

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
External Consultees Feedback						
Environmental Health Directorate	<p>With reference to request to provide any comments on the contents of such application regarding subject in caption, please be informed that this Directorate would like to submit the following comments/recommendations regarding this proposal:</p> <ol style="list-style-type: none"> 1. With the proposed variation the Directorate has no objection. 2. Any water supply that was being used in the QC Laboratory that will not be need in the new office space is to be cut back to the main supply pipe for both hot and cold to prevent any deadlegs in the water system. 3. Pest Control. 4. The provisions of L.N. 5 of 2006 regarding Legionella Control are to be taken into consideration for the Cooling Tower and water system. Legionella Risk Assessment Manual for the Control of Legionella is to be available and updated every two years. 5. Unpredicted impacts and nuisances which may arise from this operation and that may have a significant adverse effect on public health are to be immediately addressed by the applicant and the necessary mitigation measures taken; 6. Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the applicant. All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested. 	<ol style="list-style-type: none"> 1. Noted 2. Operator to reply 3. Operator to clarify what provisions there are for pest control. 4. Operator to provide reply 5. Such aspects are already covered in the existing permit 6. Provision for complaints reporting are already included in the permit and will be retained in upcoming permit. 	<p>2. Confirmed that previous water supply in QC area has been cutback for both hot and cold water to prevent any deadlegs in the water system</p> <p>3. Pest Control procedure attached. Attached as document M1.</p> <p>4. A Legionella RA was carried out in 2018. Attached is the report of 2018 as document</p>	<p>With reference to request to provide any comments on the contents of such application regarding subject in caption, please be informed that this Directorate would like to submit the following comments/recommendations regarding this proposal:</p> <p>a) In the Risk Assessment for the control of legionella the following are to be included;</p> <p>a. Samples for Heterotrophic Colony Count for Cooling Tower every month</p> <p>b. Commissioning, decommissioning and re commissioning producer for the water system and Cooling Tower.</p>	<p>Kindly update the Legionella RA as requested by EHD.</p>	<p>Point a is already done.</p> <p>Further clarification requested to EHD via email with regards to Point b.</p>

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
			t M2..			
Malta Resources Authority	<p>This assessment is based primarily on the documentation that was published on the weblink provided as on the date of the assessment. The Authority made its assessment on a good faith basis and reserves the right to review its position and, or to take action against the authors of the documentation and, or the applicant if information relevant to its assessment (particularly the prior use of the site where the development is proposed) is 'buried' or concealed (including through the submission of documentation that is not text searchable).</p> <p>This, and any other response in writing by the MRA to the application submitted for consultation or to any other documentation, should not in any way be deemed as approving or endorsing the application in any form or of condoning any matter that falls beyond the MRA's immediate remit as established under the Malta Resources Authority Act and as in force on the date of the relevant response. In particular, you are reminded that with the coming into force of the Act No. XXV of 2015 establishing the Regulator for Energy and Water Services, the Water Policy Framework Regulations and the Protection of Groundwater against Pollution and Deterioration Regulations have been excluded from the remit of Malta Resources Authority and as such the MRA has no authority to take a position on matters regulated by these regulations or indeed any other matter that does not fall within its remit. While this response may be published, any response by the MRA may not be publicly used or mentioned as a general or partial approval by the MRA of the matter referred to for consultation</p>	ERA notes reply. No reply required from Operator				
Planning Authority	No comments received.	–				
Regulatory for Energy and Water Services	The REWS has no objections to the renewal and variation of the Medichem manufacturing IPPC Permit. If Medichem has any fuel storage, the management of this Company should contact the REWS to be guided on the correct application form depending on the fuel use.	Operator to provide reply.	At the moment Diesel is stored in a 240L tank in a flammable resistant container. However in the past Medichem has procured a diesel storage tank and pump nozzle to be able to store diesel in this	<p>The REWS is seeking clarification if the operator is referring to:</p> <ul style="list-style-type: none"> a. The 240l (flammable resistant container only) b. A diesel storage tank and pump nozzle (of unknown volume) c. Or if a)and b) above are the same item <p>There are no legislation changes to the authorisation to operate a Petroleum Filling Station (commercial site) due to</p>	Operator shall the required authorisation from REWS	Done.

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
			double layered and bunded tank but was advised that in order to obtain the necessary permit from REWS to use this tank it had to undergo a fuel station permit requirement, which in view of the small amount of diesel stored on site was deemed not feasible. We would like to use this tank as a better storage of our diesel.	the fact that the tank is connected to a dispenser. Should you need to use option (b) please get in touch with the Regulator for guidance.		
Civil Protection Department	<p>It is not the first time that we have made familiarisation visits for our fire fighters to familiarise themselves with the company and have always been satisfied with the up keeping of the said company.</p> <p>The feedback, that I would like to remind is for the continuation of training to all the staff in basic firefighting and spillage control training to their staff alike.</p>	Operator to take note.	Noted. All employees are trained on basic fire fighting on an annual basis. Spill response training is also provided in-house to all Production	No feedback received		

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
			personnel.			
Water Services Corporation	It is to be noted that both entities had their permit renewed on 14/1/20.	Noted.	/	No objection from DPU.		
OHSA	Renewal and variation of the IPPC permit of Medichem Manufacturing (Malta) Ltd. (IP 0002/05). 1. The employer abides with Act XXVII of 2000 and all relevant OHS regulations; 2. The employer shall submit to OHSA (c/o COMAH Competent Authority) a list of dangerous substances with their classification under the Control of Major Accident Hazards regulations, L.N. 179 / 2015 and the maximum quantity present on site at any time, in kgs/tonnes. These regulations can be viewed at: a. http://justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=26886&l=1 3. any intended construction related works shall comply with the relevant provisions of LN 88 / 2018	1. Health and Safety aspects already included in the permit and will be retained. 2. Kindly provide information 3. Operator to take note	2. Document M3 provides a list of dangerous substances classified according to the COMAH regulation LN179/2015 is attached as per status on the 9th of May 2020. 3. Noted	N/A		
MCCAA	No comments received on this application	–				
EWA	No comments received.	–				
Internal Consultees Feedback						
Environmental Assessment Unit	Reference is made to your consultation in relation to cases in email subject above. As outlined in your correspondence, it is being understood that Medichem shall retain its current operations, namely the manufacture of APIs, whereas Combino shall also retain its current manufacturing operations of solid pharmaceutical dosage forms at their facility. In this regard, the information provided indicates that the uses are substantially the same as per current respective operations. As long as there are no physical interventions (i.e. new construction/development) and/or any change of use which would warrant development consent, there are no issues from our end. An EIA was already undertaken for Medichem Pharma several years ago.	Noted.		No further comments further from our end		
Biodiversity & Water Unit	The documents provided have been noted. Noting that any waste water generated is treated and discharged to the sewerage system, we do not have any comments to put forward. However, we have noted that the Public Sewer Discharge Permit for both installations is expired and requires renewal.	Noted.		The documents have been noted. Noting that there are no emissions to surface waters, we have no comments to add in this regard. One observation however, the Public Sewer Discharge Permit for MML	Kindly update application with a valid sewer discharge permit.	Done

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
				is expired		
Air & Waste Air Quality Team	No feedback was provided.	–		No feedback provided		
Air & Waste Waste Management Team	There are no comments from a waste team perspective on the documents provided.	Noted		<p><u>Annex C-2 Medichem Land and Ground Risk Assessment</u> (Table 3 - p12):</p> <p>Reference should be made to the consolidated version of the list of waste (i.e. Commission Decision 2000/532/EC rather than to decision 2014/955/EU);</p> <p>The EWC code being given to cytotoxic and cytostatic waste (18 01 08*) is deemed to be inappropriate. In view that chapter 18 refers to ‘wastes from human or animal health care and/or related research’, an alternative code needs to be assigned. Since this waste is being generated by a pharmaceutical company, we are of the opinion that an entry emanating from sub-chapter 07 05 (i.e. <i>wastes from the manufacture, formulation, supply and use of pharmaceuticals</i>) of the</p>	Requested clarifications/revisions to EWC codes are required to be included in the appropriate documents.	<p>Reference should to the consolidated version of the list of waste (i.e. Commission Decision 2000/532/EC rather than to decision 2014/955/EU) will be amended when the risk assessment will be reviewed.</p> <p>With regards to the EWC codes:</p> <p>a. EWC 18 01 08* is specifically considering cytostatic/cytotoxic waste. This code helps us to differentiate from the normal pharma waste 07 05 13* which can be disposed of locally. Whilst</p>

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
				<p>European List of Waste would be more appropriate; and</p> <p>Clarifications are requested on the waste which would fall under the EWC 14 06 03* (Other solvents and solvent mixtures). In view that this waste is being generated from a pharmaceutical industry, a code from sub-chapter 07 05 (<i>wastes from the manufacture, formulation, supply and use of pharmaceuticals</i>) is deemed to be more appropriate.</p>		<p>cytostatic needs to be disposed abroad and is therefore assigned also the EWC code required by the receiving facility.</p> <p>b. We will discuss this with our waste carrier as this would require changes in transports permit and also confirmation from the waste reception plant that it can accommodate more waste under a different EWC code.</p>
Air & Waste Noise	With regards to the renewal and variation of the IPPC permit of Medichem Manufacturing (Malta) Ltd. (IP 0002/05), the variation details submitted in Annex C indicate that there shall be no additional noise sources. On the contrary the variation could result in a reduction in the noise levels emitted from the site.	Operator to provide a reply.	The quality control laboratory was never considered as a significant noise source on site compared to other equipment present. This can be verified in the Noise Monitoring Report carried out in 2016.	Agreed with feedback provided		

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
Compliance & Enforcement	<p><u>Medichem Malta</u></p> <p>In view that this seems to be a minor variation in which a laboratory is to be converted into office space, there are no comments on the documents. However, it should be established whether any wastes were produced in the conversion of this lab into offices (with particular attention to contaminated equipment and chemical wastes) and how these were disposed of.</p>	Operator to provide reply.	The Quality Control laboratory was transferred to Combino, hence all the equipment and chemicals were moved to the new location and not disposed of. Any other non-hazardous waste produced was included in the AER	No further comments on the replies to our queries from the first round of consultation on this application.	Noted.	/

Annex II: Feedback received following the Statutory Consultation carried out for the application of variation and renewal of the CPL carried out between 20 March 2020 – 3 April 2020 and 15th May 2020 – 29th May 2020.

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
External Consultees Feedback						
Environmental Health Directorate	<p>With reference to your e-mail dated 16th March 2020 regarding subject indicated in caption and following New IPPC Application regarding subject indicated in caption, kindly be informed that this Directorate would like to submit the following comments/recommendations regarding this proposal.</p> <ol style="list-style-type: none"> 1. Pest Control Treatment. 2. The Directorate highly recommended the construction of the rainwater reservoir. Where rain and/ or second-class water is used it must be treated by biocide. The use of second class and/ or rainwater must not be used for human consumption. 3. It was noted that in Annex B-6 Waste and Emission, that there are no Cooling Towers on the ground of Combine Pharm premises. According to the records for the registration of Cooling Tower, the Directorate has Cooling Tower registered under the sister company of MediChem. The necessary mitigation measure for the Control of Legionella has to be carried out even though that the Cooling Towers is on the grounds of the Medichem. 4. Unpredicted impacts and nuisances which may arise from this operation and that may have a significant adverse effect on public health are to be immediately addressed by the applicant and the necessary mitigation measures taken; 5. Complaints lodged by the public regarding any adverse impacts/nuisances should be immediately addressed by the applicant. All complaints lodged and actions taken are to be recorded and such records are to be readily available to the Competent Authorities when requested. 	<ol style="list-style-type: none"> 1. Provisions for pest control have already been indicated in the Environmental Permit. Operator to confirm and provide necessary information. 2. Operator to reply. 3. Noted 4. Such aspects will be included in the permit 5. Provision for complaints reporting are already included in the permit and will be retained in upcoming permit. 	<p>Pest Control procedure is attached as document M1.</p> <p>2. Rain water is not harvested. Consideration has been made in the past, but the infrastructure of the facility as built does not offer a feasible solution .</p> <p>3. The cooling tower at Medichem is only used for Medichem services not for Combino. This is covered in the Legionella RA of Medichem.</p>	N/A		/
Malta	This assessment is based primarily on the documentation that was published on the	ERA notes reply. No reply				

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
Resources Authority	<p>weblink provided as on the date of the assessment. The Authority made its assessment on a good faith basis and reserves the right to review its position and, or to take action against the authors of the documentation and, or the applicant if information relevant to its assessment (particularly the prior use of the site where the development is proposed) is 'buried' or concealed (including through the submission of documentation that is not text searchable).</p> <p>This, and any other response in writing by the MRA to the application submitted for consultation or to any other documentation, should not in any way be deemed as approving or endorsing the application in any form or of condoning any matter that falls beyond the MRA's immediate remit as established under the Malta Resources Authority Act and as in force on the date of the relevant response. In particular, you are reminded that with the coming into force of the Act No. XXV of 2015 establishing the Regulator for Energy and Water Services, the Water Policy Framework Regulations and the Protection of Groundwater against Pollution and Deterioration Regulations have been excluded from the remit of Malta Resources Authority and as such the MRA has no authority to take a position on matters regulated by these regulations or indeed any other matter that does not fall within its remit. While this response may be published, any response by the MRA may not be publicly used or mentioned as a general or partial approval by the MRA of the matter referred to for consultation</p>	required from Operator				
Planning Authority	No comments received.	–				
Regulatory for Energy and Water Services	<p>The documents Annex B1 Non Technical Summary, Annex B9 Raw materials and Annex B12 Risk Assessment, mention that diesel is stored within the tank of a 360 kW Generator. We note that the generator is next door to the Electrical room, which might not be according to codes of practice.</p> <p>The REWS needs to know the capacity of the fuel storage of this generator.</p> <p>We note that this generator is used for emergency purposes only but the operator should confirm whether this generator is a stand-alone or grid connected.</p>	Operator to provide reply.	Fuel capacity tank is 750ltr. The generator is a stand-alone.	N/A		
Civil Protection Department	<p>It is not the first time that we have made familiarisation visits for our fire fighters to familiarise themselves with the company and have always been satisfied with the up keeping of the said company.</p> <p>The feedback, that I would like to remind is for the continuation of training to all the staff in basic firefighting and spillage control training to their staff alike.</p>	Noted, Operator to take note.	Noted. All employees are trained on basic fire fighting on an annual basis. Spill response training is being provided to QC and will be provided to production	N/A		

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
			personnel.			
Water Services Corporation	It is to be noted that both entities had their permit renewed on 14/1/20. Moreover one comment I have is about the Cessation Plan in Annex B13 for Combino Pharm. I think it would also make sense that the plan includes a reference informing the person in charge of its execution that they are to communicate their intentions to the DPU so that the process of permit surrender can commence.	Noted. Operator is still required to provide updated sewer discharge permits as part of the application. Operator to take note of WSC request in Annex B-13 Cessation Plan.	Noted. Permit submitted.	No objection from DPU.		
OHSA	<p>B) New IPPC application Combino Pharm (Malta) Ltd [EP 0036/09]</p> <ol style="list-style-type: none"> the employer abides with Act XXVII of 2000 and all relevant OHS regulations; The employer shall submit to OHSA (c/o COMAH Competent Authority) a list of dangerous substances with their classification under the Control of Major Accident Hazards regulations, L.N. 179 / 2015 and the maximum quantity present on site at any time, in kgs/tonnes. These regulations can be viewed at: <ol style="list-style-type: none"> http://justiceservices.gov.mt/DownloadDocument.aspx?app=lp&itemid=26886&l=1 any intended construction related works shall comply with the relevant provisions of LN 88 / 2018 and the employer shall submit to OHSA a copy of the last examination report of the passenger lift installed at these premises in accordance with LN 231 / 2007. 	<ol style="list-style-type: none"> Health and Safety aspects will be included in upcoming permit Kindly provide information Operator to take note and provide reply. 	The raw materials stored at Combino do not fall under the CLP hazardous classification. A list of raw materials and their CAS number were available is provided in document M4. 3. Document M5. Shows the last examination report of the passenger lift.	From the documents submitted I see that there is an LPG network. However LPG is not listed in document M3 – List of Dangerous substances. Kindly ask applicant to submit the maximum quantity of LPG stored at any time in tonnes so that we could determine the applicability of COMAH or otherwise	LPG storage in declared in Annex B-9, it is of 20,000L.	Agreed.
MCCAA	From the applications forms for the companies detailed in the subject line and in the Annex attached there is written that two chillers will be installed. The quantity of F-gas R134A needs to be accounted for in the quota system prior to importation as per Regulation 517/2014.	Operator to provide reply.	No new chillers will be installed. The document is indicating what's already in place. No F-gases were imported	Since it is being claimed that the AC units have not been imported into the EU, there is no need for quota authorisation verifications. No further comments from our end.		

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
			from outside the EU after 2018.			
EWA	No comments received.	–				
Internal Consultees Feedback						
Environmental Assessment Unit	<p>Reference is made to your consultation in relation to cases in email subject above. As outlined in your correspondence, it is being understood that Medichem shall retain its current operations, namely the manufacture of APIs, whereas Combino shall also retain its current manufacturing operations of solid pharmaceutical dosage forms at their facility.</p> <p>In this regard, the information provided indicates that the uses are substantially the same as per current respective operations. As long as there are no physical interventions (i.e. new construction/development) and/or any change of use which would warrant development consent, there are no issues from our end. An EIA was already undertaken for Medichem Pharma several years ago.</p>	Noted		No further comments further from our end		
Biodiversity & Water Unit	The documents provided have been noted. Noting that any waste water generated is treated and discharged to the sewerage system, we do not have any comments to put forward. However, we have noted that the Public Sewer Discharge Permit for both installations is expired and requires renewal	Noted				
Air & Waste Air Quality Team	No feedback was provided.	–				
Air & Waste Waste Management Team	There are no comments from a waste team perspective on the documents provided. EPU may wish to note that the waste carrier permits are expired and therefore require renewal.	Noted.		Annex B-1 Non-Technical Summary (pg 4): applicant is requested to also include the method of processing/disposal and the storage and containment of any contaminated packaging, contaminated absorbents and clothing, since these were mentioned in other	Applicant it to revise documents to provide the requested information/clarifications/amendments.	<p>Annex B-1 updated accordingly.</p> <p>a. EWC 18 01 08* is specifically considering cytostatic/cytotoxic waste. This code helps us to differentiate from the normal pharma waste 07 05 13* which can be disposed</p>

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
				<p>document but not listed in this summary; and</p> <p>Annex B-14a Waste Management (pg 2-3):</p> <p>(The EWC code given to cytostatic liquid and solid waste (18 01 08*) is deemed to be inappropriate. In view that subchapter 18 01 refers to waste generated from natal care, diagnosis, treatment, or prevention of disease in humans, an alternative code need to be assigned. Since this waste is being generated by a pharmaceutical company, we are of the opinion that an entry emanating from sub-chapter 07 05 (i.e. wastes from the MFSU (manufacture, formulation, supply and use) of pharmaceuticals) of the European List of Waste would be more appropriate; and</p> <p>Clarifications are requested on the waste which would</p>		<p>of locally. Whilst cytostatic needs to be disposed abroad and is therefore assigned also the EWC code required by the receiving facility.</p> <p>EWC 14 06 03* is not generated at CPM</p>

Comment received by:	Feedback	ERA reply and comment	MML reply			MML reply
				fall under the EWC 14 06 03* (Other solvents and solvent mixtures). In view that this waste is being generated from a pharmaceutical industry, a code from sub-chapter 07 05 (wastes from the manufacture, formulation, supply and use of pharmaceuticals) is deemed to be more appropriate		
Air & Waste Noise	In view of the proposed new IPPC application for Combino Pharm (Malta) Ltd [EP 0036/09], it is being suggested that a first noise monitoring study is to be carried out to assess the noise levels emitted from the site operations as an impact on the outside environment and where relevant on the nearest sensitive receptors, in accordance with the latest revision of BS 4142. Once the first noise monitoring study has been carried out and the noise levels present within the site surroundings and at the receptors have been determined, the frequency of the study and the noise mitigation measures required (where necessary) shall be provided.	Operator to provide reply.	It has been suggested that a first noise monitoring study (as part of the IPPC permit) is carried out to assess the noise levels emitted from the site operations as an impact on the outside environment and where relevant on the nearest sensitive receptors, in accordance with the latest revision of BS 4142. Once the first noise monitoring study has	Agreed with feedback provided	Noted.	/

Comment received by:	Feedback				ERA reply and comment	MML reply			MML reply
						been carried out and the noise levels present within the site surroundings and at the receptors have been determined, the frequency of the study and the noise mitigation measures required (where necessary) shall be provided			
Compliance & Enforcement		Document	Page	Comment					
	1	Annex B1 Non-Technical Summary	Table on last page	Cytostatic wastes (18.01 08*) cannot be incinerated locally. Operator should provide clarification whether these are disposed of locally or incinerated abroad	Operator to clarify. Agreed, the risk assessment will need to be revised to include the coverage of the Combino Pharma Ltd facility.	1. Cytostatic waste is not sent to the local incinerator. This is exported for incineration. Annex B-1 amended to clarify. 2. Land and Groundwater risk assessment planned to be done by Q3 of 2021 3. Boundary area indicated in Site Location plan provided on Annex B-3	No further comments on the replies to our queries from the first round of consultation on this application.	Noted.	/
	2	Annex B2 – Site Report	Page 1	This should be beefed up with more information on potential pollution sources and a rationale as to whether a baseline land and groundwater study is considered as required or otherwise	As requested in the EPU review kindly provide.				

Comment received by:	Feedback				ERA reply and comment	MML reply			MML reply
	3	Annex B3 – Site Location	N/A	If this plan is to be used to be put in the permit, the boundary of the permitted area should be made clearly discernible		6&8. Spill control procedure attached as document M6.			
	4	Annex B4 – Ground floor	N/A	If this plan is to be used, to be put in the permit, some colour coding, at least of the area5. pertinent to the operational permit, should be considered	4. Layout is sufficient for its purpose. 5. Point 5-9 BAT conclusions will not apply to Combino Pharma Ltd.	9. Annex B-14 updated accordingly. 10. Annex B-15a amended to include required information			
	5	Annex B8 – BAT Conclusions	BAT 4 pgs 5 & 6	Operator should be confirming use of relevant standards for waste water monitoring	6. Point 10 SOP for spill management in place, provided already as part of the EP application. Operator to submit as part of the IPPC application.	11. We understand that a first noise monitoring study, as part of the IPPC permit, will need to be carried out to assess the noise levels emitted from the site operations as an impact on the outside environment and where relevant on the nearest sensitive receptors, in accordance with the latest revision of BS 4142.			
	6	Annex B8 – BAT Conclusions	BAT 10 and BAT 11 pages 8&9	Operator should be elaborating on how the waste water management on site at Combino complies with the techniques in the BAT	7. Point 11 Noted. 8. Point 12 Operator to provide reply.				
	7	Annex B8 – BAT Conclusions	BAT 12 pages 10, 11, 12 & 13	Operator should be elaborating on how the waste water management on site at Combino complies with the techniques in the BAT	9. Point 13 Information has also been request as part of the ERA review in the form b section. Operator is to ensure that requested information is submitted				
	8	Annex B8 – BAT Conclusions	BAT 21 page 16	Operator should be elaborating on how the waste water management on site at Combino complies with	10. Point 14 Information has also been				

Comment received by:	Feedback				ERA reply and comment	MML reply			MML reply
				the techniques in the BAT		requested as part of the ERA review in the form B section. Operator is to ensure that requested information is submitted. Point 15: Operator to provide reply. Noise monitoring was not requested as part of the current environmental permit. Kindly see comment above on noise.			
	9	Annex B8 – BAT Conclusions	BAT 22 & 23 pgs 16 & 17	Albeit that a comprehensive noise study was carried out in the past, this noise report should be periodically updated11. Further elaboration on this is made in our comments on Annex B16					
	10	Annex B9 – Raw Materials	Page 1	It is stated that, in case of spills, the operator will ensure the spill of raw material ‘will not reach the drains’ and mentions that spill kits are available. An additional measure to be considered would be to store the liquids as far away from the drains as possible. The SOPs should also cater for the contingency of what were to happen if a spill did reach the drains					
	11	Annex B9 – Raw Materials	Page 2	It is stated that ‘secondary containment is available wherever possible’ for materials such as laboratory reagents, maintenance oils, additives and lubricants. The operator should					

Comment received by:	Feedback				ERA reply and comment	MML reply			MML reply
				endeavour to have secondary containment for all such materials.					
	12	Annex B12 – Risk Assessment	Page 2	Similar to the SOP within the raw materials warehouse, the SOP for liquid waste management should include what is to take place in the eventuality that any spill does manage to reach the drains.					
	13	Annex B14 – Waste Management	N/A	This section is considerably lacking in detail. The various waste streams appear to be effectively stored around the entire perimeter of the factory building. A rationale as to why this is considered as an effective way of storing the waste generated on site needs to be provided. In general ideally wastes should be grouped together into waste management areas. Also the plan does not show any protection from the elements or bunding for such waste. The form indicates that this section should have significantly further elaboration, including breaking					

Comment received by:	Feedback				ERA reply and comment	MML reply			MML reply
				down the generated wastes according to EWC Codes.					
	14	B-15 Emissions to Air	N/A	Once again, this section is lacking the required details set out in IPPC Form B, such as type, form, quantity of emissions and abatement measures for each point; and details on relevant monitoring. The details of the stand by generator are also missing. With regards to the plan itself, it should be indicated whether the individual points are vents or stacks.					
	15	B16- Noise Assessment		While appreciating that the report goes into great detail, this is now 6 years old. An updated noise assessment should be performed. This is also relevant in view of the various measures suggested for implementation in Chapter 4 of the report, as it is unclear whether these were implemented					