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Article



The Brookside Farm Wetland Ecosystem Treatment (WET) System: A Low-Energy Methodology for Sewage Purification, Biomass Production (Yield), Flood Resilience and Biodiversity Enhancement

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Abstract: Wastewater from domestic developments, farms and agro-industrial processing can be sources of pollution in the environment; current wastewater management methods are usually machine-based, and thus energy consuming. When Permaculture Principles are used in the creation of water purification and harvesting systems, there can be multiple environmental and economic benefits. In the context of energy descent, it may be considered desirable to treat wastewater using minimal energy. The constructed wetland design presented here is a low-entropy system in which wastewater is harvested and transformed into lush and productive wetland, eliminating the requirement for non-renewable energy in water purification, and also maximising benefits: biodiversity, flood resilience and yield. In permaculture design, the high concentrations of nitrogen and phosphorous compounds in sewage are viewed as valuable nutrients, resources to be harvested by a constructed wetland ecosystem and converted into useful yield. Similarly, rainwater runoff is not viewed as a problem which can cause flooding, but as a potential resource to be harvested to provide a yield. This paper presents a case study, with both water quality and productivity data, from Brookside Farm UK, where the use of Permaculture Design Principles has created a combined wastewater management and purification system, accepting all site water.

Keywords: WET system; water retentive landscape; natural wastewater treatment; permaculture design principles; low-entropy systems; sustainable drainage systems; wastewater reuse; energy descent; low-impact development; whole site water reticulation

1. Introduction: The Ecological Imperative and Permaculture Design Principles

Wetland Ecosystem Treatment (WET) Systems are soil-based, multi-species, low-entropy systems for purifying wastewater. Each design is site specific, using for construction the earth resources available on site or locally. A WET System can be used solely for the purification of wastewater, can also incorporate rainwater harvesting from roofs and yards and can be a part of whole site water reticulation planning. Permaculture Design Principles are used to design WET Systems for a number of reasons. The evolution of the WET System methodology is a response to concerns about global changes in climate and local weather patterns, biodiversity loss, and the future constraints of energy descent [1].

Environmentally sensitive solutions already exist for many of the problems facing humanity: it is already known how to build, maintain, inhabit and manage sustainable systems, but in practice this is often overlooked by developers [2–14]. There are many opportunities to create integrated solutions, using information, elements and technologies already available. Permaculture design is a positive design philosophy, and the Principles behind it recognise that the damage done to Earth's ecosystems can be repaired. Permaculture design can create regenerative systems to supply a multitude of ecosystem services without the need for non-renewable energy use. Permaculture Design Principles are used extensively in the design of WET Systems.

The permaculture design process recommends the observation of natural systems, to inspire the creation of ecologically positive and regenerative sustainable systems. The aim is that human habitation and associated development be as regenerative as possible. Thus, Permaculture Design Principles are at the heart of the design process for sustainable and regenerative systems [15–17].

Permaculture Design Principles Include:

- Each element in the design performs multiple functions and each function is supported by many elements
- Use biological resources within the design
- Maximise productive 'edge' within the system
- Capture and store energy—Create a yield
- Use and value renewable resources and ecosystem services
- Design from universal patterns to detail

In addition to these overarching Principles, WET System designs follow the twelve principles outlined by John Todd and Beth Josephson for constructed wetland ecosystems which are to be used in natural wastewater purification [18]. These principles, along with Ecological Engineering Techniques [13,14] and sound constructed wetland design [16], have been used to create the combined wastewater purification and rainwater harvesting system at Brookside Farm, Warwickshire, UK.

1.1. Permaculture Design for Sustainable Human Habitation

Human development usually disrupts the ecology of a place; development can interfere with the hydrology of a site (the rainwater runoff/soil absorption rates and potential erosion of soils). Wastewater flows from a development can also cause damaging eutrophic pollution in the wider environment, if not adequately treated [19].

Constructed or modified natural wetlands are a Low Impact Development (LID) technique which can be used to control these problems at source. Effectively designed constructed wetlands can be used for agro-industrial wastewater flows as well as sewage and show good performance for nutrient capture from livestock wastewater [20]. This has been described in previous research [21] based upon a dairy farm.

The Principles of Permaculture Design aim to integrate ecosystem services into the fabric of our dwelling places; these can include integrated systems for food supply, renewable energy production, water harvesting and purification and wastewater purification. By taking a "source to sink" approach to water management on site, they encourage practices such as harvesting rainwater from roof areas and the conservation and creation of topsoil. These Principles also recommend the creation of a functional tree-scape, a zone of managed woodland which is designed to receive organic wastes and wastewater, and in return to supply useful materials: food, fuel and fibre.

Whilst WET Systems have been developed to naturally purify wastewater as an end-of-pipe solution, they can also incorporate rainwater harvesting from roofs and yards. A new development can be designed with a Whole Site Water Reticulation plan, in which all water flows—springs, surface and subsurface flows, and rainwater runoff—are harvested and put to use on site.

1.2. Sustainable Drainage Systems—SuDS

In the UK, Sustainable Drainage Systems (SuDS) is the name given to stormwater management techniques, strategies and policies intended to attenuate water flows by harvesting rainwater runoff from impermeable surfaces, improving water quality at the site of the development, and maximising amenity value, alongside taking account of the needs of local wildlife and habitats (biodiversity) [22]. In practice, SuDS rainwater management systems are rarely able to deliver all of their potential benefits, since the designs often view the rainwater only as a problem to be removed safely from site in a controlled manner. Water attenuation solutions often comprise a series of disconnected components rather than facilitating interaction between water, soil, plants, trees and other living organisms. Thus, even where SuDS are integrated into the overall development plan for a site, the aim is to dispose of a potential problem, that of rainwater becoming a flooding issue. Time, cost and space constraints limit the positive potential of SuDS sites, with ecological benefits and opportunities for sustainable on-site resource production either not considered, or designed out at the feasibility stage.

1.3. Benefits of the WET System Approach to Water in the Landscape

A Wetland Ecosystem Treatment or WET System can be described as a Low-Energy System: consisting of a constructed, functional, wetland ecosystem comprising specifically designed earthworks, densely planted with native wetland and other indigenous, non-invasive, plant and tree species. The WET System is not only a wastewater purification system, using no non-renewable energy, but is also an agroecological production system—producing a yield.

Furthermore, the WET System can be designed to have the volumetric capacity to hold large volumes of rainwater/surface runoff, increasing the residence time of the runoff from impermeable surfaces. By holding the rainwater in the system, peak flow is reduced and the time to peak runoff is increased, managing stormwater naturally.

A WET System integrated into a consciously designed whole site water reticulation system eliminates the need for non-renewable energy use in the processes of:

- i. Purification of wastewater.
- ii. Harvesting and cleaning of rainwater prior to its use.
- iii. A supply of clean water for agricultural production.
- iv. Biomass Resource production and right-livelihood.
- v. Enhancing the Biodiversity of the site.
- vi. Flood alleviation.

The chief aim of this paper is to describe the establishment and quantify the performance of the 3-year old WET System at Brookside Farm, a large privately owned smallholding in Warwickshire, UK. Specific objectives include:

- 1. Measurement of the water quality within the series of swales that receive the wastewater and rainwater from the farm by chemical and microbiological techniques.
- 2. Determination of the yield and economic benefits from the products grown in the WET System.
- 3. Assessment of the performance of Brookside Farm's WET System, with reference to existing mature WET Systems, and photographic evidence of growth and productivity of the site in this case study.

"A thing is right when it tends to preserve the integrity, stability and the beauty of the biotic community. It is wrong when it tends otherwise". (Aldo Leopold, A Sand County Almanac)

2. Materials and Methods—Site Construction and Arrangement

The combined WET System is at Brookside Farm in Warwickshire, UK. It serves up to 30 people, both living at and visiting the site. This overall number comprises the 6–10 permanent residents, and 20–25 visitors and guests, who stay on site for the various courses and workshops held on the land.

This study is based upon the lead author's own action research cycle, using embedded observation, where his role is that of Reflective Transdisciplinary Practitioner (RTP) and where the boundary object of this report is the WET System at Brookside Farm. It presents a description of the WET System and an analysis of the wastewater flowing through it, as well as historical and photographic analysis of the site both before and after the creation of the WET System.

It represents the first attempt to describe and quantify the performance of the Brookside Farm WET System. Over the next three years, there will be regular monitoring of the WET System as part of the PhD programme of research into Low-Entropy Systems Design currently under way at CAWR by the lead author of this paper.

2.1. WET Systems and Permaculture Design Principles

The Design Principles and design concept shown in this case study have been successfully developed and applied on a wide range of sites. These include domestic sewage purification at many different scales, and bio-industries such as brewing and food processing, cider makers, dairy farms, and cheese and ice cream makers. The WET Systems created to date do not cater for wastewater containing toxic bio-accumulatory substances.

Although over 200 WET Systems have been created since their inception in 1993, there has been no published work on them in the peer reviewed literature: the point of this paper is to rectify this and to initiate study on this form of water management system.

2.2. Maximising the Soil–Water Interface

The purification processes which occur over the huge surface area present in the "root zone" of a constructed wetland were outlined by Professor R. Kickuth in the early 1970s [23,24]. The WET System design uses high aspect ratio swales as the basis of the constructed wetland. This maximises the amount of planted wetland edge and also the overall Plug Flow kinetic of the water passing through the system. This placement of different ecotones adjacent to each other, and intimately interconnected, represents one of the most potentially productive systems because of the proximity of water to soil, without the soil being constantly waterlogged which would result in anoxic and underproductive conditions.

2.3. The Classic Dryland Infiltration Swale

A swale is simply a ditch or depression created on-contour, with an adjacent associated area of mounded or loosened soil which is densely planted with trees so that it acts to intercept and harvest overland rainwater flow, enabling water to percolate into the ground and to recharge groundwater. This type of swale was developed in Australia by P.A. Yeomans for use in brittle environments with low seasonal rainfall [8].

2.4. The Temperate Zone Non-Infiltration Swale

In contrast to the classic dryland Swale, which harvests rainwater, the WET System Swale is a non-infiltration Swale for a temperate climate with higher year-round rainfall, and can be designed to accept and process wastewater. The subsoil used to form this type of swale ditch is not loosened; either its base is compacted (puddled) to make it watertight, or it is lined with a waterproof liner. Water, therefore, has to flow through the topsoil, which is placed on top of the compacted subsoil or liner and then densely planted. A WET System comprises a series of non-infiltration, on-contour, swales which slow down the flow of water or wastewater. As the wastewater passes through these soil banks, drawn by capillary action and the evapotranspiration of the trees and the marginal plants, it is purified by the micro-organisms (fungi and bacteria) which inhabit the soil in the root zone of this densely planted, soil-based, multi-species constructed wetland. The input is led through a series of biological transformations to create a useful yield. This is in distinct contrast to conventional Reedbed Treatment Systems which, for purification, rely on a gravel matrix, usually planted with a single species of reed (*Phragmites communis*) [23].

2.5. Brookside Farm

In 2010, the owners of Brookside Farm wished to develop the productive capacity of their newly acquired site in an environmentally sensitive way, using Permaculture Design Principles [15]. In 2013, the lead author of this paper was asked to design and create a productive, integrated, sewage purification and rainwater harvesting system for the holding, to be located in a compacted horse-grazing paddock.

2.6. Brookside WET System

The WET System at Brookside was created in an area where there was little topsoil. It was compacted grass pasture, which for many years had been used to graze horses. During the site investigation, a trial pit excavation found the groundwater to be around 1.8 m below ground level. Brookside Farm had a rudimentary wastewater system in place when the current owners moved into site; the original arrangement was a septic tank, which carried out Primary Treatment only (i.e., the only function was the settlement of solids), with the settled sewage liquid being released to, and causing gross pollution of, the brook at the edge of the property.

The new twin chamber septic settlement tank provided the initial or primary treatment and settled out the solids from the sewage flow; the WET System was designed to provide primary treatment (settlement), secondary treatment (nutrient removal), and tertiary treatment (polishing).

2.7. WET System—Functional Earthworks and Dense Planting

The WET System has seven swales, each of approximately 60 m² and with a depth of 1500 mm at the deepest point. The swales were designed to absorb the wastewater and collect the rainwater run-off from nearby barns, to provide a nutrient-rich, well-watered environment for the production of a useful yield. A compacted retaining bund completely surrounding the WET System was created to prevent both the ingress of the seasonal floodwater, which affects some areas of the farm, and the discharge of any untreated wastewater. The barn roof water (from around 500 m² of roof area) was led by gravity flow, not to the sewage treatment part of the WET System, but via new rainwater pipework to the fourth swale within the WET System. This arrangement was to prevent the clean rainwater entering the septic system and washing the sewage through too quickly.

The first three swales were lined with a clay-based liner to ensure that no septic wastewater reached the groundwater. As topsoil was the purification medium, the whole of the planting area of the WET System—both the swale banks and the swale pools—was covered with the topsoil from the site; this topsoil acted as the planting substrate for the wetland and marginal species.

The swale banks and ponds making up the WET System were designed to direct the wastewater flow along and through specially constructed banks of topsoil which were stabilised by the planting of wetland plants and trees. The intention of the planting was to balance the creation of as much varied root zone as possible with the development of effective, attractive, high quality, well designed wildlife habitat and useful yield.

The first two swale banks were planted with basketry willows and heavy feeding wetland marginals, whilst the remainder of the swale banks and surrounding bunds were planted with wetland plants and trees, fruit and nut trees, soft fruit bushes and a wildflower herb understorey. The various cultivars of densely planted basketry willows on the swale banks are managed as short rotation coppice.

2.8. Woodchip mulch—Particulate Organic Carbon

The swales of the WET System at Brookside Farm were mulched with a deep layer of woodchip prior to planting. In WET System design, this woodchip has multiple functions: it provides long-term weed suppression after the initial completion of the earthworks stage, and also gives the WET System an immediate ability to accept septic wastewater. The woodchip acts as a particulate organic carbon source, helping to absorb and mineralise the nitrogen within the wastewater whilst the planted species became established [25].

The high surface area provided by the woodchip was rapidly colonised by the soil mycorrhizae (direct observation by the author of white filamentous growth and fruiting bodies) and other micro-organisms known to be common in moist soils rich in organic matter, this being the microbial community which converts the waste into a resource. This deep layer of woodchip has now decomposed to form a topsoil layer, adding to the long-term efficacy of this soil-based constructed wetland.

2.9. Outputs from the Wetland System

The WET System willow coppice at Brookside Farm will be fully established in winter 2016–2017; the 4000 coppice willows are all traditional basketry cultivars. The site will also produce an annual fruit and nut harvest, of damsons, plums, apples, pears, cherries, quince, walnuts, hazelnuts, chestnuts, blueberries, gooseberries, raspberries, redcurrants and blackcurrants. The weight of fruit yields taken from the WET System was recorded during 2016 by the owners of Brookside Farm.

2.10. Water Quality Sampling and Chemical Analysis

One litre grab samples were taken from each of the swale pools on the 7 July 2016. There was no precipitation on the day of sampling and the samples were analysed by ALS Environmental Laboratories, Coventry, for four microbiological and eight chemical water quality determinands. The laboratory used was UKAS accredited. UKAS is the UK laboratory accreditation service; this is a UK national quality mark that is traceable to ISO/EIC 17025:2005 standards "General Requirements for the competence of testing and calibration laboratories" [26].

The sampling strategy was designed to provide information on the water quality in each of the swales making up the WET System. A reference sample was taken, from a ditch adjacent to, but not connected to the WET System. The purpose of the ditch reference sample was to compare the quality of the local surface water, running off the arable fields surrounding the study site, with that achieved by the WET System at Brookside Farm.

3. Results

As shown in the Figures 1–3, the swales have matured from bare ground and open water to achieve complete cover in the three years since they were planted.



Figure 1. The compacted horse grazing field, prior to installation of the Wetland Ecosystem Treatment System.



Figure 2. The finished excavated swales in preparation for planting, 2013.



Figure 3. The Brookside Farm WET system 10 months after planting, showing the establishment of plants.



Figure 4. Plants growing in one of the sewage purification swales at Brookside Farm.

The progression of the swlaes post construction condition (Figures 1 and 2) to systems with complete cover and a range of plant types (Figures 3 and 4) demonstrates that installation of the WET Systems resulted in plant establishment. On regular visual inspection, water quality appears good, with no smell, and ongoing testing of this performance criteria will be performed in the next three years of the PhD programme.

3.1. Chemical and Microbiological Analysis of the Swale Pools at Brookside

The data in Figures 5 and 6 below show a large reduction in chemical pollutant concentrations after the input of settled sewage from the farmhouse in the first swale. The concentrations are reduced to very low concentrations for all determinands by the sixth of the seven swales, with the exception of environmental heterotrophic bacteria. Presumptive and confirmed *E. coli* were undetectable in the discharge from the last swale, which gives confidence that removal processes were working effectively for biological as well as chemical pollutants.

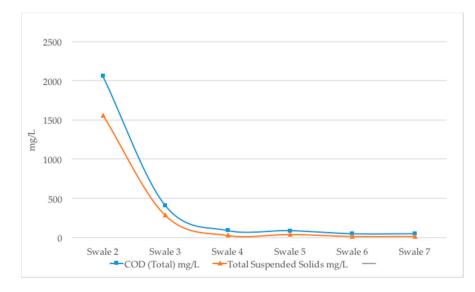


Figure 5. Chemical oxygen demand and total suspended solids in the WET System swales with transit through the reticulation system.

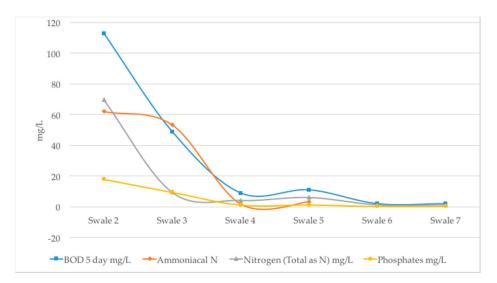


Figure 6. Water quality results as effluent passes through the WET System swales.

The results from this limited study demonstrate that under the meteorological conditions on site and with the sampling strategies used, the quality of discharge water from the WET System at

Brookside Farm was significantly better than that running from adjoining arable fields into a nearby ditch, as shown in Table 1, Total Suspended Solids and *E. coli* in the reference ditch were particularly high in comparison with the WET System after full treatment.

Analyte	Swale Two	Outlet to Discharge	Adjacent Ditch
Biological Oxygen Demand mg/L	113	2	12
Chemical Oxygen Demand (Total) mg/L	2060	47	249
pH (pH Units)	7.2	8.2	7.8
Ammoniacal N mg/L	62.1	< 0.41	< 0.41
Nitrate (as N) mg/L	< 0.7	<0.70	< 0.70
Nitrogen (Total as N) mg/L	69.7	1.4	1.4
Phosphates (total as P) mg/L	18	0.28	0.76
Total Suspended Solids mg/L	1560	16	388
<i>E. coli</i> (Presumptive) cfu/100 mL	71	0	>100
E. coli (Confirmed) cfu/100 mL	71	0	>100
Total Viable Count (37 °C 2 day) cfu/100 mL	>1000	>1000	>1000
Total Viable Count (22 °C 3 day) cfu/100 mL	>1000	>1000	>1000

Table 1. Water quality near the inlet in swale two and at discharge. Chemical and biological determinands from a nearby reference ditch are presented.

Table 2. Produce from the WET System plants with weight yield and estimated values.

Produce	Yield (kg)	Estimated Value (£)
Elderberries	0.30	19.47
Blackcurrants	3.00	179.70
Redcurrants	0.28	2.50
Raspberries	0.50	10.00
Blueberries	0.10	2.50
Cherries	2.00	30.00
Apples	33.5	67.00
Pears	1.00	2.00
Plums	12.5	56.13
		Total 369.30

3.2. Economic Benefits from On-Site Production

In the winter 2015–2016, these willow coppice stools produced over 15,000 coppice willow wands for sale, the rods being between 1 and 3 metres long. This could increase to around 40,000 willow wands per year in the future, depending upon the management regime adopted. These willow wands can be harvested for basket-making, other traditional crafts, or as kindling or as a fuel for a rocket stove or biomass burner. The annual crop of coppiced willow wands from the WET System will enable the owners of Brookside Farm to run willow basketry workshops or to sell their willow harvest. At current prices (between 20 pence to 50 pence per wand) for good quality organic (unsprayed) willow wands, a single year's yield would bring in between £3000 and £7000.

If the owners were to replace foodstuffs purchased in retail outlets with WET System produce, it would reduce fresh produce costs by a minimum of $\pounds 10$ per week during summer (where soft summer fruits are available) and similarly in the autumn season where fruits (e.g the apples in Figure 7) and nuts would be available. More detail on production is given in Table 2. A conservative estimate for the yearly value of foodstuffs is around $\pounds 400$ per year for many decades into the life of the WET System.



Figure 7. The Brookside Farm WET System in July 2016. The image shows one of the apple trees bearing fruit.

4. Discussion

Data obtained from the Brookside Farm site and presented in this paper, has begun the systematic and long-term monitoring of this WET System to quantify its performance by commonly recognised water quality criteria. The acceptance of all water including rainwater and wastewater into the WET System shows the capacity of the system design to deal with volume as well as wastewater purification with no added energy. Observing the ability of the Brookside Farm WET System to deal with intense rainfall conditions at the same time as continued wastewater treatment is a goal of future monitoring.

The wildlife benefits of this constructed, wetland ecosystem are shown in the pictures of the maturing site and this benefit to the local ecology supplements the monetary value of the yield from fruits, nuts and willow.

Water Quality Data from Other Established WET System Sites

Since 1993 WET Systems, using the Design Principles described above, have been implemented in many locations, for a variety of wastewater types. Data is available on WET Systems serving a family run brewery, a residential visitor centre and a livestock market, as presented below:

Devon Brewery. Data was obtained from the Brewery in 2006. The wastewater had an average Biological Oxygen Demand of around 3500 mg/L. The value from the WET System represents the result obtained whilst the consent limit is what the UK Environment Agency considered acceptable to discharge to a watercourse. This data, shown below in Table 3, was generated by an independent, accredited analytical laboratory and was verified by the Environment Agency in a report to the lead author.

Table 3. Water quality results from a family run brewery in Devon after WET System treatment.

Analyte	Values from the WET System	Consent Limit
Ammonia (as N) mg/L	<5	30
BOD as $O_2 mg/L$	<2.92	40
pH	6.7	9
Suspended solids mg/L	<3	60

Preston Montford Field Studies Centre, a residential field studies centre near Shrewsbury.

The centre had a population of up to 180 visitors and staff. The centre's sewage treatment system was regularly failing its consent to discharge when the site's manager requested a WET System be installed. Historical water data taken from established WET Systems, shown in Figure 8 and Table 4 below, has consistently shown good performance in line with Environment Agency discharge consent and also an improvement in water quality performance over extended time periods: the results at Brookside Farm are in line with the data from similar sites.

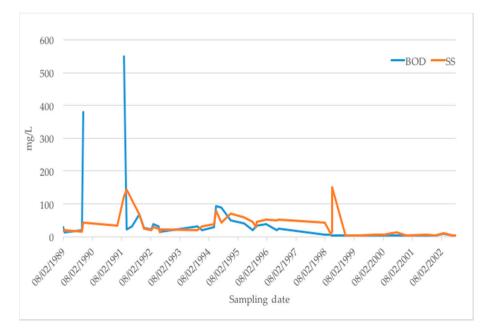


Figure 8. Results from Preston Montford Field Studies Centre near Shrewsbury between 1989 and 2005. BOD and suspended solids values are presented in mg/L. Samples were taken seasonally over 16 years. The WET System was installed in November 1997.

Table 4. Results from Hereford Cattle Market showing water quality values for effluent flowing into the WET System and the values derived from a pond at the end of the WET System process.

Analyte	Inlet	Outlet
pН	8.1	7.5
Ammoniacal Nitrogen	115 mg/L	<0.27 mg/L
Total N	174 mg/L	10.3 mg/L
Phosphates	51 mg/L	4.8 mg/L
BOD	2190 mg/L	15 mg/L
COD	8050 mg/L	184 mg/L
TOC	280 mg/L	mg/L

5. Conclusions

The Brookside Farm WET System fulfils its function of low-entropy wastewater purification, using no non-renewable energy, it purifies the water to the high level shown by the water quality data also yielding willow and food crops.

The WET System provided enhanced biodiversity and wildlife habitat. Although this has not yet been fully quantified by a wildlife survey, the contrast between the overgrazed horse paddock before and after the WET System was planted shows increased species of flora and fauna, as flowering plants multiply and bring in more insects, and the water attracts dragonflies, other invertebrates, and amphibians.

Quotes from the client on their views on the constructed wetland system:

Anthony Headlam: "The problem we had was a septic tank which was leaking all over the property and then into the nearby brook. We were introduced to Biologic Design by a friend, and they have not only solved the problem, but also given us an amazingly abundant space. We have turned a barren 1600 m^2 area of overgrazed and compacted horse pasture into a lush, productive forest garden as well as a sustainable water harvesting and sewage cleansing system. We couldn't be more delighted".

Katherine Headlam: "Because of the pollution caused by the previous sewage arrangements on the farm, it's a huge relief to have created our WET System and now to watch it develop. We had a choice of either having a conventional energy-consuming packaged sewage treatment plant, or to look for a more sustainable and ecologically sound alternative. Choosing a WET system has also opened up a huge opportunity for us to meet different people, make new friends and engage with people who share our desire to look for more sustainable ways of living. Apart from the crops which we now harvest from the WET System, we now have a number of further opportunities to engage in spin-off activities such as arts and crafts, aquaponics and meditation, and it's getting better and better as time goes by and the system matures".

The results obtained demonstrate that the diverse and robust nature of these living systems, when fully integrated into the design and management of human habitation, can give economic and ecological as well as spiritual benefits.

Research will continue into the seasonal performance of the WET System for water quality and flood attenuation with varying inputs and environmental conditions. A full assessment of the economic and wildlife benefits provided at Brookside will also form a part of the ongoing monitoring programme.

"Water is the driving force of all nature". (Leonardo da Vinci)

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Conflicts of Interest: Julian C. Abrahams is the founder and the ecological designer at Biologic Design and also created the Brookside Farm System. The rest of the authors declared no conflict of interest. "The founding sponsors had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, and in the decision to publish the results".

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