Assessment of Indicative BAT for Production of Speciality Organic Chemicals Sector (EPR 4.02)

Guidance Section No[1].	Requirement	Operating to Guidance Requirement	Demonstration of Indicative BAT
1	**Managing your activities**		
1.1	**Environmental performance indicators** Monitor and benchmark your environmental performance, and review this at least once a year. Your plans for minimising environmental impacts should be incorporated into on-going improvement programmes. Indicators can be derived using the Horizontal Guidance Note H1 Environmental Risk Assessment (see GTBR Annex 1). It is suggested that indicators are based on tonnes of organics produced (tOP) as they provide a good basis for measuring performance within an installation or a single company year on year.	Yes	The Croda Europe Leek site implements and adheres to an Environmental Management System (EMS) certified to ISO14001:2015 requirements. The EMS & Pollution Prevention and Control Permit procedure (SHE/050) establishes documented objectives and targets at relevant functions and levels within the organisation. This includes the assignment of individual responsibilities for specific levels of employee and the provision for the site director to ensure that resources are availability to establish, implement, maintain and improve the EMS and it is the responsibility of the SHE Manager to ensure that the EMS is established, implemented and maintained in accordance with ISO 14001. According to the site procedure SHE/050 Environmental Management System and Pollution Prevention and Control Permit, the EMS is assessed every 6 months by BSI against the Certification Assessment Plan with a strategic review every 3 years. Nonconformities and observations identified will be completed as necessary. Croda Group SHE carries out environmental review of the site at intervals not greater than every 5 years. As the proposed new site process is still under development, it is continually reviewed at all phases (theory, pilot, small scale and full scale), to optimise the process; therefore the process is subject to improvements (as identified). There are also KPIs (environmental and others) set up at a corporate level. Example targets for the Leek site (based on a 2015 baseline year and linked to site production) include: • To maintain and continually improve the SHE Management systems; • to generate 27% of the Groups total energy requirements from non-fossil fuel sources by the end of 2020; • to reduce the Leek site carbon emissions by 20% by 2025; • To minimise the mass of VOC's released to air from our process - to reduce total VOC emissions by 10% by 2020; • To minimise the quantities of waste disposed to landfill - reduce total Group waste to landfill by 10% by 2020;

[1] With direct reference to sections of Environment Agency guidance, How to comply with your Environmental Permit Additional guidance for Speciality Organic Chemicals Sector (EPR 4.02), dated March 2009

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- To reduce the Croda Group requirements for mains water - to reduce total Group water consumption by 10% by 2020.

Performance against these targets is reviewed and reported on an annual basis.

Croda regularly reviews and disseminates to all employees, company and corporate objectives and targets, compliance obligations, operational requirements and opportunities for improvement.

The Site Environmental Management System document (SHE/050) states that the Site Director and SHE Manager consider the site policy, aspects and compliance obligations, risks and opportunities together with a review of past performance in order to determine annual environmental objectives and targets.

These objectives may be embedded within the Site Director, SHE Manager and other manager's annual appraisal objectives including timeframes for implementation in accordance with the Croda International Plc Performance Appraisal arrangements.

Progress is monitored through the quarterly SHE review process including measured data if practicable.

SHE Objectives are recorded in the Environmental Training Programme (SHE/050/LF03) and are documented, controlled and communicated within the Q-Pulse system. Objectives are updated annually.

Objectives and related performance is periodically communicated to relevant internal and external stakeholders through the communication process.

As an integral requirement of the EMS and the environmental permit, the site monitors, collates and reports environmental performance data periodically. SHE Data Gathering Procedure SHE/047 describes all raw data inputs that are monitored and measured (e.g. utilities, production, incidents) and associated reporting outputs (e.g. Environment Agency (EA), Group, Chemicals Industries Association (CIA)) regarding environmental impacts and targets.

The performance of the SHE Management system, in terms of continual improvement, suitability and adequacy is reviewed at an Annual SHE Review meeting. The review includes the main elements of the management system and topics / aspects from the Group SHE Manual towards future site objectives and targets.

It is anticipated that the site will remain compliant with the applicable BAT requirements.

Recent Compliance Assessment Reports from the Environment Agency have included the following comments following audit of the EMS.

- *As ISO14001 and the EPR permit have very different structures and basis, the interface between the two is handled principally through document SHE/050 Rev 8 ENVIRONMENTAL*

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			MANAGEMENT SYSTEM AND POLLUTION PREVENTION & CONTROL PERMIT (Sampled). *This has 2 Appendices. Appendix 2 Gap Analysis For EPR Permit and Site Arrangements (Sampled) takes the permit on a condition by condition basis and details the site systems, procedures and work instructions which are used to maintain compliance. This is a very thorough approach with all conditions covered, not just those related to monitoring and reporting as is often found.* • *Environmental Continuous Improvement is a high level corporate goal and is driven by the management system. The principal on-site forum is the quarterly SHE Meeting attended by the site senior management team (Minutes sampled). Current items ongoing include a 50% reduction target vis 2015 carbon emissions, £40K spending on drain improvements and an inspection of bunding by a competent structural engineer.*
1.2	**Accident management** In addition to the guidance in Getting the Basics Right, guidance prepared in support of the COMAH Regulations may help you in considering ways to reduce the risks and consequences of accidents, whether or not they are covered by the COMAH regime.	Yes	The site is not a COMAH Establishment. The site has several arrangements that cover the assessment of potential accidents: • New processes EPP/001 Hazard Studies Procedures that include HAZOP studies • Existing processes Process Risk Reviews are completed against a 5 year Group programme. • Modified processes are considered by the SOP/062 Change Review and Authorisation Group Procedure. HAZOPs were developed for the activities undertaken at the site as part of the initial plant design and have been undertaken for the new process. The site has an Emergency Procedure in place (SHE/004) that provides arrangements for actions to be taken in emergency situations including drills, exercises and false alarms, and alarm testing. Foreseeable accident and incident risks are identified within the Environmental Risk Assessment Procedure Report (SHE/053). Site procedures are in place to review and manage the aspects and impacts of site activities including the management of discharges to the environment. Existing procedures will be updated with the potential accident risks from the proposed operation. The Environmental Risk Assessments when implemented together with other relevant elements of the system ensure that the intended outcomes are achieved, undesirable effects are prevented and/or reduced, whilst achieving continual improvement. It is anticipated that the site will remain compliant with the applicable BAT requirements. Recent Compliance Assessment Reports from the Environment Agency have included the following comments regarding accident management: • *The site has well developed arrangements for emergency response. Forseeable scenarios have been identified in a structured manner. Procedures have been developed to deal specifically with the dominant risks. Roles are clearly identified and described. Role holders*

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			have deputies and training is structured and regularly refreshed. Exercises are conducted and learning and review is of a high standard.
1.3	**Energy efficiency:** Some large processes are major users of heat and power and others produce energy from their exothermic reactions. For these there may be greater opportunities for optimising energy efficiency in comparison to the smaller installation in the sector and to many industrial sectors. Assess the environmental impact of each process and choose the one with the lowest environmental impact. (We recognise that your choice may be constrained, for example, by the integration of processes on a complex site).	Yes	As a pharmaceutical product, the manufacturing process at the site is restricted by the need to ensure specific quality requirements. Opportunities for improving energy efficiency of the propose operation have been considered at each stage of the operations and implemented as appropriate. This includes carrying out reactions at ambient temperature and pressure, limiting solvent stripping to minimum time periods, and stripping solvents during the synthesis stage using high vacuum pumps at ambient temperature, thus reducing the energy demand of the process, and improving the energy efficiency of the new operation. Initiatives for energy efficiency improvement at the site are driven by overarching corporate level climate agreement and carbon reduction targets. SHE/025 Climate Change Agreement Procedure describes the arrangements to manage the monitoring and reporting against the targets within these agreements, and the Qualitative Requirements to manage and save energy. The site has a Climate Change Agreement (reference: CIA/T00168). SHE Data Gathering Procedure SHE/047 includes the arrangements to measure and report energy consumed by site processes. As part of the site's current environmental permit, the site operations are audited regularly by the EA and have been found to be compliant with good industry practice. Current energy efficiency measures and procedures will be applied to the new process, as appropriate, to maintain the site's compliance record. Sustainability is a key driver for Croda on a corporate level and a target is to generate 27% of energy from non-fossil sources by 2020 has been set. All sites are individually required to reduce carbon emissions by 20% from baseline by 2025. At Leek the fossil fuel reduction is achieved both via the CHP and by purchase of green energy at a significant mark-up. Current projected non fossil fuel percentage for 2019 is 47%, the majority being from CHP. The 2025 carbon reduction target has already been surpassed at Leek. The site has a good record of reviewing site operations and implementing measures to minimise carbon emissions from the site operations. The site was nominated for a 'Low Carbon' award on the basis of the energy efficiency initiatives implemented onsite. It is anticipated that the site will remain compliant with the applicable BAT requirements. Recent Compliance Assessment Reports from the Environment Agency have included the following comments regarding Energy Efficiency:

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			• *Sustainability is a key driver for Croda and a target is to generate 27% of energy from non-fossil sources by 2020. All sites are individually required to reduce carbon emissions by 20% from baseline by 2025.* *At Leek the fossil fuel reduction is achieved both via the CHP and by purchase of green energy at a significant mark-up. Current projected non fossil fuel percentage for 2019 is 47%, the majority being from CHP. The 2025 carbon reduction target has already been surpassed at Leek.* • *It was clear that energy and resource efficiency are given a high priority and that this aspect of operations receives challenging targets and thorough review.* *Between 2010 and 2015:* – *Super Refining Plant Chiller replacement* – *Boiler Hotwell modifications* – *Replace Luwa Plant water cooling tower with closed loop system* – *General improvements in Lipid Plant, e.g. chillers and vacuum pump replacements* – *Lipid Plant LED lighting* – *Distillation Plant R41 capacity and efficiency improvements* – *Clathration Earth Treatment Plant electricity use improvements* *In 2016:* – *All meters planned now replaced, METER READINGS AND DATA ENTRY PROCESS FOR THE LEEK SITE SHE/025/TI/007 rev 06 revised including amended meters spreadsheet* *Energy saving in 2016:* – *Increase temp of server room* – *Clathration Earth Treatment Plant hot water coil to replace electric heater* – *Earth Treatment Plant reduce fan speed* – *Clathration plant fan speed reduction and increase on VOC detection* – *Urea dissolution tank heating coil now returns condensate to boiler*
1.4	**Efficient use of raw materials and water** As a general principle, you need to demonstrate the measures you take to; • reduce your use of all raw materials and intermediates; • substitute less harmful materials, or those which can be more readily abated and when abated lead to substances that are more readily dealt with; and • understand the fate of by-products and contaminants and their environmental impact. You should where appropriate: 1. Maximise heat transfer between process streams where water is needed for cooling. Use a recirculating system with indirect	Yes	The choice of raw materials for the process is limited by the product quality requirements due to the intended use of the product in a pharmaceutical product. The specific quality requirements also make it impossible to directly re-use any materials in the manufacturing process. Croda has reviewed opportunities to minimise or avoid the use of more hazardous raw materials throughout the development of the production process from concept, through pilot scale and now to small scale production. This has included the substitution of the use of chlorinated solvents within the process to less harmful solvents, and optimisation of raw materials usage in the processing stages. It is anticipated that the process will continue to be reviewed and improved as the site moves into small scale production during 2021, with further refinements expected at scale up to full scale manufacturing thereafter. To limit the use of water, the new condenser (emission point A11) is intended to use a closed loop cooling media with an energy efficient chiller to avoid the use of a once-through cooling system.

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	heat exchangers and a cooling tower in preference to a once-through cooling system. 2. Where water is used in direct contact with process materials, recirculate the water after stripping out the absorbed substances.		Water is mainly used in the process in the cooling and heating jackets of the reactor vessels in the pilot plant. Water used in the jackets is cooled via a closed loop cooling system supplied via cooling towers. The site has a site-specific procedure for receipt of packaged raw materials (i.e. in drums or IBCs) (reference: PRD/002/TI/003), which will be amended as appropriate for the additional raw materials to be used on site as a consequence of the proposed operation. A strict quality assurance management procedure is in place for controlling the purity and content of the raw materials used on site. Opportunities for improving efficiency of water use on site are continuously reviewed as part of the Croda commitment to reduce water use.
1.5	**Avoidance, recovery and disposal of wastes** Waste should be recovered unless it is technically or economically impractical to do so. You should list in detail the nature and source of the waste from each activity as the response to the emissions inventory requirement of the Application. Where there are a very large number of relatively small streams it may be appropriate to aggregate similar and comparatively insignificant waste streams. You should where appropriate: 1. Demonstrate that the chosen routes for recovery or disposal represent the best environmental option. Consider avenues for recycling back into the process or reworking for another process wherever possible. 2. Provide a detailed assessment identifying the best environmental options for waste disposal where you cannot avoid disposing of waste.	Yes	The operations at the site are driven by strict product quality requirements, and as the new product will subsequently be used in the manufacture of a pharmaceutical product, the options for reuse of materials within the process for avoidance/reduction in wastes generated by the proposed process are therefore very limited. Where subsequent synthesis stages cannot process the full quantity of intermediate product, these intermediates are stored for future use – no intermediate is wasted. Processes are carefully monitored and controlled to minimise, wherever possible, the generation of waste batches of product or other wastes, where possible. As the process is still under development and scale up, opportunities to improve yield efficiency and reduce waste generation will continue to be reviewed. Some of the process intermediates in the proposed operation are not yet registered under the REACH Regulations, wastes (including solvents) containing these materials cannot therefore currently be recycled or re-used. Therefore, it is proposed that the waste solvents from the new process will need to be sent off-site for disposal (incineration with heat recovery) during the small scale production phase of the product development. It is proposed that the options for recycling or offsite re-use of such materials will be reviewed as and when a viable option for recovery / re-use is identified, or the site moves to full-scale batch production. Croda has also set goals for waste minimisation at a corporate level. Details of the waste management procedure are provided in Section 3.5 of the Main Permit Application report (reference: 60641314-ACM-PM-RP-EN-001-A) submitted with this permit application. Existing site procedures (as described below) will be extended to include the proposed operation. Waste Management Procedure SHE/037 includes arrangements that clearly separate and record the different waste streams from the installation.

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			Waste Management Procedure SHE/037 also provides the arrangements to review all aspects of environmental continual improvement. Waste Management Procedure SHE/037 includes the requirement for the requirement to recycle or recover materials unless technically or economically impossible. The storage areas on site for hazardous packaged waste are labelled to identify the classification of the material, the maximum storage capacity and the maximum storage period. Waste Management procedure SHE/037 includes the management of skips so as to prevent and control litter on the site. General waste is bagged, and skips lidded as required. The SHE Manager manages the program of waste minimisation audits and associated report to the environment agency. Change Review and Authorisation Group Procedure SOP/062 includes an assessment of pollution implications in order to ensure adequate prevention and control of pollution and waste. The introduction of new plant and equipment shall also assess whether the change constitutes a variation to the existing process (non-chargeable variation, simple standard variation, standard variation or substantial variation) and the EA notified accordingly. All wastewater generated on the proposed facility will be managed as per existing site management procedures. BAT 2 of the CWW Bref is to maintain an inventory of wastewater as part of the Environmental Management System and the site systems are considered to be currently BAT compliant. It is proposed that a further review of BAT for the avoidance, recovery and disposal of wastes arising from the new process will be undertaken when the site moves to full scale manufacture.
2	**Operations**		
2.1	**Design of a new process** During new project development environmental issues should be an integral part of discussion at every stage of the design, beginning with the initial concepts. At the initial stage of the development of the process there should be a formal and comprehensive study – the first stage in a formal HAZOP study – of the likely environmental consequences from: • The use of raw materials, and production of all intermediates and products • All routine emissions, discharges and solid/liquid waste streams and • Non-routine or unplanned releases and disposals.	Yes	The design of the new plant and equipment is being managed through the existing site procedures - Engineering Projects Procedure EPP/008 and Construction Design and Management EPP/002. Site Change Review and Authorisation Group Procedure SOP/062 considers change, including planned or new developments, and new or modified activities, products and services. It includes an assessment of environmental implications in order to ensure adequate prevention and control of pollution and waste. The introduction of new plant and equipment also requires an assessment of whether the change constitutes a variation to the existing permit (non-chargeable variation, simple standard variation, standard variation or substantial variation) and the EA required to be notified accordingly.

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	You should where appropriate: 1. Consider all potential environmental impacts from the outset in any new project for manufacturing chemicals. 2. Undertake the appropriate stages of a formal HAZOP study as the project progresses through the process design and plant design phases. The HAZOP studies should consider amongst other things the points noted above.		The new processed have been subject to review under site procedure EPP/001 Hazard Studies Procedures that include the requirement to undertake HAZOP studies. As the process is still in development and is not at full-batch scale production yet, the design is under continued review, and the process will be reviewed prior to every upscaling event until it reaches its full scale. Potential environmental impacts of the facility's operations have been assessed within the HAZOP studies and as part of the Environmental Permit application process and are described in Section 6 of the application supporting document. All process equipment at the site is operated using a mixture of automated and manual processes, to ensure that all operations are appropriately controlled and associated environmental impacts are minimised. Alarms are provided in appropriate locations to ensure emergency situations are quickly identified and ameliorated. Storage of raw materials and wastes is managed to minimise accidental losses.
2.2	**Storage and handling of raw materials, products and wastes** You should where appropriate: 1. Store reactive chemicals in such a way that they remain stable, such as under a steady gas stream, for example. If chemical additions are necessary then tests should be carried out to ensure the required chemical composition is maintained. Inhibitors may also be added to prevent reactions. 2. Vent storage tanks to a safe location. 3. Use measures to reduce the risk of contamination from large storage tanks. In addition to sealed bunds, use double-walled tanks and leak detection channels. 4. Use HAZOP studies to identify risks to the environment for all operations involving the storage and handling of chemicals and wastes. Where the risks are identified as significant, plans and timetables for improvements should be in place.	Yes	The new processes have been subject to review under site procedure EPP/001 Hazard Studies Procedures that include the requirement to undertake HAZOP studies. Process raw materials, intermediates and products are not considered likely to present risk of uncontrolled or unplanned reaction. Storage of potentially hazardous or reactive materials will be managed to ensure the requirements of COSHH and other pertinent guidance are applied. Croda has undertaken risk assessments for the proposed process in line with the ALARP ("as low as reasonably practicable") suite of guidance, so as minimise the potential risks from the process, including storage of raw materials. All solvent storage has been designed in accordance with the guidance HSG176 - Storage of flammable liquids in tanks. Stability of all raw materials and intermediates has been considered throughout the development of the plant design. Material with relatively lower stability when in contact with environmental elements (air, water etc), such as STAB which produces hydrogen if it gets in contact with water, is stored in its own dedicated storage area to minimise risk and maintain stability of the material. Three new bulk storage tanks are being installed for solvent and solvent waste storage, which will comply with the CIRIA C736 guidance with regard to containment and be representative of BAT. Nitrogen blankets will be used to minimise ignition and fire risk as appropriate. These tanks will vent via a balanced breather system and a chilled condenser to minimise solvent loss to atmosphere prior to venting via emission point A11. All process vessels within the new chromatography process will also vent via the chilled condenser to minimise solvent loss to atmosphere prior to venting via emission point A11. The

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			new plant (chromatography and bulk solvent storage and associated infrastructure) is being designed to comply with BAT. The existing pilot plant venting and vacuum systems with water cooled condensers for solvent emissions abatement will continue to be used for the reaction phases during the small-scale production phase with a full review of the reactors and associated control and abatement systems to meet BAT proposed prior to further scale up to full production in the future. Due to the limited annual throughput of the proposed operation, it is anticipated that only small quantities of the final product will be stored on site. The final product will be stored in sealed bottles within a dedicated refrigerated product storage area in the Chromatography building. The storage areas for hazardous packaged waste are appropriately labelled on site to identify the classification of the materials, the maximum storage capacity and the maximum storage period. Waste Management procedure SHE/037 includes the management of skips so as to prevent and control losses of litter from the site. General waste is bagged, and skips lidded where required. SHE Data Gathering Procedure SHE/047 describes all raw data inputs (e.g. utilities, production, and incidents) and associated reporting outputs (e.g. EA, Group, CIA. SHE/047 uses release estimation techniques in order to determine the amount of total VOC's lost to atmosphere annually. Dip pipes are used when transferring volatiles and the site uses dusty materials in only very small quantities. Recent Compliance Assessment Reports from the Environment Agency have included the following comments regarding containment: • *New bunds are constructed to CIRIA 736. Existing bunds were constructed to good engineering practice at the time and on inspection appear appropriate.* *All bunds are known to provide 110% of the largest vessel and 25% of the total as a minimum.* *I noted during my inspection a bund being replaced and extended at a cost of £180K, constructed with regard to CIRIA 736.*
2.3	**Plant systems and equipment** A wide range of ancillary equipment is required throughout the process, which may include: ventilation, pressure relief, vacuum raising, pumps, compressors, agitators, valves, purging and heating/cooling. Some of these systems give rise to a waste stream, for example wet vacuum systems or dust extraction equipment, and all of them have the potential to give rise to fugitive emissions. You should formally consider potential emissions from plant systems and equipment. You should where appropriate: 1. Formally consider potential emissions from plant systems and equipment and have plans and timetables for improvements,	Yes	The new plant (chromatography and bulk solvent storage and associated infrastructure) is being designed to comply with BAT. The existing pilot plant venting and vacuum systems with water cooled condensers for solvent emissions abatement will continue to be used for the reaction phases during the small-scale production phase with a full review of the reactors and associated control and abatement systems to meet BAT proposed prior to further scale up to full production in the future. The new processed have been subject to review under site procedure EPP/001 Hazard Studies Procedures that include the requirement to undertake HAZOP studies.

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	where the potential for substance or noise pollution from plant systems and equipment has been identified. 2. Carry out systematic HAZOP studies on all plant systems and equipment to identify and quantify risks to the environment. 3. Choose vacuum systems that are designed for the load and keep them well maintained. Install sufficient instrumentation to detect reduced performance and to warn that remedial action should be taken.		All plant systems and equipment have been assessed for technical suitability and are considered to be fit for purpose. Most of the proposed process will be undertaken at ambient pressure. The site has its own power plant which has sufficient capacity to provide the additional power and heat requirements associated with the proposed operation. The two new emission points (A11 and A12) introduced to the site from the proposed operation will be added to the permit. As an ongoing developing process, process improvements are continually being considered for the proposed operation, particularly for emissions reduction potential. In the short term i.e. during the small scale production, the current chiller which will use water at ambient temperature will be upgraded to a chilled condenser (operating using cooled water), therefore reducing emissions to air. In addition, it is intended that within 6 months of permit being issued, and in time for the full scale production stage commencing, a permanent scrubber will be installed to replace the temporary scrubber currently on site. Items of plant and equipment, the failure of which could lead to an adverse environmental impact, are maintained as per EMP/001 Maintenance Management System Procedure and EMP/002 Site Calibration Procedure. The additional plant and equipment for the proposed operation will be added to the existing procedure. Change Review and Authorisation Procedure SOP/062 and engineering projects procedure EPP/008 Construction Design and Management Procedure EPP/002 consider noise and vibration during changes in site operations. The new process activities and plant has been designed to minimise potential of offsite noise impacts through the implementation of the site's standard target noise levels for new plant both for operator protection, and to maintain noise levels at the site boundary at <65dB. This noise level has been demonstrated to prevent offside noise nuisance occurring. EMP/001 Maintenance Management Procedure includes maintenance and inspection of potential plant failures that could lead to increased noise levels. Noise complaints are investigated and acted upon in accordance with Incident Investigation and Reporting Procedures SHE/039. These procedures will be amended as necessary to include the proposed new activities. Change Review and Authorisation Procedure SOP/062 includes an assessment of pollution implications in order to ensure adequate prevention and control of pollution and waste. The introduction of new plant and equipment also assessed whether the change constitutes a variation to the existing permit (as a non-chargeable variation, simple standard variation, standard variation or substantial variation) and the EA notified accordingly. The proposed operation has been assessed as per these procedures and appropriate mitigation measures applied, as appropriate. Vacuum systems for the proposed operation have been designed for the relevant process load and will be maintained regularly, to ensure optimum performance. Instrumentation to detect reduced performance and to warn that remedial action is in place and will be amended to include the plant and equipment associated with the proposed operations.

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			Section 4.1.4 of the existing site Environmental Permit also requires Croda to undertake an annual review of fugitive emissions (including VOC's) from the site against the requirements of BAT and report the findings. This assessment will be extended to include the proposed new site activities.
2.3	**Plant systems and equipment – over-pressure protection systems** You should where appropriate: 1. Carry out a systematic HAZOP study for all relief systems, to identify and quantify significant risks to the environment from the technique chosen. 2. Identify procedures to protect against overpressure of equipment. This requires the identification of all conceivable over-pressure situations, calculation of relief rates, selection of relief method, design of the vent system, discharge and disposal considerations, and dispersion calculations. In some cases careful design can provide intrinsic protection against all conceivable over-pressure scenarios, so relief systems and their consequential emissions can be avoided. 3. Maintain in a state of readiness all equipment installed in the venting system even though the system is rarely used.	Yes	The new processed have been subject to review under site procedure EPP/001 Hazard Studies Procedures that include the requirement to undertake HAZOP studies. There are appropriate pressure relief systems in place for the plant associated with the proposed operations, including reactor vessels PP1/PP2 and PP3. In reactor PP1/PP2, over pressure protection is via rupture disc with set pressure of 4 psi. In reactor PP3, over pressure protection is via three rupture discs (one on each vessel, receiver and separator) each with set pressure of 5 psi. All pressure relief systems for the new operation will be subject to a written scheme of inspection, in line with existing site procedures (to be amended, as appropriate, for the proposed operations) to ensure they remain in good operating condition. Pressure regulators will also be in place. The site applies a Site Pressure Relief Philosophy (EPP/005/TI/001) in conjunction with a Testing and Re-setting Procedure (EMP/001/TI/071) for relief devices on site. These are based on good engineering practice, Croda standards and the recommendations from other relevant standards and guidance such as API, EN ISO and HSG. The documents address design and assessment of all overpressure systems on site and applies to all new and existing pressure systems. It is anticipated that the site will remain compliant with the applicable BAT requirements.
2.3	**Plant systems and equipment – heat exchangers and cooling systems** You should where appropriate: 1. Consider leak detection, corrosion monitoring and materials of construction, preferably in a formal HAZOP study. Plans and timetables for improved procedures or replacement by higher integrity designs should be in place where the risks are identified as significant. 2. If corrosion is likely, ensure methods for rapid detection of leaks are in place and a regime of corrosion monitoring in operation at critical points. Alternatively, use materials of construction that are inert to the process and heating/cooling fluids under the conditions of operation. 3. For cooling water systems, use techniques that compare favourably with relevant techniques described in the Industrial Cooling Systems BREF.	Yes	The new processed have been subject to review under site procedure EPP/001 Hazard Studies Procedures that include the requirement to undertake HAZOP studies. Appropriate heat exchangers and cooling systems have been incorporated into the design of the new process and use of existing pilot plant systems. Heat exchange and cooling systems have been designed to use standard cooling media (e.g. water / oil) and there is limited unusual risk with regards to materials of construction. Losses from the systems are identified through flow and temperature monitoring on the heat transfer systems which act as a surrogate indicator of the integrity and functionality of the system. The PP3 reactor vessel has a jacket served by thermal oil for heating and cooling; the thermal oil used in PP3 works at ambient temperature unlike other thermal oils that work at high temperatures. A separate heat exchanger (cooled by water) is used to control the oil temperature to the jacket. Due to the operating temperatures of the thermal oil being used, heating water is only required to be at temperatures of 30 - 40ºC. The heating/ cooling media are therefore not classified as 'dangerous to the environment'. It is anticipated that the site will remain compliant with the applicable BAT requirements.
2.3	**Plant systems and equipment – purging facilities**	Yes	All primary emission points from both the pilot plant reactors and the new chromatography and solvent storage systems are routed via solvent emission abatement systems (Condensers) prior to venting to atmosphere via a number of point source emission locations.

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	Assess the potential for the release to air of VOCs and other pollutants along with discharged purge gas and use abatement where necessary.		The new plant (chromatography and bulk solvent storage and associated infrastructure) is being designed to comply with BAT. The existing pilot plant venting and vacuum systems with water cooled condensers for solvent emissions abatement will continue to be used for the reaction phases during the small-scale production phase with a full review of the reactors and associated control and abatement systems to meet BAT proposed prior to further scale up to full production in the future. In the short term, condensers will be improved by using chilled water rather than cooling water An H1 assessment has been completed for the anticipated emissions to air from the proposed operations which included consideration of the speciated VOC emissions. This assessment has demonstrated that even when applying a relatively conservative approach the assessment, It is considered that the new process is unlikely to result in the exceedance of any EALs for all the scenarios assessed. With the planned improvements for the site, and the ultimate goal for the achievement of BAT for the new process, this will result in an overall reduction in the level of impact from the new process activities to a level of insignificance.
2.4	**Reaction stage** It is important to consider how the chemistry and engineering options may contribute to releases to the environment from the reaction stage, both directly and as a consequence later in the process. It is also important that these considerations are made at the process design stage – before plant design and equipment selection is commenced. You should where appropriate: 1. With a clear understanding of the physical chemistry, evaluate options for suitable reactor types using chemical engineering principles. 2. Select the reactor system from a number of potentially suitable reactor designs - conventional STR, process-intensive or novel-technology - by formal comparison of costs and business risks against the assessment of raw material efficiencies and environmental impacts for each of the options. 3. Undertake studies to review reactor design options based on process-optimisation where the activity is an existing activity and achieved raw material efficiencies and waste generation suggest there is significant potential for improvement,. The studies should formally compare the costs and business risks, and raw material efficiencies and environmental impacts of the alternative systems with those of the existing system. The scope and depth of the studies should be in proportion to the potential for environmental improvement over the existing reaction system. 4. Maximise process yields from the selected reactor design, and minimise losses and emissions, by the formalised use of	Yes	Croda has developed the proposed new process from concept, through pilot scale and now plans to move to small scale production . Hence the reaction process has been subject to continual refinement and adjustment through the product development process. The current proposal is to move into the small-scale manufacture stage of development which will continue to use the existing pilot plant stirred batch reactors and associated systems. For the proposed scale of production at this phase in the project development, such reactor systems are considered to be the only viable option. As the product is being manufactured to meet very specific quality criteria to allow subsequent use by others in Pharmaceutical manufacture, there are limited opportunities to alter the reaction processes or raw materials used. However, In progressing the process to this stage, Croda has already made significant improvements in the process chemistry and engineering options to optimise yield and remove the use of chlorinated solvents use in the process. It is anticipated that the process will continue to be reviewed and improved as the site moves into small scale production during 2021, with further refinements expected at scale up to full scale manufacturing thereafter. All key operational stages will have abatement measures in place (as required) to avoid adverse environmental impacts.

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	optimised process control and management procedures (both manual and computerised where appropriate). 5. Minimise the potential for the release of vapours to air from pressure relief systems and the potential for emissions of organic solvents into air or water, by formal consideration at the design stage - or formal review of the existing arrangements if that stage has passed.		All plant and equipment at the installation is subject to routine maintenance to ensure efficient operation and to identify any damages/faults in the equipment, which would then assist in identifying suitable replacement equipment. Periodic reviews of the processes at the installation are undertaken by the operator to ensure that the manufacturing processes are optimised. As such, the proposed process will be optimised in case new / emerging technology becomes available which could benefit the manufacturing process. All existing procedures will be amended to include the proposed new activities.
2.4	**Minimisation of liquid losses from reaction systems** You should where appropriate: 1. Use the following features that contribute to a reduction in waste arisings from clean-outs • low-inventory continuous throughput reactors with minimum surface area for cleaning • minimum internals such as baffles and coils in the reactor • smooth reactor walls, no crevices • flush bottom outlet on reaction vessels • all associated piping to slope back to the reactor or to a drain point • sufficient headroom under the reactor for collection of all concentrated drainings in drums or other suitable vessel, if necessary • minimal pipework, designed to eliminate hold-up and to assist drainage • pipework designed to allow air or nitrogen blowing • system kept warm during emptying to facilitate draining • HAZOP studies used to assess the potential for the choking of lines by high-melting-point material • campaigns sequenced so that cleaning between batches is minimised • campaigns made as long as possible to reduce the number of product change-overs • where a complete clean is necessary, use cleaning methods that minimise the use of cleaning agents, (e.g. steam-cleaning, rotating spray jets or high-pressure cleaning) or use a solvent which can be re-used • carry out HAZOP studies to minimise the generation of wastes and to examine their treatment/disposal • consider use of disposable plastic pipe-liners • eliminate or minimise locations for solids to settle-out.	Yes	Croda has developed the proposed new process from concept, through pilot scale and now plans to move to small scale production. Hence the reaction process has been subject to continual refinement and adjustment through the product development process. The current proposal is to move into the small-scale manufacture stage of development which will continue to use the existing pilot plant stirred batch reactors and associated systems e.g. vacuum pumps. As the product is being manufactured to meet very specific quality criteria to allow subsequent use by others in Pharmaceutical manufacture, there are limited opportunities to alter the reaction processes. It is anticipated that the process will continue to be reviewed and improved as the site moves into small scale production during 2021, with a detailed review and update of the reaction systems and supporting infrastructure to meet BAT expected at scale up to full scale manufacturing thereafter. Minimisation of liquid losses will be considered as part of this review. The proposed operations within the existing reaction vessels are to be undertaken in dedicated vessels, equipment and pipework as appropriate, within appropriate buildings, with suitable controls applied to each process stage to optimise the manufacturing process and minimise fugitive losses and the generation of waste on clean out. Due to the nature of the operation, i.e. manufacturing of pharmaceutical product, regular cleaning and maintenance is required to ensure that the relevant pharmaceutical regulatory and hygiene requirements are met.

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	• consider duplicate or dedicated equipment where it can reduce the need for cleaning that is difficult.		
2.4	**Reaction stage – minimisation of vapour losses** There are many techniques for minimising the potential for vapour losses and for collection and abatement of vapour displaced into vent lines. You should where appropriate: 1. Review your operating practices and review vent flows to see if improvements need to be made. 2. Consider opportunities to enhance the performance of abatement systems.	Yes	The reaction stages include several steps where emissions to air occur, and all emission routes include a water cooled condenser to minimise solvent emissions. Much of the reaction process is undertaken under a Nitrogen blanket within a balanced system at atmospheric pressure with a small vent to atmosphere – emissions during such steps are anticipated to be minimal. There are solvent removal steps which occur via the low and high vacuum systems which have the potential for increased emissions of solvents, again, these are abated by the condenser system. As per 2.3 above, It is anticipated that the process will continue to be reviewed and improved as the site moves into small scale production during 2021, with a detailed review and update of the reaction systems and supporting infrastructure to meet BAT expected at scale up to full scale manufacturing thereafter. Minimisation of vapour losses will be considered as part of this review.
2.5	**Separation stages – liquid-vapour separations** On completion of the reaction it is usually necessary to separate the desired product from the other components in the reaction system. You should where appropriate: 1. Choose your separation technique following a detailed process design and HAZOP study. Follow formal operating instructions to ensure effective separation and minimisation of losses. Adhere to design conditions such as heat input, reflux flows and ratios, etc. 2. Install instrumentation to warn of faults in the system, such as a temperature, pressure or low coolant-flow alarms.	Yes	Solvent separation from the synthesis process is undertaken using vacuum systems (low and high vacuum) which is used to strip solvent from the reaction materials. The vacuum systems have been designed and installed in accordance with the site management systems controls, which include the requirement to undertake hazard studies on all plant designs. All stripped solvent laden vapour is passed through condenser system to achieve solvent removal, and the condenser unit is installed with controls i.e. flow and temperature monitoring to ensure it is operating efficiently, with an additional temperature monitor on the vent stream exiting the condenser to confirm that the system is operating effectively
2.5	**Separation stages– liquid-liquid separations** You should where appropriate: 1. Use techniques which maximise physical separation of the phases (and also aim to minimise mutual solubility) where practicable. 2. When the phases are separated, use techniques which prevent (or minimise the probability and size of) breakthrough of the organics phase into a waste-water stream. This is particularly important where the environmental consequences of subsequent releases of organics to air or into controlled waters may be significant (eg. where the effluent is treated in a DAF unit or some of the organic components are resistant to biological treatment).	Yes	The installation carries out liquid-liquid separation processes such as distillation and chromatography. These processes have been selected due to their technical suitability for the required product and are considered to be fit for purpose and compliant with BAT. Column chromatography has been determined to be the best process for final product separation as product quality is sensitive to temperature and the process can be performed at ambient conditions. Chromatography is an effective technique for separation of mixtures containing similar fractions and can be performed at ambient conditions. The mixture to be separated is dissolved in a solvent called the mobile phase, which carries it through a column containing a fixed material called the stationary phase. The different constituents of the mixture have different affinities for the stationary

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	3. When a separation is done by hand, use a "dead man's handle", backed-up by good management, to improve the chance of the flow being properly controlled as the phase-boundary approaches. 4. Consider if automatic detection of the interface is practicable. 5. Where you are discharging to drain, consider whether there should be an intermediate holding or "guard" tank to protect against accidental losses from the organics phase.		phase causing them to remain for longer or shorter periods of time on the stationary phase, allowing for separation. The stationary phase comes in the form of a filter housed within the column. The current process at development and pilot scale uses one filter per chromatography run. As process development continues the possibility of re-using / recycling filters and alternative stationary phase options will be investigated. The solvent blend which makes up the mobile phase has been developed to contain the smallest possible quantities of solvents with minimised environmental hazards. The new process involves use of solvent washes at different stages to separate the different phases of reacted solvents. At present, due to the nature of the final product, the filters being used are not re-used, however, due to the environmental as well as financial implications, Croda is reviewing the possibility of re-using the filters. It is therefore considered that the process will comply with BAT when at full scale production stage.
2.5	**Separation stage – liquid-solid separations** Different separation techniques will be BAT for different applications, with factors like solubility, crystallisation rate and granular size being important. The main solid-liquid techniques are centrifuging, filtration, sedimentation, clarification, drying and ion exchange. You should where appropriate: 1. Use techniques to minimise, re-use and/or recycle rinse water, and to prevent breakthrough of solids. 2. Install instrumentation or other means of detecting malfunction as all of the techniques are vulnerable to solids breakthrough. 3. Consider installing "guard" filters of smaller capacity downstream which, in the event of breakthrough, rapidly 'clog' and prevent further losses. 4. Have good management procedures to minimise loss of solids, escape of volatiles to air and excessive production of waste water.	Yes	Liquid solid separation is not a fundamental aspect of the synthesis process. Filtration is however used within the processing of the final product to ensure that no solids enter the product material.
2.6	**Purification stage** Waste associated with the purification stage may arise from: • impurities in the raw materials – so a change in the raw material specifications may reduce waste arisings • by-products generated by the process – so a change in reaction conditions, catalyst, solvent etc. may improve the selectivity of the reaction or eliminate by-product formation.	Yes	The purification stage (chromatography) has been designed to BAT and will be reviewed as the process is upscaled to full batch scale manufacturing. Chromatography is carried out to remove impurities associated with the synthesis process in order to obtain the required purity of the final product. The choice of raw materials for the process is limited due to the intended end use of the product, therefore, there is limited opportunity for substituting the materials used at the installation. A strict quality assurance management procedure is in place for controlling the purity and content of the raw materials purchased.

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2.7	**Chemical process controls** Reaction conditions such as temperatures, pressures, rocking or stirring rates, catalyst age, input and output flow rates, addition of materials (and so on) are imperative to the efficient conversion of raw materials to product. You should where appropriate: 1. Monitor the relevant process controls and set with alarms to ensure they do not go out of the required range.	Yes	Process equipment throughout the site is operated by a mixture of automated and manual processes to ensure high process efficiency vis yield and operability, with some key indicators being relayed to trips and alarms. The actual controls in place depend upon the vessel and process area: operators have a key role in monitoring the processes. SOPs are in place governing production runs with associated set point controls for the process. Appropriate fault detection measures (i.e. trips and alarms) are installed at the installation; these control systems are inspected and maintained under the facilities planned preventative maintenance (PPM) program. Critical to environment alarms are installed at appropriate locations within the installation to manage and control plant operations. This includes alarms and trips on the VOC abatement system, the chiller package and exhaust. The VOC abatement control system continuously (when the process is ongoing) monitors the temperature of the cooling media and the final vent operation such that any issues with the operation of the abatement system can be identified, and the process shut down to prevent any emissions to the atmosphere. The chiller package includes a flow and temperature alarm in the cooling loop connected to the condenser, whilst the exhaust system comprises a high temperature alarm.
2.8	**Analysis** You should where appropriate: 1. Analyse the components and concentrations of by products and waste streams to ensure correct decisions are made regarding onward treatment or disposal. Keep detailed records of decisions based on this analysis in accordance with management systems.	Yes	The production process will be subject to staged analysis of the intermediates and products to ensure that they meet specific quality control requirements. All waste generated at the site is managed by Croda personnel under the Waste Management Group procedure (SHE/037), which includes requirements relating to waste inventory, waste storage, waste inspections, packaging & labelling, off-site waste management, and waste prevention, reduction and recycling. Croda undertakes appropriate duty of care for waste generated on site, including periodic audits. Croda regularly review the waste streams against the requirements of the waste hierarchy. Croda maintains an inventory of wastes produced at the site through their Waste Management Group Procedure. Through the continued implementation of the above procedures / systems of work; the site has demonstrated that it currently manages, and will continue to manage, wastes appropriately in compliance with relevant regulatory requirements. All existing procedures will be extended to the proposed operations.
3	**Emissions and monitoring**		
3.1	**Point source emissions - air** You should where appropriate: 1. Formally consider the information and recommendations in the BREF on Common Waste Water and Waste Gas Treatment/ Management Systems in the Chemical Sector (see Reference 1)	Yes	Emissions via the new emission point A11 from the chromatography process and new bulk solvent storage areas is being designed to meet the requirements of BAT and will include a new chilled condensation unit to minimise emissions of VOC to air The system will also be nitrogen blanketed and operate as a balanced atmospheric system with emissions only occurring by displacement.

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	as part of the assessment of BAT for point-source releases to air, in addition to the information in this note. 2. Identify the main chemical constituents of the emissions, including VOC speciation where practicable. 3. Assess vent and chimney heights for dispersion capability and assess the fate of the substances emitted to the environment. 4. Use the following measures to minimise emissions to air: • recover emissions rich in organics by fractionation and then recycle • recover and reuse solvents • continuously monitor off-gas concentration from reaction vessels, dryers, condensers, evaporators and scrubbers where off-gases are shown to be environmentally significant		Emission point A12 covers the emissions from the reaction stages in the existing pilot plant, this system is installed with water cooled condensers to minimise solvent emissions, and the high Vacuum system is also installed with a temporary sodium hypochlorite spray contactor to abate potential odour associated with trace dimethyl sulphide at certain stages in the reaction process. An H1 assessment has been completed for the anticipated emissions to air from the proposed operations which included consideration of the speciated VOC emissions. This assessment has demonstrated that even when applying a relatively conservative approach the assessment, It is considered that the new process is unlikely to result in the exceedance of any EALs for all the scenarios assessed. With the planned improvements for the site, and the ultimate goal for the achievement of BAT for the new process, this will result in an overall reduction in the level of impact from the new process activities to a level of insignificance. Details of point source emissions are provided in section 4 of the Application supporting report submitted with this permit application. Due to the intended use of the new product in the preparation of pharmaceutical products, and the associated high purity levels required, it is not possible to reuse solvents on site in the manufacturing process. The operator will continue to review the process to ensure minimisation of wastes and other releases from the proposed operations. It is anticipated that the process will continue to be reviewed and improved as the site moves into small scale production during 2021, with a detailed review and update of the reaction systems and supporting infrastructure to meet BAT expected at scale up to full scale manufacturing thereafter. Minimisation of emissions to air will be considered as part of this review.
3.1	**Point source emissions - water** You should where appropriate: 1. Control all emissions to avoid a breach of water quality standards as a minimum. Where another technique can deliver better results at reasonable cost it will be considered BAT and should be used. 2. Use the following measures to minimise water use and emissions to water: • where water is needed for cooling, minimize its use by maximising heat transfer between process streams • use water in recirculating systems with indirect heat exchangers and a cooling tower rather than a once through system. (A water make-up treatment plant and a concentrated purge stream from the system to avoid the build up of contaminants are likely to be necessary.) • leaks of process fluids into cooling water in heat exchangers are a frequent source of contamination. Monitoring of the cooling water at relevant points should be appropriate to the nature of the process fluids. In a recirculatory cooling system, leaks can be identified before significant emission to the	Yes	There will be no direct emissions to controlled waters from the new activity. The process drainage system is separate to the surface water drainage at the installation. Existing non-hazardous wastewater stream (with the fish oil processing activities) are treated within the onsite ETP before discharge to the sewer. The only effluent from the proposed operation to be sent to sewer (following treatment in the on-site ETP) will be the wash water from the final clean of the reactor vessels, which is unlikely to contain hazardous substances. All process areas are appropriately controlled and managed to prevent direct discharge of potentially contaminated water from the installation to controlled waters.

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	environment has occurred. The potential for environmental impact is likely to be greater from a once through system. Planned maintenance can help to avoid such occurrences • water used for cleaning can be reduced by a number of techniques, e.g. by spray leaning rather than whole vessel filling • strip process liquor and treat if necessary, then recycle/reuse • use wet air oxidation for low volumes of aqueous effluent with high levels of organic content, such as waste streams from condensers and scrubbers • neutralise waste streams containing acids or alkalis to achieve the required pH for the receiving water • strip chlorinated hydrocarbons in waste streams with air or steam and recycle by returning to process where possible • recover co-products for re-use or sale • periodically regenerate ion exchange columns • pass waste water containing solids through settling tanks, prior to disposal • treat waste waters containing chlorinated hydrocarbons separately where possible to ensure proper control and treatment of the chlorinated compounds. Contain released volatile chlorinated hydrocarbons and vent to suitably designed incineration equipment • non-biodegradable organic material can be treated by thermal incineration. However, the thermal destruction of mixed liquids can be highly inefficient and the waste should be dewatered prior to incineration.		
3.1	**Point source emissions to land** Landfill of wastes should only be contemplated after all other alternatives have been thoroughly examined and rejected. Use the following measures to minimise emissions to land: • use settling ponds to separate out sludge (Note: Sludge can be disposed of to incinerator, encapsulation, land or lagoon depending upon its make up.) • chlorinated residues should be incinerated and not released to land. (Chlorinated hydrocarbons are not to be released to the environment due to their high global warming and ozone depletion potentials.) • either recycle off spec product into the process or blend to make lower grade products where possible • many catalysts are based on precious metals and these should be recovered, usually by return to the supplier.	Yes	No direct emissions to land will occur as a result of the proposed activity.

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3.2	**Fugitive emissions to air** You should where appropriate: 1. Identify all potential sources and develop and maintain procedures for monitoring and eliminating or minimising leaks and releases of VOCs from all non-process stream sources. 2. Choose vent systems to minimise breathing emissions (for example pressure/ vacuum valves) and, where relevant, should be fitted with knock-out pots and appropriate abatement equipment. 3. Use the following techniques (together or in any combination) to reduce losses from storage tanks at atmospheric pressure: • maintenance of bulk storage temperatures as low as practicable, taking into account changes due to solar heating etc. • tank paint with low solar absorbency • temperature control • tank insulation • inventory management • floating roof tanks • bladder roof tanks • pressure/vacuum valves, where tanks are designed to withstand pressure fluctuations • specific release treatment (such as adsorption condensation).	Yes	Section 4.1.4 of the existing site Environmental Permit also requires Croda to undertake an annual review of fugitive emissions (including VOC's) from the site against the requirements of BAT and report the findings. This assessment will be extended to include the proposed new site activities. All primary sources of emission (including vents from the new bulk solvent storage tanks) will be routed to suitable abatement systems prior to discharge to air via a suitably designed emission point.
3.2	**Fugitive emissions to surface water, sewer and groundwater** You should where appropriate: 1. Provide hard surfacing in areas where accidental spillage or leakage may occur, e.g. beneath prime movers, pumps, in storage areas, and in handling, loading and unloading areas. The surfacing should be impermeable to process liquors. 2. Drain hard surfacing of areas subject to potential contamination so that potentially contaminated surface run-off does not discharge to ground. 3. Hold stocks of suitable absorbents at appropriate locations for use in mopping up minor leaks and spills, and dispose of to leak-proof containers. 4. Take particular care in areas of inherent sensitivity to groundwater pollution. Poorly maintained drainage systems are known to be the main cause of groundwater contamination and surface/above-ground drains are preferred to facilitate leak detection (and to reduce explosion risks). 5. Additional measures could be justified in locations of particular environmental sensitivity. Decisions on the measures to be taken should take account of the risk to groundwater, taking into	Yes	All process activities are to be undertaken inside contained buildings with no drainage to surface water drains. The new bulk solvent storage tanks will be designed and installed in line with BAT and in compliance with the CIRIA C736 guidance on containment systems. All process areas will be provided with impermeable hardstanding. The installation has appropriate procedures and controls in place for prevention and management of accidental spills; all site operatives are trained in the application of the site procedures (ref: SHE/004/TI/003 Loss of Containment & Spillages, SHE/004 LF04 Spillage Arrangements training programme, SHE/004 Emergency Procedure, SHE/050 LF03 Environmental Training Programme). The site also has a 'Spillage Prevention Policy'. These procedures cover chemical losses as well as fuel / oil spillages. Site drainage manhole covers are colour coded to identify the surface water and process drains to prevent cross contamination. There are material offloading procedures in place (PRD/002/LF/10 Instructions to drivers with Tanker loading Offloading check sheet, PRD/002/TI/002 Receipt, Loading and Offloading of tankers) that all delivery drivers must adhere to with the delivery areas provided with appropriate

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	consideration the factors outlined in the Agency document, Policy and Practice for the Protection of Groundwater, including groundwater vulnerability and the presence of groundwater protection zones. 6. Surveys of plant that may continue to contribute to leakage should also be considered, as part of an overall environmental management system. In particular, you should consider undertaking leakage tests and/or integrity surveys to confirm the containment of underground drains and tanks		hardstanding and containment. Spill kits are located throughout the site and staff are appropriately trained to manage spills. The surface water drainage system can be isolated preventing any lost / spilt material entering the Surface water drainage system. The site team is given appropriate training on management of spills and other site procedures. The site is currently carrying out CCTV surveys for the drainage on site to ensure the integrity of the surfaces within the system. Additionally, the site is carrying out an ongoing programme of improvements to secondary bunds and tertiary drainage system in line with BAT requirements. The potential for fugitive emissions to water from the installation has been considered in the Environmental Risk Assessment prepared in support of the Permit Variation (Appendix C, 60641314-ACM-PM-RP-EN-001-A). It is therefore considered that the site will remain compliant with the applicable BAT requirements.
3.3	**Odour** The requirements for odour control will be installation-specific and depend on the sources and nature of the potential odour. You should where appropriate: 1. Manage the operations to prevent release of odour at all times. 2. Where odour releases are expected to be acknowledged in the permit, (i.e. contained and treated prior to discharge or discharged for atmospheric dispersion): • for existing installations, the releases should be modelled to demonstrate the odour impact at sensitive receptors. The target should be to minimise the frequency of exposure to ground level concentrations that are likely to cause annoyance. • for new installations, or for significant changes, the releases should be modelled and it is expected that you will achieve the highest level of protection that is achievable with BAT from the outset. • where there is no history of odour problems then modelling may not be required although it should be remembered that there can still be an underlying level of annoyance without complaints being made. • where, despite all reasonable steps in the design of the plant, extreme weather or other incidents are liable, in our view, to increase the odour impact at receptors, you should take appropriate and timely action, as agreed with us, to prevent further annoyance (these agreed actions will be defined either in the permit or in an odour management statement).	Yes	The majority of the raw materials, intermediates and products in use at the site are not inherently odourous. During pilot scale development of the process, it was identified that during one stage of the reaction trace emissions of dimethyl sulphide (a product of reaction) via the High Vacuum system could occur, and this could lead to slight on-site odour issues (no offsite odour issues occurred). Croda has therefore (with the agreement of the Environment Agency) designed and installed a temporary scrubber (sodium hypochlorite spray contactor) to remove the dimethyl sulphide and prevent potential odour impacts. A procedure is in place to respond to odour complaints should they arise but have had no substantiated complaints in over 10 years. As an ongoing developing process, process improvements are continually being considered for the proposed operation, particularly for emissions reduction potential. In the short term i.e. during the small-scale production, the current chiller which will use water at ambient temperature will be upgraded to a chilled condenser (operating using cooled water), therefore reducing emissions to air. In addition, it is intended that within 6 months of permit being issued, and in time for the full-scale production stage commencing, a permanent scrubber will be installed to replace the temporary scrubber currently on site. It is considered that a detailed odour management plan is not required for the new process

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	3. Where odour generating activities take place in the open, or potentially odorous materials are stored outside, a high level of management control and use of best practice will be expected. 4. Where an installation releases odours but has a low environmental impact by virtue of its remoteness from sensitive receptors, it is expected that you will work towards achieving the standards described in this guidance note, but the timescales allowed to achieve this might be adjusted according to the perceived risk. 5. Where further guidance is needed to meet local needs, refer to Horizontal Guidance Note H4 Odour (see GTBR).		
3.4	**Noise and vibration** You should where appropriate: 1. Install particularly noisy machines such as compactors and pelletisers in a noise control booth or encapsulate the noise source. 2. Where possible without compromising safety, fit suitable silencers on safety valves. 3. Minimise the blow-off from boilers and air compressors, for example during start up, and provide silencers.	Yes	There are no particularly noisy new items of equipment proposed for installation as part of the new process. Croda has internal standards for selection of new plant and equipment on site, including the noise emissions. Croda employs Workplace Noise Standards for all new plant and equipment, with all new equipment required to generate <80dB (1m from the source). Additionally, Croda employs a noise standard of <65dB at site boundary. These standards are being applied to any new equipment installed as part of the new process. The nearest sensitive receptors are approximately 100m away on Junction Street to the east of the site; however, there are other industrial facilities between the site and the receptors, therefore the potential of noise generated by the site causing a nuisance for the receptors is considered unlikely. These standards have been used for many years and no complaints have been registered.
3.5	**Monitoring and reporting of emissions to air and water** You should where appropriate: 1. Carry out an analysis covering a broad spectrum of substances to establish that all relevant substances have been taken into account when setting the release limits. The need to repeat such a test will depend upon the potential variability in the process and, for example, the potential for contamination of raw materials. Where there is such potential, tests may be appropriate. 2. Monitor more regularly any substances found to be of concern, or any other individual substances to which the local environment may be susceptible and upon which the operations may impact. This would particularly apply to the common pesticides and heavy metals. Using composite samples is the technique most likely to be appropriate where the concentration does not vary excessively. 3. If there are releases of substances that are more difficult to measure and whose capacity for harm is uncertain, particularly when combined with other substances, then "whole effluent toxicity" monitoring techniques can be appropriate to provide	Yes	The current permit does not include any monitoring requirements for the existing emission points. Emissions from the reaction stages within the Pilot Plant via emission points A12 will comprise: • emissions via a very small roof level breather vent during the majority of the reaction process – during these stages, the system is a balanced system with a nitrogen blanket and no forced extraction i.e. it will be displacement and breather losses only. • Emissions during high vacuum operation during which solvent is stripped from the reaction vessels, abated via a condenser and the scrubber before being emitted to air from a dedicated vent pipe • Emissions from the low vacuum SR sump vent – these will be displaced solvent within the headspace of the SR sump which will vent via a dedicated breather vent Hence, for the majority of the process stages the emissions are via balanced atmospheric breather systems which does not easily allow for monitoring or assessment of representative emissions data. The high vacuum emissions only occur for a short time during each batch which again makes collection of accurate emissions monitoring data difficult. The key emissions in the synthesis

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	direct measurements of harm, for example, direct toxicity assessment.		process will be during the solvent removal process from PP3 and PP1/PP2 (via vent A12) during oxidation stage which will last for approximately 5 hours and 3 hours respectively. Emissions from the low vacuum system will be limited to solvent removal from PP1/PP2 through low vac pump into SR sump (via vent A12) via open catch pot, which will last for approximately 7 hours. Croda therefore proposes to implement a calculation method to assess potential solvent emissions from emission point A12 if required – the specific methodology will be agreed with the EA as part of the permitting process. Emissions from the chromatography process and the bulk solvent storage tanks will be via new emission point A11. This vent system is being designed to meet the requirements of BAT and will include a new chilled condensation unit to minimise emissions of VOC to air. The system will also be nitrogen blanketed and operate as a balanced atmospheric system with emissions only occurring by displacement. Again, this makes the collation of representative emissions monitoring data difficult, and Croda therefore proposes to implement a calculation method to assess potential solvent emissions from emission point A11 if required. Croda will also agree an approach to confirmatory emissions monitoring with the Environment Agency should it be required
3.5	**Monitoring and reporting of waste emissions** You should where appropriate: 1. Monitor and record: • the physical and chemical composition of the waste • its hazard characteristics • handling precautions and substances with which it cannot be mixed	Yes	The storage areas for hazardous packaged waste have been labelled appropriately on site to identify the classification of the material, the maximum storage capacity and the maximum storage period. Waste Management Procedure SHE/037 includes arrangements that clearly separate and record the different waste streams from the installation. This procedure also provides the arrangements to review all aspects of environmental continual improvement and includes the requirement for the requirement to recycle or recover materials unless technically or economically impossible. All existing procedures will be extended to include the proposed operations.
3.5	**Environmental monitoring (beyond installation)** You should where environmental monitoring is needed: 1. Consider the following in drawing up proposals: • determinands to be monitored, standard reference methods, sampling protocols • monitoring strategy, selection of monitoring points, optimisation of monitoring approach • determination of background levels contributed by other sources	N/A	An impact assessment undertaken in support of the EP application has demonstrated that none of the emissions from the installation are predicted to lead to any significant offsite environmental impact. The proposed operations are similar in nature to the activities currently permitted to be undertaken on site therefore minimising any significant additional risks. Therefore, no monitoring is proposed to be undertaken beyond the installation boundary. It is therefore considered that this BAT requirement is not applicable to the proposed operations.

Guidance Section No[1].	Requirement	Operating to Guidance Requirement	Demonstration of Indicative BAT
	• uncertainty for the employed methodologies and the resultant overall uncertainty of measurement • quality assurance (QA) and quality control (QC) protocols, equipment calibration and maintenance, sample storage and chain of custody/audit trail • reporting procedures, data storage, interpretation and review of results, reporting format for the provision of information.		