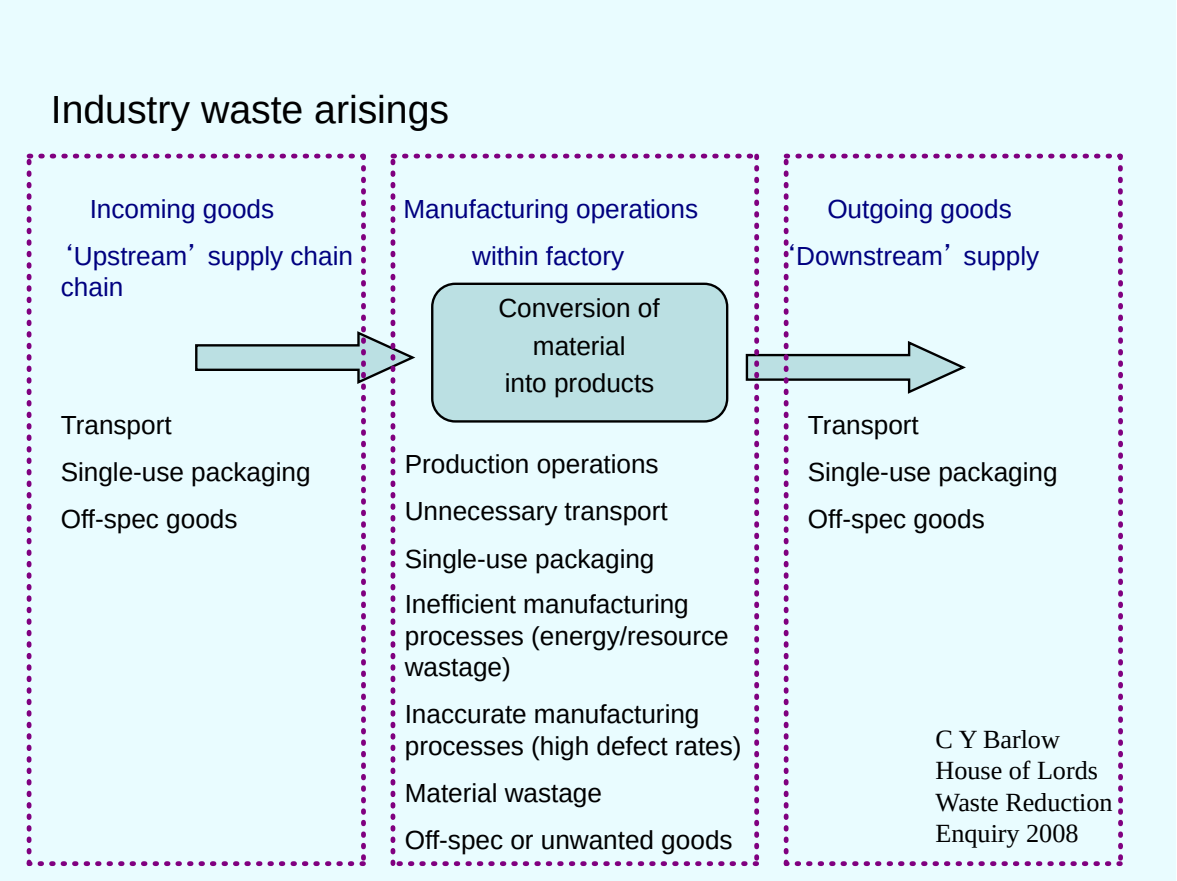
METIIA – Paper 6, 2018 - Cribs

Question 1, Part a



Environmental impact: Material wastage most important, then energy for factory operations and space heating. Impact can be assessed by performing a full environmental audit of the factory and its operations; indications of likely rankings can be obtained from McKinsey Abatement curves which are discussed further in (b).

Question 1, Part b

Reduce: Waste reduction Materials, energy, transport.

Relating to production of goods:

Factory processes

Supply chains

Office processes

Quality control is good for reducing waste (off-spec goods coming in, being made, being rejected or re-worked in factory, being sent out to customers). Re-work is a form of waste: it is an un-necessary extra manufacturing stage.

"Lean" manufacturing is good for reducing waste.

Office buildings and processes: Commercial buildings account for approximately 10% of global carbon dioxide emissions, with space heating dominating energy usage. The second biggest energy factor is likely to be water heating, followed by lighting and “appliances”. This last category includes office equipment (e.g. computers, photocopiers, printers)

Space heating and water heating: Principal measures which can be taken to improve thermal insulation are, in decreasing order of energy savings:

Insulation of exterior walls; improved roof insulation; double-glazing; draughtproofing.

Bringing in considerations of cost, the most effective simple measure is draughtproofing, followed by improved roof insulation.

Lighting

Lighting typically accounts for up to 20% of the energy in commercial buildings. Moving to LEDs and CFLs reduces energy consumption by an order of magnitude.

Office equipment

Office equipment (e.g. computers, monitors, photocopiers, laser printers) going into 'stand-by' or ‘sleep mode’ gives significant energy savings.

Materials

Double-sided printing and copying can save up to 50% of the paper being used...

Re-use:

Re-using products saves energy/waste by eliminating *product disposal*, *material production* and *manufacture/delivery* stages

Water:

Recirculating water systems

Packaging:

Re-usable pallets; re-usable containers for goods and components. Can be logistically complex.

Office:

Avoid disposables (e.g. use china and glasses, not plastic cups)

Machines:

Mend and Recondition machines

Recycling

Eliminates product disposal stage.

Conventional recycling also reduces *material production* impact (less material produced, e.g. less mining, but also only need part of the material production process)

Minimum impact recycling (material re-use) eliminates *material production* stage.

Potential for recycling materials varies; metals from aerospace manufacturing operations are high-value and recycling is particularly economically and environmentally beneficial.

Recycling of other materials (e.g. plastics from packaging) should be done both in the factory and in the ‘office’ operations. Financial influences are slight, but landfill should be reduced.

In assessing financial implications, use may be made of **McKinsey Abatement Cost Curves**

These present the cost of measures aimed at reducing greenhouse gas emissions, presented in order of increasing cost. The width of the bars tells us the *abatement potential*: the amount of CO_2 that could be saved by implementing each of the measures.

The measures on the left all have negative cost (i.e. present opportunities to save money as well as improving environmental performance). Many of these are to do with reducing waste (mainly of energy). The measures on the right require capital investment and so cost money up-front, but this is where the biggest opportunities for reducing CO_2 emissions are to be found.

The financial ranking of measures for an aerospace factory is likely to be the same as the environmental ranking for (a): materials and manufacturing quality most important, followed by energy usage (manufacturing operations and equipment, plus a relatively small contribution from 'office' functions) and space heating.

Question 1, Part c

(i) Quality control (reduction in off-spec goods production) publicity in the factory can include some mention of environmental aspects.

(ii) Emphasise the environmental rather than economic benefits in 'Switch off' publicity.

(iii) Increased awareness of environmental benefits of correct disposal of waste (put in the right bins, not contaminated or mixed with incorrect other materials).

In all these cases, there are real environmental benefits (in decreasing order). But (iii) may have most impact in educating the workforce because this is something they come across in everyday life.

*A **basic answer** will identify some of the facts in each part, but may be incomplete and may not provide critical evaluation.*

*A **good answer** should demonstrate comprehensive knowledge and understanding of the relevant factors, and show some critical evaluation of their relative importance.*

*An **excellent answer** will, in addition, include a good range of specific examples.*

Question 2, Part a, (i)

It is important, in the basic answer, to include a definition about tissue, which is a groups of cells that are specialised to carry out a common function. A more advanced answer would highlight that these are a combination of cells and extracellular matrix and the examples can include the four types of tissue, (i) Epithelial, (ii) Muscle, (iii) Nervous, (iv) Connective.

A basic overview definition of tissue engineering can be given, e.g. "Instead of replacing defective tissues with manmade devices, try to re-grow healthy tissues by making living implants with active cells". However an excellent answer for the initial description or definition of tissue engineering and other applications should capture at least 2 more general points, such as:

- providing cellular prosthesis or replacement parts for the human body;
- providing formed acellular replacement parts capable of inducing regeneration;
- providing tissue or organ-like model systems populated with cells for basic research and for many applied uses such as the study of disease states;
- providing vehicles for delivering engineered cells to the organism; and
- surfacing non biological devices.

There are a range of challenges to regulating tissue engineering products. It was noted in lectures that separate committee was needed to be set up in Europe to assess such products (EU: Advanced Therapy Medicinal Products (ATMP) Regulation (1394/2007)). Challenges include having three categories of product under one regulatory text, which is complex. Also, it was noted in the lectures that sometimes the primary mode of action is unclear, the variability in the source material can make it difficult to show the product was made correctly, there are usually small batch sizes and short shelf-lives and so challenging to run standard clinical evaluation. Also, randomized controlled clinical trials may not always be feasible because alternative treatments are not available. Standards are sometimes ill-defined. In addition, as in this Directive some discretionary powers are left to Member States to develop detailed procedures, it may lead to a number of discrepancies and to an uneven growth of this field across the EU.

Question 2, Part a, (ii)

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Question 2, Part b, (i)

Considerations about the metal alloy would include:

Physical properties, such as strength, ductility, possibly some wear at the link to the femoral head. The fatigue strength should be noted because of the cyclical loading experienced. The density of the material is important for the patient, in terms of trying to make it sufficiently light. This is acceptable as a basic answer but a more advanced development of this point would note the material should still be machinable, to ensure manufacturability and the mechanical properties should also allow transfer of the load to the femur and avoid bone resorption.

The alloy would need to be reliably corrosion resistant for the chloride environment. A very good answer would note the addition of chromium oxide to ensure the formation of a resistant layer.

It should be noted that it is important that the alloy does not include ions that can be released and lead to an immune response. Equally important is that the alloy enables (or at least does not prevent) bone integration. This may mean it has to be compatible with a biocompatible interface layer formation (eg a bioceramic) or be compatible with a particle coating technology that will encourage integration.

Two points explained in detail from those above are acceptable, three is good. Really excellent answers would explore broader issues still and note that regulatory clearance, possibly clinical trials, sterilisation and biocompatibility tests, etc. may also need to be carried out.

Question 2, Part b, (ii)

A basic answer would give a very brief reference to the change while an excellent answer would explain the change in more detail, including the benefit that this change will bring. Examples include:

- There is a greater emphasis in new regulations on obtaining clinical trial information. Not requiring trials due to "equivalence" will be much more rigorously interpreted (e.g. Class III can no longer use this rule). This is both to provide more confidence regarding safety (e.g. report by FDA about poor safety due to previous approach) and also to take a step towards harmonisation.

- Class III medical device manufacturers must create a summary of safety and clinical performance in a way that can be understood by patients. This is again to improve confidence in safety.

- Implants for aesthetic purposes are now also covered by the regulations. This is again to improve confidence after PIP and other scandals.
- The regulations have tried to take a step towards harmonisation with FDA. Harmonisation will be important for reducing the time and cost for product development, making it easier to bring new medical devices to market.
- There needs to be a unique identifier for each device and linked information. this is to improve market surveillance and traceability.
- There now needs to be a qualified person in each organisation responsible for regulatory compliance. This is again to improve confidence in devices.
- The legislation approach was changed from that of Directives (where the Member State can define how best to implement the requirements into their own legislation, and are given significant time to adopt) to Regulations (where the legislation is directly applicable immediately in all Member States).

Question 3, Part a, (i)

A good answer would identify any three dimensions and provide a clear explanation. Excellent answers provide detailed explanations of each dimension, show an understanding about the potential interconnections and give clear examples to illustrate the understanding. The four most common dimensions include:

1. Engineering scale-up of a novel technology / Technology Development Scale-up

Novel products have specific technical uncertainty and risk and this has to be managed when going from the lab prototype to the integrated/packaged product. This is essentially managing the development of the fundamental technology at the core of the product.

2. Production scale-up of a tech-based product / Process/production Scale-up

Novel production technologies can also be transformative, e.g. additive manufacturing) However, they also need to prove scalability in terms of function, application and cost as the volumes and line speeds increase.

3. Operational and organisational scale-up of a manufacturing business / Business Scale-up

Along with the technical scale-up, there will be a necessary scale-up of operational capabilities, organisation structures, etc. This will require development of employees, leadership, customers, finance and infrastructure.

4. Scaling-up of product value chains or markets / Value Chain Scale-up

The value-chain network will also scale to support the new emerging technology. For example, transport techniques, material format for transport and integration, level of supply. There is a need to have others responding to your innovation / changes across your value chain.

Question 3, Part a, (ii)

Infra-technologies are underpinning technical tools that are critical enablers for both product and process scale-up. Examples of different types of such tools include measurement and analysis methods, scientific databases, standard references, process models, etc. Specific examples for such infra-technologies showed an excellent understanding of the concept. These technologies support both generic and proprietary technologies (product or process) and are critical for the translation from the science base to commercialisation. This was an important concept for outstanding answers. Scale-up and translton can be inhibited due to lack of investment in these technologies. However, these are generally funded by governmental agencies and programmes because they are underpinning technologies and translational.

Question 3, Part b:

It may be noted that while Technology Readiness is used to characterise the maturity of a new technology, it is open to interpretation for manufacturing. Manufacturing Readiness is

assessed as a management and communication tool to enable manufacturing-related risks to be addressed and negative impacts on cost, schedule, etc. to be minimised. It allows a common language about manufacturing maturity and has been successful in the past in the defence sector in enabling rapid translation. An excellent answer will look at the assessment in terms of the Manufacturing Readiness Threads, give specific examples (e.g. Design, Materials, Personnel), describe how they are assessed (e.g. Manufacturing Levels 1-10, with 1 being feasibility and 10 as full rate production). These are linked to Technology Readiness Levels also, to ensure coherent development. An outstanding answer may note that each thread has a number of more detailed sub-threads, that are then assessed to identify the correct level. There are 4 milestones in the management tool to help reach full scale manufacturing and an outstanding answer may include details about at least one of these. e.g. The first milestone looks at manufacturing in a production relevant environment.

Examiner's comments:

Question 1:

The question was very discriminating, giving a good spread of marks in all sections and enabling candidates to demonstrate their knowledge and understanding well. In general, answers showed that almost all candidates had engaged well with sustainability and had a good understanding of the main principles. Only a couple of answers demonstrated almost total lack of knowledge and understanding. Most answers made pertinent comments relating to aerospace industry, but a few lost marks by making no reference to it at all.

(a) Generally well answered. The question specifies waste in the operations of the aerospace factory; many answers contained correct but irrelevant information about other aspects of sustainability, and waste in operations not related to the factory.

(b) Generally good answers, with sensible examples of the three Rs. Failure to address financial aspects was a common omission.

(c) Very good answers with some good ideas, showing strong understanding of the importance of cultural aspects and how they can be influenced.

Question 2:

There were quite a few candidates who showed great depth and breadth of knowledge across this broad range of topics, including answers receiving full marks in certain sections. While a number of candidates found certain questions very difficult, there were very few that could not balance this against other parts.

(a) (i) This was answered very well by the cohort. The weakest part of the answer was noting two reasons clearly for running biocompatibility tests.

(a) (ii) This question was weaker for most of the cohort, as they struggled to identify clearly and explain two challenges when developing regulations. Also, an understanding of the term tissue was not always clearly explained. However, a significant number of students still received full marks.

(b) (i) There is a very wide range of considerations from which to choose, to answer this question. An outstanding answer would identify five or more clearly. However, full marks were attributed if fewer were identified and explained in more detail. This was very well answered by the cohort, showing a good broad understanding of the topic.

(b) (ii) The final part of the question was quite differentiating, with some unable to complete and others showing an excellent level of knowledge.

Question 3:

This was a new "contemporary issue" included in this year's course based on current trends in industry and research. On the whole, it was clear that the cohort were able to show a very good understanding of the complexities of scaling up emerging technologies and especially the interconnections between the considerations discussed in lectures.

The focus for part (a) of the question was to show an understanding of multiple considerations of scale-up that need to be monitored simultaneously. This was very well answered by the cohort, with some really excellent answers showing a detailed knowledge.

Part (b) was more challenging for the cohort. The differentiators between good and excellent answers was the ability to convey an understanding about what the term was referring to, why this is important to manage and also how it is assessed specifically.