

Gate Burton Energy Park

EN010131

Applicant Response to Rule 17 Request - Waste
Document Reference: EN010131/APP/8.33
December 2023

APFP Regulation 5(2)(a)
Planning Act 2008
Infrastructure Planning (Applications: Prescribed Forms and Procedure) Regulations 2009

Prepared for:

Gate Burton Energy Park Limited

Prepared by:

AECOM Limited

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1. Introduction

- 1.1.1 This Technical Note has been prepared in response to the Rule 17 Request for Information issued by the Examining Authority on 8 December 2023 during Examination on the Gate Burton Energy Park Development Consent Order application.
- 1.1.2 As requested, this technical note applies the Methodology W1 from the Institute of Environmental Management & Assessment (2020) Guide to Materials and Waste in Environmental Impact Assessment (referred to hereafter as the “IEMA Guide”) to waste arising from the Scheme including cumulative impacts.
- 1.1.3 This assessment has been undertaken by Mike Bains BSc CChem MRSC, who was a contributing author of the IEMA Guide.

2. Study Area

- 2.1.1 Two study areas are defined in the IEMA Guide.
- The “development study area” is the red line boundary of the Scheme, within which waste will be generated. In this case, this is the Order limits for the Scheme.
 - The “expansive study area” is the area which contains the waste facilities that could be used to manage the waste. For non-hazardous waste, this is assessed as being the East Midlands, and for hazardous waste it is assessed as being England.
- 2.1.2 East Midlands is used for non-hazardous waste (rather than Lincolnshire or Nottinghamshire alone or in combination) recognising the fact that waste may not always be managed in the Waste Planning Authority where it is generated and may instead be managed at the regional level. England is used for hazardous waste, since this type of waste is managed nationally at a small number of facilities.

3. Methodology

3.1.1 IEMA guidance states that:

“The sensitivity of waste relates to availability of regional (and where appropriate, national) landfill void capacity in the absence of the proposed development. Landfill capacity is recognised as an unsustainable and increasingly scarce option for managing waste.

Note: In this guidance, it is considered that infrastructure that is used to process and recover arisings (and hence divert them from landfill) is a beneficiary of waste feedstock, and has the ability to reduce adverse impacts. Such facilities are therefore an influencing factor in the reduction of the magnitude of waste impacts on landfill void capacity, rather than being a sensitive receptor in their own right.”

3.1.2 Hence the receptor considered is landfill void capacity. Other waste management capacity (e.g. for the recycling of PV modules) is not considered as a sensitive receptor in the IEMA Guide.

3.1.3 The sensitivity of receptors (i.e. landfill void capacity) is determined based on the expected change in capacity between the current time and the assessment year, using the following criteria.

Table 1: Receptor Sensitivity

Effects	Criteria for Inert and Non-Hazardous Landfill Capacity Sensitivity	Criteria for Hazardous Landfill Capacity Sensitivity
Negligible	Across construction and/or operation phases, the baseline/future baseline (i.e. without the Scheme) of regional inert and non-hazardous landfill capacity expected to remain unchanged, or is expected to increase through a committed change in capacity.	Across the construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional (or where justified, national) hazardous landfill capacity is expected to remain unchanged or is expected to increase through a committed change in capacity.
Low	Across construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional inert and non-hazardous landfill capacity is expected to reduce minimally by <1% as a result of wastes forecast.	Across the construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional (or where justified, national) hazardous landfill capacity is expected to reduce minimally by <0.1% as a result of wastes forecast.
Medium	Across construction and/or operation phases, the baseline/future baseline (i.e., without the Proposed Development) of regional inert and non-hazardous landfill capacity is expected to reduce noticeably by 1-5% as a result of wastes forecast.	Across the construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional (or where justified, national) hazardous landfill capacity is expected to reduce noticeably by 0.1-0.5% as a result of wastes forecast.
High	Across construction and/or operation phases, the baseline/future baseline (i.e. without the Scheme) of regional inert and non-hazardous landfill capacity is expected to reduce considerably by 6-10% as a result of wastes forecast.	Across the construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional (or where justified, national) hazardous landfill capacity is expected to reduce considerably by 0.5-1% as a result of wastes forecast.

Effects	Criteria for Inert and Non-Hazardous Landfill Capacity Sensitivity	Criteria for Hazardous Landfill Capacity Sensitivity
Very High	Across construction and/or operation phases, the baseline/future baseline (i.e. without the Scheme) of regional inert and non-hazardous landfill capacity is: expected to reduce very considerably (by >10%); expected to end during construction or operation; is already known to be unavailable; or would require new capacity or infrastructure to be put in place to meet forecast demand.	Across the construction and/or operation phases, the baseline/future baseline (i.e., without the Scheme) of regional (or where justified, national) hazardous landfill capacity is: expected to reduce very considerably (by >1%); expected to end during construction or operation; is already known to be unavailable; or, would require new capacity or infrastructure to be put in place to meet forecast demand.

3.1.4 Magnitudes of impact are assessed against the following criteria.

Table 2: Magnitude of Impacts

Magnitude of Impact	Inert and Non-Hazardous Waste	Hazardous Waste
No change	Zero waste generation and disposal from the development.	Zero waste generation and disposal from the development.
Negligible	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by <1%.	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by <0.1%.
Minor	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by 1-5%.	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by <0.1-0.5%.
Moderate	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by 6-10%.	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by <0.5-1%.
Major	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by >10%.	Waste generated by the development will reduce Expansive Study Area landfill capacity baseline by >1%.

3.1.5 Effects thresholds and significance are as follows:

Table 3: Effects Thresholds

		MAGNITUDE OF IMPACT				
		NO CHANGE	NEGLIGIBLE	MINOR	MODERATE	MAJOR
SENSITIVITY OF RECEPTOR	VERY HIGH	Neutral	Slight	Moderate or Large	Large or Very Large	Very Large
	HIGH	Neutral	Slight	Slight or Moderate	Moderate or Large	Large or Very Large
	MEDIUM	Neutral	Neutral or Slight	Slight	Moderate	Moderate or Large
	LOW	Neutral	Neutral or Slight	Neutral or Slight	Slight	Slight or Moderate
	NEGLIGIBLE	Neutral	Neutral	Neutral or Slight	Neutral or Slight	Slight

Table 4: Significance Criteria

EFFECT	WASTE
Neutral	Not Significant
Slight	Significant
Moderate	Significant
Large	
Very large	

4. Baseline

Current Baseline

4.1.1 Environment Agency data on landfill capacity in 2022 in the East Midlands (for inert/non-hazardous waste) and England (for hazardous waste) is shown below.

Table 5: Landfill Void Capacity, 2022

Landfill Type	East Midlands (m3)	England (m3)
Hazardous Merchant	657,000	7,922,000
Hazardous Restricted	-	708,000
Non Hazardous with SNRHW cell*	16,980,000	51,122,000
Non Hazardous	14,858,000	151,482,000
Non Hazardous Restricted	-	0
Inert	18,685,000	129,125,000
Total	51,181,000	340,359,000

*Some non-hazardous sites can accept some Stable Non Reactive Hazardous Wastes (SNRHW) into a dedicated cell, but this is usually a small part of the overall capacity of the site.

Source: Environment Agency 2022 Waste Data Interrogator – Waste Summary Tables for England
(<https://www.data.gov.uk/dataset/aa53a313-f719-4e93-a98f-1b2572bd7189/2022-waste-data-interrogator>)

Future Baseline

4.1.2 Future baseline landfill void capacity is relevant for the assessment of operational waste (for periodic replacement of equipment) and decommissioning waste.

4.1.3 There is no published information on landfill capacity at future dates. Whilst individual Waste Planning Authorities carry out Needs Assessment to determine whether they have sufficient landfill capacity to accommodate waste arisings during their Waste Plan period (typically 25 years), there is no requirement to forecast or provide landfill capacity beyond this period.

4.1.4 Trend analysis over such lengthy period is inevitably difficult, since even moderate declines in landfill capacity over recent years would, if extended over the 60 year timeline to decommissioning, would predict zero landfill

capacity at that time. Conversely, any recent increases in landfill capacity (i.e. due to new sites being permitted) would be extrapolated to unrealistically high future estimates.

- 4.1.5 It is likely that future void capacity will decline if current policies on landfill diversion and the circular economy are maintained, with landfill becoming a decreasingly important part of the waste management system. It is not however possible to accurately predict what will be the landfill void capacity in 25 years time, still less 60 years time.
- 4.1.6 If the landfill void capacity is extrapolated to fall to zero in the future, then an assessment using the IEMA guidance is not possible, since even a vanishingly small amount of waste requiring landfill (e.g. 1 tonne) would be greater than 10% of the remaining capacity, if that remaining capacity is estimated to be zero. This would mean any project with a long timescale before waste is created would be assessed as having a significant adverse waste effect.
- 4.1.7 The IEMA Guide recognises this difficulty and states:
- “Due to uncertainties relating to future technologies and infrastructure, this first edition of the guidance does not incorporate a proposed methodology to assess impacts and effects during decommissioning or end of first life. Due to uncertainties relating to future technologies and infrastructure, this first edition of the guidance does not incorporate a proposed methodology to assess impacts and effects during decommissioning or end of first life.”*
- 4.1.8 Two approaches have been taken in this Technical Note:
1. Assuming that the level of landfill void capacity in the future will be broadly similar to the current situation; and that the waste planning authorities will plan for and provide sufficient landfill capacity to accommodate future requirements.
 2. Comparing waste arisings against the amount of construction and demolition waste that is currently being generated in the region per year (on the assumption that this would remain constant over time, which is the assumption taken when Waste Planning Authorities forecast their future needs).
- 4.1.9 The IEMA Guide does not provide assessment criteria for assessing waste arisings against existing annual arisings, and hence this information is provided for information only, and not used in assessing impacts.
- 4.1.10 Waste arisings from the Proposed Development have been compared to construction and demolition waste in the East Midlands (matching the expansive study area for landfill void capacity), and also to construction and demolition waste arisings in Nottinghamshire and Lincolnshire. This is done to provide a point of comparison with the waste assessments for Cottam and West Burton solar projects. For these two projects, the project proponent compared waste expected to be sent to landfill from each project to the amount of construction and demolition waste expected to be sent to landfill annually in each county.

5. Waste Arisings

5.1.1 Estimated waste arisings from the construction of the Scheme are shown in Table 6, assuming a 70% recovery rate for all materials. In practice, it is very likely that a higher recover rate could be achieved, based on current industry good practice: the current construction and demolition (C&D) waste recovery rate for England is approximately 92.6%.

Table 6: Waste Arisings - Construction

Waste type	Total waste (m3)	Recovery/recycling (m3)	Landfill (m3)
Concrete	441	309	132
Aggregate	731	512	219
Excavated soil	2,853	1,997	856
Aluminium	15	11	5
Plastic (cabling)	42	30	13
Paperboard	22,149	15,504	6,645
Wood	16,193	11,335	4,858
Plastic	1,790	1,253	537
Totals	44,215	30,950	13,264

5.1.2 Estimated waste from operations and decommissioning are shown in Table 7.

5.1.3 The operational and decommissioning waste estimates also assume a 70% recovery rate for all materials. Again, it is considered that this is likely to be an underestimate and that the actual recovery rate would be significantly higher, as described below.

5.1.4 The operational waste estimates are based on the following “replacement rates” – i.e the proportion of that element of the Scheme that will need replacement within the operational period, where 100% means that complete replacement will be required during the operational period.

- PV modules: 110%
- PV Inverter: 150%
- Transformers: 105%
- BESS Batteries: 150%

Table 7: Waste Arisings – Operational and Decommissioning

Material	Operational waste (tonnes)	Decommissioning waste (tonnes)	Operational waste (m3)	Decommissioning waste (m3)	Recovery Rate	Operational waste recovered (m3)	Operational waste disposed (m3)	Decommissioning waste recovered (m3)	Decommissioning waste disposed (m3)
Aggregate	-	15,504	-	14,627	70%	-	-	10,239	4,388
Concrete	-	8,202	-	8,820	70%	-	-	6,174	2,646
Module	38,053	34,594	122,752	111,593	70%	85,926	36,826	78,115	33,478
PV Inverter	247	165	950	633	70%	665	285	443	190
Transformers	2,363	2,250	9,087	8,654	70%	6,361	2,726	6,058	2,596
Structure	-	21,000	-	48,837	70%	-	-	34,186	14,651
Electrical Cabling	-	464	-	1,080	70%	-	-	756	324
MV Switchgear	-	189	-	728	70%	-	-	509	218
BESS Batteries	517	344	383	255	70%	268	115	179	77
Totals:	41,179	82,713	133,171	195,226		93,220	39,951	136,658	58,568

Recovery and Recycling Assumptions

5.1.5 Two assessments have been carried out, with different assumptions around recovery rates:

1. A “realistic worst case”, based on current and likely future recovery rates.
2. An “absolute worst case” based on the assumption that all waste goes to landfill.

5.1.6 The “absolute worst case” is considered to be extremely unlikely to occur for the following reasons:

- The current C&D waste recovery rate for England is approximately 92.6% and has remained at a similar level since 2010¹.
- Waste generated by the Scheme comprises readily recyclable materials:
 - Concrete and aggregate are widely recycled for use in construction
 - Metals have a very high recycling rate with a very well developed market, historically driven by economics but increasingly also by the need for decarbonisation of the metal production sector.
 - PV panels are recyclable and there are numerous examples of companies recycling them. Capacity for PV panel recycling in the UK is relatively low at present because there is currently little waste being generated. There are strong economic and regulatory drivers for recycling, and it is technically proven, and hence it is realistic to expect a high recycling rate.
- Primary legislation (the Waste Electrical and Electronic Equipment Regulations 2013 (as amended)) places an obligation on producers (manufacturers and importers) of electrical and electronic equipment (which includes PV panels) to finance the collection and recycling of their products. Producers of PV panels are obligated to join a Producer Compliance Scheme (PCS), which then ensures their legal obligations are met, most significantly for the collection and recycling of old PV panels.

5.1.7 The “realistic worst case” assumes a 70% recycling rate. The Applicant considers this is a realistic worst case since:

- a. It is considerably lower than the current C&D waste recovery rate for England; and
- b. The majority of project waste during operation and decommissioning will comprise PV panels and metal supporting structures and frames, both of which are expected to have very high recycling rates as a result of technical, economic and regulatory drivers.

5.1.8 The assessment assumes that current policy, regulatory and fiscal incentives for recycling and otherwise diverting waste from landfill will be maintained. The Applicant considers this is a realistic worst case for assessment since:

¹ <https://www.gov.uk/government/statistics/uk-waste-data/uk-statistics-on-waste#recovery-rate-from-non-hazardous-construction-and-demolition-cd-waste>

- Any move away from the current policy framework would be inconsistent with the underlying principles of waste management that have been progressively implemented over the past 20+ years, as well as being inconsistent with the policy objectives of Net Zero (since recycling and recovery have a significant role to play in achieving Net Zero); and
- If at any point the policy framework were to move away from favouring recovery and recycling, then there would need to be a large expansion in landfill capacity to accommodate the waste that was no longer recovered or recycled; in which case landfill void capacity would no longer be considered a sensitive receptor. A move away from favouring recycling and recovery without an associated increase in landfill void capacity would not be a tenable policy.

6. Impact Assessment

6.1.1 The impact assessment is presented in Table 8.

6.1.2 The receptor is landfill void capacity in the East Midlands, for non-hazardous and inert waste combined. Since there is no reliable information on void capacity in the future, it is assumed to remain at current levels but has been assigned a “Very High” sensitivity recognising the potential for it to decline significantly in future years.

Table 8: Impact Assessment Summary

	Construction	Operation	Decommissioning
Baseline			
Regional landfill capacity (m3)	50,523,629	50,523,629	50,523,629
Regional C&D waste arisings (tonnes)	5,174,588	5,174,588	5,174,588
Lincs & Notts C&D waste arisings (tonnes)	2,086,000	2,086,000	2,086,000
Scheme Waste			
Total waste from Scheme (tonnes)	14,400	41,179	82,713
Total waste from Scheme (m3)	44,215	133,171	195,226
Waste to landfill, m3 (realistic worst case estimate - 70% recovery rate)	13,264	39,951	58,568
Waste to landfill, m3 (assuming zero recycling/recovery)	44,215	133,171	136,658
Comparison Against Baseline			
%age of regional landfill capacity required for Scheme (realistic worst case estimate)	0.03%	0.08%	0.12%
%age of regional landfill capacity required for Scheme (assuming zero recycling/recovery)	0.09%	0.26%	0.27%
% of regional C&D waste arisings	0.3%	0.8%	1.6%
% of Lincs & Notts C&D waste arisings	0.7%	2.0%	4.0%
Assessment			
Receptor Sensitivity	Very High	Very High	Very High
Realistic Worst Case			
Magnitude of Impact	Negligible	Negligible	Negligible
Effect	Slight adverse	Slight adverse	Slight adverse
Significance	Not significant	Not significant	Not significant
Absolute Worst Case			
Magnitude of Impact	Negligible	Negligible	Negligible
Effect	Slight adverse	Slight adverse	Slight adverse
Significance	Not significant	Not significant	Not significant

- 6.1.3 The assessment shows that, even under the absolute worst case assessment, effects would not be significant.
- 6.1.4 At decommissioning, assuming this occurs in a single year, waste from the Scheme would equate to approximately 1.6% of C&D waste arisings in the East Midlands, and 4% of C&D waste arisings in Lincolnshire and Nottinghamshire.
- 6.1.5 This assessment is in line with the assessments for Cottam and West Burton solar projects at the regional level (i.e. the expansive study area as defined in the IEMA Guide), with the exception that the Cottam and West Burton projects also assess and report impacts at the sub-regional level and identify a moderate or large (and therefore significant) effect on “landfill waste handling” in Nottinghamshire (but not Lincolnshire) during decommissioning only.
- 6.1.6 The quantities of hazardous waste are expected to be limited to batteries, estimated at 517 tonnes during operation and 344 tonnes during decommissioning. It is very unlikely that batteries would be sent to landfill, and even if they were, this would represent only a very small fraction of hazardous landfill void capacity in England of almost 8 million m³; impacts on hazardous landfill void capacity are therefore assessed as slight and not significant.

7. Cumulative Impacts

7.1.1 The cumulative assessment follows the same approach as for assessment of the Scheme, and considers waste generated from the following other Solar PV schemes in Lincolnshire and Nottinghamshire:

- West Burton Solar Farm
- Tillbridge
- Gate Burton Energy Park
- Cottam Solar Project
- One Earth Solar Farm
- Solar Farm - Bumble Bee Farm
- Solar Farm - Field Farm Wood Lane
- Solar Farm - Sturton Road
- Stow Park Solar Farm
- Development Site to the North of Brick Yard Road
- Former High Marham Power Station Solar Photovoltaic Farm
- Land North And South Tuxford Road

7.1.2 Waste estimates are not available for all of these projects, and hence estimates have been generated specifically for this cumulative assessment by:

- Estimating PV module waste based on a nominal module capacity and weight of 650 kW and 35 kg respectively;
- Assuming that the ratio of other waste to PV module waste for these other schemes is the same as for Gate Burton (i.e. 42% of total waste by mass comprises PV modules, and the remaining 58% is other waste).

7.1.3 The cumulative assessment focuses on decommissioning waste since:

- The assessment above demonstrates that the peak of waste generation would be during decommissioning and this is therefore the worst case in terms of waste generation; and
- Operational waste generation is not expected to be concurrent for all projects, given that their PV modules and other components would have different operating periods and it is very unlikely that all facilities would replace their equipment at the same time.

7.1.4 For the purposes of this cumulative assessment, it is assumed that all schemes are decommissioned over a single 5 year period.

7.1.5 The cumulative impact assessment is presented in

7.1.6 Table 9.

Table 9: Cumulative Impact Assessment Summary

Scheme	Approx. Size (MW)	PV panel waste (tonnes)	Other waste (tonnes)	Total waste (tonnes)
West Burton Solar Farm	480	28,000	38,947	66,947
Tillbridge	500	29,167	40,570	69,737
Gate Burton Energy Park	500	34,594	48,119	82,713
Cottam Solar Project	600	35,000	48,684	83,684
One Earth Solar Farm	740	43,167	60,044	103,211
Solar Farm - Bumble Bee Farm	49.9	2,911	4,049	6,960
Solar Farm - Field Farm Wood Lane	49.9	2,911	4,049	6,960
Solar Farm - Sturton Road	49.9	2,911	4,049	6,960
Stow Park Solar Farm	35	2,042	2,840	4,882
Development Site to the North of Brick Yard Road	45.4	2,648	3,684	6,332
Former High Marham Power Station Solar Photovoltaic Farm	43	2,508	3,489	5,997
Land North And South Tuxford Road	49.9	2,911	4,049	6,960
TOTAL:	3,143	188,769	262,574	451,343
Cumulative Waste (per year, assuming all schemes decommissioned within 5 year period)				
Total waste from cumulative schemes (tonnes)		37,754	52,515	90,269
Total waste from cumulative schemes (m3) (assuming density of 0.31 t/m3 for PV panels and 1.6 t/m3 for other waste)		121,786	84,024	205,810
Waste to landfill, m3 (realistic worst case estimate)		36,536	25,207	61,743
Waste to landfill, m3 (assuming zero recycling/recovery)		121,786	84,024	205,810
Baseline				
Regional landfill capacity (m3)				50,523,629
Regional C&D waste arisings (tonnes)				5,174,588
Lincs & Notts C&D waste arisings (tonnes)				2,086,000
Comparison Against Baseline				
%age of regional landfill capacity required for Scheme (realistic worst case estimate)				0.12%
%age of regional landfill capacity required for Scheme (assuming zero recycling/recovery)				0.41%
% of regional C&D waste arisings				1.7%
% of Lincs & Notts C&D waste arisings				4.3%

Scheme	Approx. Size (MW)	PV panel waste (tonnes)	Other waste (tonnes)	Total waste (tonnes)
Assessment				
Receptor Sensitivity				Very High
<i>Realistic Worst Case</i>				
Magnitude of Impact				Negligible
Effect				Slight adverse
Significance				Not significant
<i>Absolute Worst Case</i>				
Magnitude of Impact				Negligible
Effect				Slight adverse
Significance				Not significant

7.1.7 The assessment shows that, even under the absolute worst case assessment, effects would not be significant.

7.1.8 This assessment is in line with the assessments for Cottam and West Burton solar projects at the regional level (i.e. the expansive study area as defined in the IEMA Guide), with the exception that these projects also assess impacts at the sub-regional level and identify a moderate or large (and therefore significant) effect on “landfill waste handling” in Nottinghamshire (but not Lincolnshire) during decommissioning only.

7.1.9 At decommissioning, assuming this occurs over a single 5 year period for all schemes, waste from the cumulative schemes would equate to approximately 1.7% of C&D waste arisings in the East Midlands, and 4.3% of C&D waste arisings in Lincolnshire and Nottinghamshire.

7.1.10 In the case of hazardous waste, it is very unlikely that batteries would be sent to landfill, and even if they were, this would represent only a very small fraction of hazardous landfill void capacity in England of almost 8 million m³; cumulative impacts on hazardous landfill void capacity are therefore assessed as slight and not significant.

8. Implications for the Development Consent Order Application

- 8.1.1 The assessment presented in this Technical Note concludes that when assessing waste generated by the Scheme using the Methodology W1 from the IEMA Guide, there are no new or different significant adverse effects identified when compared to the assessment presented in Chapter 15 of the Environmental Statement **[APP-024/3.1]**.
- 8.1.2 The IEMA Guide recognises the difficulties of assessing waste impacts at decommissioning and explicitly does not present a methodology for assessing these impacts. It is recognised that the assessments carried out for the West Burton and Cottam Solar Projects come to the conclusion that there is the potential for significant adverse effects from the waste generated from those projects during decommissioning, but at the sub-regional level (for Nottinghamshire only). The reason for this differing conclusion is that, in the absence of a methodology in the IEMA Guide, these projects have adopted a different approach to determining future baseline and have also assessed impacts at sub-regional level. Without prejudice to the Applicant's conclusion of no likely significant effects, if the ExA or Secretary of State did determine there is the potential for likely significant effects on waste from as presented in the Planning Design and Access Statement **[EN010131/APP/2.2]** for the Gate Burton Energy Park, there is a critical and urgent need for development of large scale solar projects, and the benefits of the Scheme significantly outweigh any limited adverse effects.