congeners.

3. Results and discussion

3.1. Tier 2 microbiological risk estimates and chemical hazard quotients

Tier 2 generic quantitative risk assessments (Fig. 2a) performed on subsets of the hazard master lists (Tables 1a, b) for significant exposure pathways are in Tables 2a, b and 3a, b. Tables 2a, b present estimated risks of infection for human and animal receptors through significant exposure pathways for quality-assured, source-segregated compost and AD digestates treated to PAS 100 and PAS 110 standards respectively. Tables 3a, b present chemical hazard quotients and associated risk end-points for crops, human and animals through significant exposure pathways for source-segregated, quality-assured compost and AD digestates treated to PAS 100 and PAS 110 standards respectively. A summary of issues raised by the risk assessments, the stakeholder engagements and expert reviews follows.

3.2. Residual risks and risk management controls

The risk estimates, hazard quotients and end-points produced were used to identify policy level conclusions and risk management actions. Policy-level risk assessments do not deploy site-specific exposure factors, but act as means of identifying exposure scenarios that may require analysis in greater detail, say through Tier 3 detailed (site-specific) quantitative risk assessment (Fig. 2a). The microbial risks associated with the use of quality-assured, source segregated composts on land through significant exposure pathways (human consumption of ready to eat vegetables; Table 2a) were deemed negligible. For microbial risks, the ‘by-pass’ of treatment is an important contributor to risks becoming realised (Gale 2002, 2004, 2005a). Here, for quality-assured,

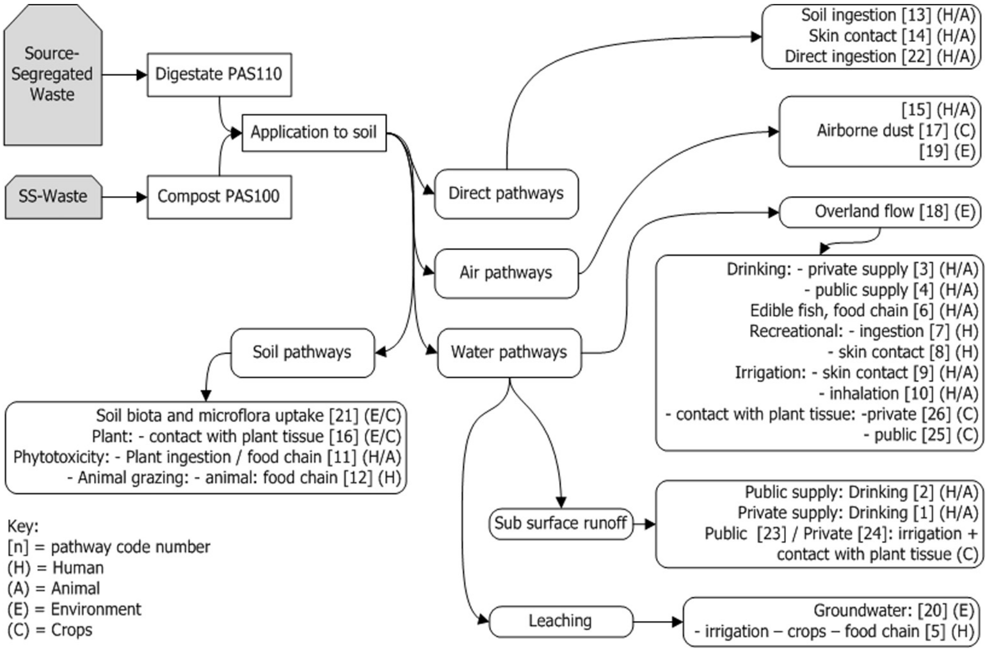


Fig. 3. Conceptual exposure model. 26 key exposure pathways [with code number, n] were identified for human (H), animal (A), environmental (E) and crop (C) receptors and assessed to inform the prioritisation of significant pathways for potential hazardous residuals in quality-assured composts and AD digestates.

source-segregated AD digestates, the estimated number of infections per year due to the land application of digestate (Table 2b) assumed a 6-log reduction in bacterial pathogens during AD treatment with an estimated 0.0001% by-pass for pasteurisation (5-log for exotic viruses; and no reduction for scrapie); a land application of 50 fresh tonnes digestate/ha/yr and (by reference to human pathogens) a 42-day harvest interval after application. With the exception of scrapie, for which conservative processing assumptions were purposefully made, the risks of infection in humans and livestock following the land application of quality-assured, source-segregated AD digestate were generally higher than those estimated for quality-assured, source-segregated composts but also deemed very low to negligible. In some instances, the predicted risks are wholly worst case. For example, the model assumed, conservatively, no grazing interval following the application of digestate to pasture resulting in the prediction of 1 classical swine fever case in pigs every 4000 years (Table 2b). In practice, a grazing interval would be stipulated, reducing the estimated risk to one case in 5 million years. Putting scrapie into context, the percentage contributions to the GB sheep population are negligible (Table 2b).

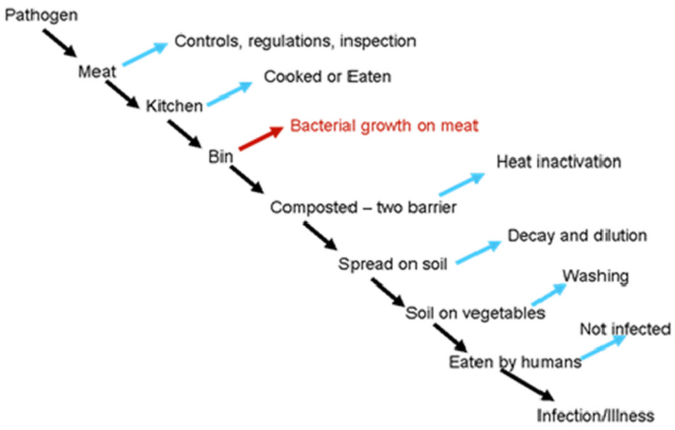
These risk estimates adopted a precautionary approach. Even so, the risks presented in Table 2b suggest it would be prudent for growers of sensitive crops for human consumption, such as high value, short growth period baby leaf salads, wishing to use source-segregated AD digestates, to satisfy themselves that materials are of appropriate sanitary quality. This may require a degree of AD processing and product testing over and above the baseline norms adopted in this risk assessment. This prudence would then also serve as a precautionary measure to prevent the spread of plant pathogens.

An assessment was made of the chemical risk of harm to crops, animals and humans from exposure to a range of hazardous residuals potentially present in composts and AD feedstocks; such as PCBs and PCDD/Fs, PAHs and heavy metals (Table 3a) supported by analytical data (Chambers et al., 2010). Feedstocks derived from human food waste and processed by composting and AD are expected to contain negligible chemical contamination. For example (COT, 2011a), PFOS, PFOS derivatives, PBDEs, tributyl-tin, bisphenol A, clopyralid and aminopyralid were not detected above the limits of detection in any of the digestate samples. PBDEs, tributyl-tin and bisphenol A, clopyralid and aminopyralid were not detected above the limits of detection in any of the livestock manures sampled, but PFOS derivatives (perfluoroheptanoic acid 24 μg/kg dry matter (dm); perfluorononanoic acid 6.32 μg/kg dm) were measured in one of the twenty livestock manures sampled in this project. Low concentrations of DEHP were measured in food-based digestates (1.58–2.42 mg/kg dm), while concentrations in the manure-based digestate were below the limits of detection. Concentrations of heavy metals (Zn, Cu) may be higher in digestates that use pig slurries as an input feedstock, though monitoring data report chemical contaminants in digestate at concentrations similar to those in background soil and herbage throughout the United Kingdom (Nicholson et al., 2010; Environment Agency, 2007; WRAP, 2011, 2016b). Reviewing the hazard quotients in Table 3a in light of the analytical data on contaminants, it was concluded that the likelihood of incremental harm from chemical exposures was low and quantitative risk estimates were not progressed further.

The SSG frequently raised the potential for plant toxins to cause harm to grazing stock. There are sporadic cases of cows being poisoned by ensiled grass heavily infested with ragwort (Johnson and Molyneaux, 1984) where the presence of pyrollizidine alkaloids (PA), the class of toxic agents in ragwort, had not been tested. The risks associated with the transmission of plant toxins to humans and animals consuming crops grown on land to which quality-assured AD digestate has been applied were assessed to be low (Table 3b). The use of ragwort in AD systems would be highly unusual. Nevertheless, for precaution, AD plant operators should aim to eliminate ragwort in feedstock for AD (Hough et al., 2010). If it is present, they should ensure it constitutes < 1% by pre-digested weight of the feedstock (Table 3b).

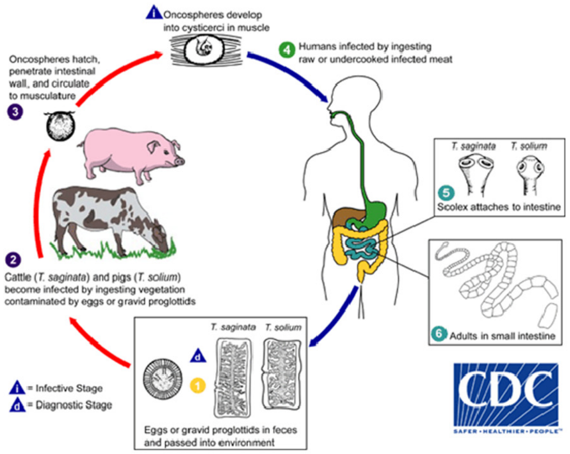
3.3. Stakeholder input and expert committee review

This research served as a reminder of the critical value of stakeholder input and expert review to risk assessment practice. Despite the presence of a pre-existing standard for compost (The Composting Association, 2005) and a mechanism for considering the removal of composts and AD residues from waste regulation when it met this standard, evidence demonstrating the safety of these products in their secondary uses was deemed insufficiently transparent for certain stakeholders - indeed some categorically opposed the declassification of compost and AD products first hand without requiring further evidence.



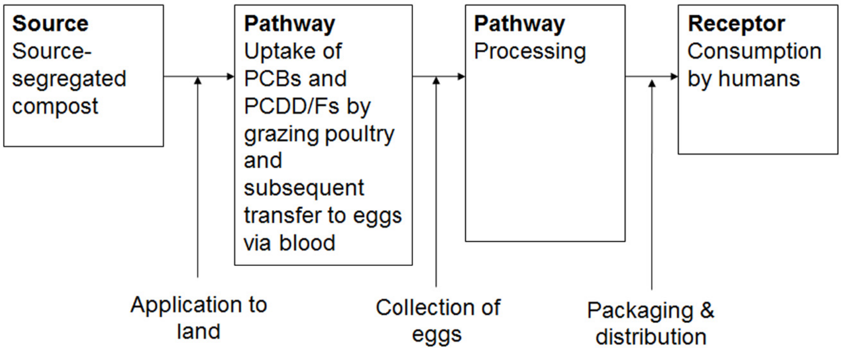
Example scenario for microbial risk: pathogens in waste food, source-segregated and composted under PAS100 quality protocols, with compost spread onto soil and onward contact with ready-to-eat vegetables

(a)



Example scenario for microbial risk: generalised infectivity model from residual pathogens in compost applied to land and onward transmission through animal grazing.

(b)



Example scenario for chemical risk: human exposure to PCBs and PCDD/Fs in eggs from free-range laying hens grazing land amended with PAS100 green compost

(c)

(caption on next page)

Fig. 4. Approach to generic quantitative microbial risk assessment and chemical hazard quotient tasks (a) to (c). Fig. 4a–c are illustrative examples of the models used to generate risk estimates and hazard quotients, so to guide readers. CDC infectivity infographic with permission.

Table 2a
Tier 2, generic quantitative microbial risk assessment for the use of quality-assured, source-segregated composts in UK agriculture. Estimated risks of infection to humans through consumption of ready-to-eat vegetable crops grown on soil treated with compost.

Hazard	Estimated risk of infection (per person per year) from consuming ready-to-eat vegetables	Estimated number of years between infections in UK population (rounded)
Human pathogens		
C. parvum	5.8×10^{-14}	7,600,000
L. monocytogenes	1.1×10^{-11}	40,000
Campylobacter sp.	2.8×10^{-11}	16,000
Salmonella spp.	1.3×10^{-8}	30
E. coli O157 (illness)	1.7×10^{-8}	30

Framing and agreeing the 'realistic worst case' exposure scenarios dominated the TAG and SSG group discussions. In practice, certain uses for composts and AD digestates could never be approved openly by some stakeholder communities, because of perceived market risk; for example, the application of compost or AD digestate ahead of 'ready-to-eat' crops. In these circumstances, counter-factual arguments evoking nutrient and soil amendment benefits had no sway. The perception of consequences for the consumers of 'ready-to-eat crops' together with the long list of potential hazards, deemed 'foreseeable' although presented at insignificant doses, caused concern for some stakeholders.

This merits discussion because risk assessors continually wrestle with stakeholder engagement and its role in raising the confidence of communities who may be averse to new proposals, such as the reuse of biological wastes as beneficial products. Behind some of the reticence experienced here was the context of the approach developed for the composting of catering waste (Gale, 2002) and others' engagement in it. While it might be argued that relevant stakeholders should have been involved more deeply in the risk assessment to inform the catering waste composting standard, the focus at the time was on risks to livestock and on assembling a defensible assessment methodology on one hand; while developing a standard for composting that was achievable in a time of national crisis (BSE, FMD). With hindsight, a future starting point for policy and regulatory officials could be to elicit concerns more actively from stakeholder community and take the process forward using the tiered approach above. The problem, however, is in identifying appropriate stakeholder communities who may not even realise at the time what the future implications are until revealed by risk estimates. These decision processes are iterative and involve getting stakeholders and risk assessors appraised of one another's concerns early on. This is a learning point for those contemplating similar exercises.

In the various exchanges, expert committees were presented with the validity of microbiological exposure assumptions and the use of toxicological hazard quotients. Issues of concern for expert committees included the contributing doses of contaminants for sensitive receptors in the context of accepted daily doses (ADDs) from all sources to the total UK diet. Securing an assurance of risk acceptability from the expert committees proved problematic despite the precautionary approach. It is also worth noting that the reluctance of expert committees to officially endorse risk estimates within research studies and the study conclusions, albeit for understandable reasons of avoiding potential public liability, can often be misinterpreted as a failure to obtain high-level, independent, technical support for proposals.

4. Conclusions

Can wastes be recovered for a circular economy in ways that garner societal support with respect to perceived risk? Will virgin materials (e.g. peat, as compost) always be viewed as superior in quality, and thus deemed lower risk, that products recovered from the waste stream (e.g. soil conditioners produced from quality-assured, source-segregated compost)? Much comment (Webster et al., 2013; Webster, 2015; Lacy and Rutqvist, 2015; Pollard et al., 2016) has been made on the circular economy and the arrangement of successive cascades for resource recovery (Fig. 1). Far less attention has been given to the policy and regulatory barriers to be overcome if circularity is to function in a competitive economy.

This study considered a UK regulatory, industrial and application setting, with the associated assumptions about process treatments for compost and anaerobic digestion, the tenor of regulatory implementation and the policy momentum built up around these issues in a UK

Table 2b
Tier 2 generic quantitative microbial risk assessment for the use of quality-assured, source-segregated anaerobic digestion residues in GB agriculture.

Hazard	Predicted number of infections per year from AD	Predicted number of years between infections from AD (rounded)	Reported number of GB infections in 2010	Predicted percentage increase in infections per year through AD
Human pathogens				
E. coli O157 (illness)	0.007	150	1064[c]	0.0007
Campylobacter sp.	0.0022	450	69008[c]	0.000003
Salmonella spp.	0.0018	560	8998[c]	0.00002
L. monocytogenes	2.3×10^{-8}	44,000,000	156[d]	0.00000001
C. parvum	6.4×10^{-5}	16,000	4470[c]	0.0000004
Animal pathogens				
Classical scrapie[a]	0.038	30	21616[e]	0.0002
Atypical scrapie[a]	0.013	80	46003[e]	0.00003
Total scrapie	0.051	20	67619[e]	0.00007
FMDv[b] (cattle)	0.8×10^{-7}	12,000,000	0	N/A
(sheep)	1.6×10^{-7}	6,000,000		
(pigs)	0.5×10^{-7}	20,000,000		
CSFv[b]	2.4×10^{-4}	4000	0	N/A

[a] Assumes 15 day retention time for mesophilic AD.

[b] Assumes a "no grazing" ban between application of digestate and livestock grazing. In practice, a 3 week time interval in accord with EU Control Regulation 1069 (European Council, 2009) would be observed allowing further pathogen decay in the soil and greatly reduced risks.

[c] Health Protection Agency, 2011; Health Protection Scotland, 2011.

[d] For England and Wales in 2010.

[e] No. of scrapie infections entering GB food chain per year based on 2009 prevalence data.

Table 3a

Tier 2, generic quantitative chemical risk assessment for the use of quality-assured, source-segregated composts in UK agriculture. Estimated chemical hazard quotients for crop and human receptors.

Scenario description	**Estimated hazard quotients (shaded= ≥1)**				
Crops. Exposure of sensitive crops to herbicide residues in source-segregated green waste compost applied to agricultural land		Reduction in yield			
		potatoes	peas, beans		
	2,4D	0.001	N/A		
	Alachlor	0.01	N/A		
	Atrazine	1	0.1		
	Clopyralid	1	1		
	Oryzalin	N/A	0.001		
	Oxadiazon	<0.00001	N/A		
	Terbuthylazine	0.00001	0.00001		
Crops. Impact of fungicide residues in source-segregated green waste compost on barley grain quality with particular reference to fermentative properties		Hazard quotient (concentration: MRL)			
		barley grain	young beer		
	Azaconazole	0.1	0.01		
	Azoxystrobin	0.01	0.01		
	Bitertanol	0	0		
	Cyproconazole	0	0		
	Cyprodinil	0.1	0.01		
	Difenoconazole	1	0.1		
	Dimethomorph	0.00001	0.00001		
	Dodemorph	0.01	0.001		
	Epoxiconazole	0.001	0.0001		
	Etaconazole	0.1	0.1		
	Fenbuconazole	0.1	0.1		
	Fenhexamide	0	0		
	Fempropimorph	0	0		
	Flusilazole	0.1	0.01		
	Flutolanil	0.01	0.01		
	Imazalil	0	0		
	Myclobutanil	0	0		
	Oxadixyl	0.01	0.01		
	Propiconazole	0.01	0.01		
	Pyrifenox	0.1	0.01		
	Tebuconazole	0.001	0.0001		
	Thiabendazole	0.1	0.1		
	Thiophanate-methyl	0	0		
	Triadimenol	0.001	0.001		
Crops. Uptake of cadmium and lead from source-segregated green waste compost applied to cereal crops		wheat: animal feed	wheat: human consumption	maize: animal feed	maize: human consumption
	Cd	0.01	0.1	0.01	0.1
	Pb	0.001	0.01	0.01	0.1
Humans. Exposure to PCBs and PCDD/Fs in ready to eat crops grown in soil amended with source-segregated green waste compost		average person	95 %ile vulnerable person	highly exposed infant	
	PCB 28	<0.00001	0.00001	0.00001	
	PCB 52	0.00001	0.0001	0.0001	
	PCB 95	0.00001	0.00001	0.00001	
	PCB 101	0.00001	0.00001	0.00001	
	PCB 118	0.0001	0.0001	0.0001	
	PCB 132	0.00001	0.00001	0.00001	
	PCB 138	0.00001	0.00001	0.00001	
	PCB 149	0.00001	0.00001	0.00001	
	PCB 153	0.00001	0.0001	0.0001	
	PCB 174	<0.00001	0.00001	0.00001	
	PCB 180	0.00001	0.00001	0.00001	
	Dioxins	<0.00001	<0.00001	<0.00001	

(*continued on next page*)

Table 3a (*continued*)

Humans. Exposure to marine biotoxins from composted shellfish applied to ready to eat crops	Marine biotoxins	Average Person	95 %ile Vulnerable Person	Highly Exposed Infant
	PSPs	0.0001	0.0001	0.0001
	ASPs	0.01	0.1	0.1
	OAs	0.0001	0.0001	0.001
	YTXs	<0.00001	<0.00001	<0.00001
	AZAs	0.0001	0.0001	0.0001
Humans. Exposure to lead via consumption of eggs from free range hens grazed on compost-amended land		Average person	95 %ile vulnerable person	highly exposed infant
		0.1	1	0.1
Humans. Exposure to cadmium via consumption of kidney/liver from cattle grazed on compost-amended land		average person	95 %ile vulnerable person	highly exposed infant
	Kidney	0.00001	0.0001	0.00001
	Liver	0.01	0.01	0.01
Humans. Exposure to PCBs and PCDD/Fs in eggs from free-range laying hens grazing land amended with PAS100 green compost		average person	95 %ile vulnerable person	highly exposed infant
	PCBs	0.1	1	0.1
	PCDD/Fs	0.001	0.01	0.01
Humans. Exposure to arsenic in carrots grown in soil amended with PAS100 green compost		average person	95 %ile vulnerable person	highly exposed infant
		0.001	0.01	0.01
Humans. Exposure to potentially toxic elements (PTEs) from consumption of ready to eat crops to which PAS100 green compost has been applied		average person	95 %ile vulnerable person	hjghly exposed infant
	Cd	0.1	0.1	0.1
	Cu	0.1	0.01	0.1
	Pb	0.01	0.01	0.01
	Ni	0.01	0.1	0.1
	Zn	0.01	0.01	0.01

context. Quality protocols in the UK context have proven a success for converting wastes into non-waste products and have since been extended to a series of former wastes, including recycled gypsum, steel slag aggregate, flat glass and poultry litter (Environment Agency, 2015). Extension of these findings to a wider international audience, however, are contingent on an exploration of similar contextual issues that set the basis for policy level risk assessment. Through this research, the UK policy, regulatory and business communities learnt the necessity of first agreeing a standard; then being sure that material meeting the standard would be safe and 'fit-for-purpose' within a secure market; and only then devising a regulatory approach to lift material complying with this standard out of the legal framework. Risk management still relies wholly on maintaining the integrity of barriers to prevent exposure, notably, the exclusion of unsuitable wastes from waste processing; the effective treatment of suitable wastes in processing plants; the appropriate use of quality-assured, source segregated products using accepted codes of good practice; and the attenuation of any residual, post-treatment hazards in the environment prior to reaching a receptor of concern.

This paper has focused on summarising the risk assessment work required to inform the legal decision on waste declassification. The burden of proof was high and the process lengthy and substantive in resource terms and in its complexity. The risk estimates and the extended scrutiny applied to them reflected a societal (and trade sector) unease about perceived interference with aspects of the biological cycle, in particular, and a perceived impact on the quality and brand

Table 3b

Tier 2 generic quantitative chemical risk assessment for the use of quality-assured, source-segregated AD residues in GB agriculture.

Animals	Scenario 1	Scenario 2	Ingestion rates[a] (mean mg PAs/kg bodyweight/day)	
Digestate type/Pyrrolizidine alkaloids (PA)	Total PAs on soil surface (mg/m^2)	Concentration of PAs in top 10 cm of soil profile	Cattle (370 kg cattle)	Sheep (40 kg lambs)
Whole digestate (wet AD) (0.1% ragwort)	3.1	–	1.4[b]	3[c]
Whole digestate (wet AD) (0.1% ragwort)	–	0.31 mg/m^3 (1.5 × 10^{-4} mg/kg soil)	7.1 × 10^{-3}[b]	3.4 × 10^{-3}[c]
Whole digestate (wet AD) (5% ragwort)	154	–	69.4[d]	148[e]
Whole digestate (wet AD) (5% ragwort)	–	15.4 mg/m^3 (7.7 × 10^{-3} mg/kg soil)	0.4[b]	0.2[c]

[a] Assuming all PAs on and around the soil surface were ingested over a 20 day period.

[b] Cattle are not likely to suffer harm following ingestion of PAs at this concentration over a 20 day period.

[c] Cattle may suffer harm following ingestion of PAs at this concentration over a 20 day period, though cattle other than calves are unlikely to.

[d] There are no reports of safe or dangerous concentrations of PAs in fodder for sheep though they are known to be less sensitive to PAs than cattle or horses. It is unlikely that they will suffer harm from ingestion of PAs at this dose rate.

[e] It is not known whether sheep will suffer harm following ingestion of PAs at this ingestion rate.

value of premium products grown on land. If a circular bioeconomy is to secure market and citizen support, the ongoing need for risk assessments that probe the impact of potential exposures will remain. This said, the stakeholder engagement in this study that was pivotal to the final outcome served as a further reminder to the scientific community that diminishingly small risk estimates and hazard quotients are no guarantee of how risks associated with remanufactured products might be perceived by producers, suppliers or consumers.

Notwithstanding the success a risk-informed evidence base brought to the secondary use of quality-assured, source-segregated composts and AD digestates in the UK, researchers continue to identify residual contaminants in a wide spectrum of biological wastes, including emerging contaminants and pathogens discharged through aqueous or solid waste streams such as Ag, TiO_2, ZnO and Au nanoparticles (Barton et al., 2015; Judy et al., 2011); pharmaceutical and personal care product residues (Chari and Halden, 2012; Chen et al., 2014); persistent organic compounds such as perfluorochemicals (Sepulvado et al., 2011) and brominated flame retardants (Venkatesan and Halden, 2014); bioaerosols downwind of application sites (Dungan, 2014); antimicrobial resistant pathogens (Gondim-Porto et al., 2016); prions (Xu et al., 2014); and most recently, microplastics (Mahon et al., 2017). This list of emerging contaminants is already stimulating calls to revisit risk assessments and driving upstream interventions in sustainable product design, in the elimination of persistent organic compounds from consumer products and in waste segregation policies at household, industrial and commercial premises. These are important interventions in their own right with respect to our progress towards a circular economy.

Abbreviations

2,4 D	2,4-Dichlorophenoxyacetic acid, a systemic herbicide that selectively kills most broadleaf weeds through causing uncontrolled growth
ACMSF	The Food Standards Agency's Advisory Committee of the Microbiological Safety of Food
AD	anaerobic digestion, the process of degrading organic material while excluding oxygen
ADD	average daily dose
ADI	acceptable daily intake
ASPs	amnesic shellfish poisoning
AZAs	azaspiracids, a family of lipophilic polyether marine toxins in scallops
CFU	colony forming unit
COT	The Food Standards Agency's Committee of Toxicity
CSF$_v$	classical swine fever virus
DEHP	Bis(2-ethylhexyl) phthalate, the most common of the phthalate plasticisers
EC	European Commission
EU	European Union
EWC	European Waste Catalogue
FMD$_v$	foot and mouth disease virus
HQ	hazard quotient, a ratio of potential exposure to a substance and the level at which no adverse effects are expected. If the hazard quotient is estimated to be < 1, no adverse health effects are expected as a result of exposure.
$mg\,kg^{-1}$ dw	milligram per kilogram dry weight (measure of compound within dry matter applied to soils)
MRL	maximum residue limit, the maximum amount of pesticide residue expected to remain in food products when a pesticide is used according to label directions, and that will not be a concern to human health
OAs	okadaic acid, produced by dinoflagellates during harmful algal blooms and is a diarrhetic shellfish poisoning toxin
PA	pyrrolizidine alkaloids, plant toxins present in ragwort
PAS	Publicly Available Specification. British Standards Instiution PAS100 for composted materials and British Standards Instiution PAS 110 for anaerobic digestates
PAHs	polynuclear aromatic hydrocarbons
PBDE	polybrominated diphenyl ethers, organobromine flame retardants
PCBs	polychlorinated biphenyls, and their numbered congeners
PCDD	polychlorinated dibenzo-p-dioxins, and their numbered congeners
PCDF	polychlorinated dibenzofurans, and their numbered congeners
PFOS	perfluorooctanesulfonic acid, an anthropogenic fluoro-surfactant
POPs	persistent organic pollutants; organic compounds that resist environmental degradation through chemical, biological, and photolytic processes, e.g. PCBs (polychlorinated biphenyls), PAHs (polycyclic aromatic hydrocarbons)
PSPs	paralytic shellfish poisoning, a marine toxin disease with gastrointestinal and neurologic symptoms that has been reported worldwide
PTEs	potentially toxic elements, e.g. metals such as cadmium, arsenic, lead, copper, nickel and zinc
RfD	reference dose
SOPs	standard operating procedures (Fig. 2)
SSG	sector steering group for AD digestate risk assessment
SS-Waste	source-segregated biodegradable wastes (Fig. 3)
TAG	Technical Advisory Group, the composting advisory group, comprising stakeholders and key sector representatives
tds	tonnes dry solid (metric used to define a soil loading rate)
YTXs	Yessotoxin (YTX) is a marine polyether toxin found in shellfish

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