Attachment 8-2-1 Waste Management and Waste Hierarchy

1.0 WASTE STREAMS

Attachment 8-1 outlines the existing and anticipated waste types by List of Waste (LoW) Code. Operational waste is generated on a daily basis by the operator. The waste associated with the DS2 expansion is expected to be similar in nature to the wastes already generated at the current Pfizer Ireland Pharmaceuticals facility and will be generated from process and non-process related activities. The wastes can be allocated into the following types:

- **Hazardous**, including flammable waste, toxic waste, corrosive acids and bases and wastes dangerous to the environment;
- **Biohazardous,** including contaminated discarded sharps, inactivated biohazardous waste, animal by-products and clinical waste; and
- **Non-hazardous,** including general office waste, recyclable waste and organic / food waste from staff areas.

The quantities presented in Attachment 8-1 relate to both the existing facility and the DS2 expansion. The quantities relating to the DS2 expansion are based on reasonable assumption underpinned by the expected operations of the proposed facility. These actual quantities once operational will be recorded using the Environmental Management system (EMS) and will be advised to the Environmental Protection Agency (EPA) each year as part of the Annual Environmental Report (AER) for the installation. The quantities relating to the existing facility are based on the 2022 figures as presented in the Annual Environmental Report (AER) 2022 for the installation.

2.0 WASTE MANAGEMENT

There is a Standard Operating Procedure (SOP-12247) in place for the facility regarding procedure for waste management. This SOP ensures the proper management and recycling of wastes generated at the installation. The SOP enables the facility to contribute to the targets and policies outlined in the *Eastern-Midlands Region Waste Management Plan 2015-2021* and *EPA Draft National waste management plan for a circular economy (2023).* The SOP is reviewed regularly All wastes generated on site are packaged and labelled appropriately at the waste satellite locations before movement to the onsite central waste storage.

Mitigation measures are in place to manage impacts arising from waste generated during operation of the installation and are summarised below:

- All waste materials on-site are segregated into appropriate categories, including (but not limited to):
    - Organic waste;
    - Dry Mixed Recyclables;
    - Mixed Non-Recyclable Waste;
    - Glass;
    - Cardboard;

  - Plastic;
  - Waste electrical and electronic equipment (WEEE) including computers, printers and other ICT equipment;
  - Waste Electrical and Electronic Equipment
  - Cooking oil;
  - Cleaning chemicals (paints, adhesives, resins, detergents, etc.);
  - Bulky waste;
  - Waste from inorganic chemical processing; and
  - Waste from organic chemical processing.
- All waste materials are stored in colour coded bins or other suitable receptacles in designated, easily accessible locations. Waste receptacles are clearly identified with the approved waste type to ensure there is no cross contamination of waste materials;
- All waste collected from the site of the proposed development will be reused, recycled, or recovered, where possible, with the exception of those waste streams where appropriate facilities are currently not available; and
- All waste leaving the site is transported by suitable permitted contractors and taken to suitably registered, permitted, or licensed facilities.

Designated personnel on the EHS team regularly inspect the onsite waste storage facilities and infrastructure, provide advice on waste segregation requirements, prepare and control documented procedures for waste management, manage the waste contractors, audit, and maintain a full paper trail of waste documentation for all waste movements from the site which are recorded in the EMS. They also ensure that all waste contractors used by the installation and all recovery/disposal outlets, are suitable for use, appropriately authorised and audited, as required.

3.0 WASTE HANDLING AND STORAGE

All waste generated at the facility is categorised as being either hazardous, biohazardous or non-hazardous in nature in accordance with the EPA document *Waste Classification – List of Waste & Determining if Waste is Hazardous or Non-Hazardous.*

Unless approved by the EHS department, colleagues are prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.

All wastes must be packaged in appropriate bags, drums, IBCs or bins. All bags and containers must be clean, undamaged and made of, or lined with, materials which will not react with or are otherwise incompatible with the waste.

All waste containers are labelled which are used to identify the location the waste was generated, the contents of the container and its classification as hazardous or non-hazardous.

The general requirements for management of hazardous and biohazardous waste, by the waste generator, are outlined as follows:

- Correct segregation;
- Correct packaging of waste;

- Full and accurate labelling; and
- Transfer to waste satellite location.

Once these steps are completed correctly, waste is then ready for movement from waste satellite locations to onsite central waste storage by site services.

The segregation procedure and subsequent packaging and labelling requirements for non-routine or new hazardous or biohazardous wastes, which may arise in any area, must be pre-approved by the EHS department prior to removal from the area.

3.1 HAZARDOUS WASTE STORAGE AND HANDLING

Due to the strict regulations and the potential for injury/illness and environmental impact from dangerous substances, there are specific requirements for hazardous waste management in place at the site. Recyclable hazardous waste is segregated from non-recyclable hazardous waste into the following waste streams:

- PPE, wipes contaminated with hazardous substances;
- PPE, wipes contaminated with a solvent;
- Batteries – lead/acid batteries, mixed batteries containing nickel, cadmium alkaline batteries;
- Fluorescent tubes;
- Aerosols;
- Waste electrical and electronic equipment (WEEE) e.g. computers, light fittings, electrical appliances;
- Corrosive waste;
- Laboratory chemicals;
- Empty containers containing residues of or contaminated by hazardous materials e.g. empty solvent containers;
- Construction waste e.g. paint; and
- Laboratory solvents, vials, test tubes.

Up to 205 litres of hazardous waste (except for acutely hazardous waste (i.e. toxic or very toxic), which is limited to 1kg) can be stored in waste satellite locations. When a container is full, the date on which it reached capacity is marked on the label and the container is moved within three days to a central waste storage location.

Details of all hazardous waste transferred from waste satellite location is tracked using an electronic waste tracking system. Site Services place a barcode on the hazardous waste label of all correctly segregated, packaged and labelled waste.

The barcode is scanned by Site Services and the waste is tracked from the point of generation at the satellite waste location until it is sent off site for disposal. Sealed and correctly labelled waste is collected by Site Services from the waste satellite locations and brought to central waste storage locations.

The SOP *Procedure for Waste Management* currently in place at the site details the appropriate segregation and collection methods for these hazardous waste streams. Only the Site Services department are responsible for hazardous waste streams.

3.1.1 Solid Hazardous Waste

Secondary contaminated solid hazardous waste (e.g. PPE and packaging that has come in contact with a dangerous substance) is disposed of in red hazardous waste bags. When bags are full they are sealed using a cable tie.

Solid hazardous waste is required to be double bagged if the secondary contaminated material is likely to leak from a single bag e.g. spill mats that are saturated with liquid from a hazardous material clean up or if the material is acutely hazardous (i.e. toxic or very toxic).

Hazardous sharps waste is disposed of in dedicated Hazardous Sharps Bins and labelled to distinguish the waste from biohazardous sharps bins.

3.1.2 Liquid Hazardous Waste

Liquid flammable hazardous waste is discharged to steel or plastic drums/containers. Small quantities of flammable solvents are stored in red jerricans (polyethylene cans with flame arrestor and spring-loaded cap).

Liquid corrosive and toxic hazardous waste is discharged to UN approved plastic drums/containers. Small quantities of corrosive or toxic liquid waste is disposed and stored in dedicated 5 – 20 litre UN approved plastic containers.

Corrosive waste is stored in plastic drums. Corrosive acid waste must be segregated from corrosive alkali waste.

All hazardous waste is labelled. For UN approved drums one label is placed in the top third panel of the drum. For IBCs one label is placed on the steel plate of the IBC and another label is placed on the opposite side of the first label's position.

When an IBC/drum is approximately 80% full, 20% void is left to allow for expansion of the waste during transportation, the IBC/drum is sealed. The IBC/pallets loaded with drums are then removed from the area and relocated to a designated collection point as agreed with Site Services.

Hazardous liquid waste that is not identified is held in a designated quarantine area in the Site Services waste storage area until the specific information on the waste contents are identified.

Expired/out of specification chemicals are not placed in the red hazardous waste bags. Instead, such waste is left in the original container, leaving the original label visible where possible. A hazardous waste label is then attached and the waste is left at the nearest waste satellite location.

Empty containers ≤ 2.5 litres previously containing hazardous materials/dangerous substances such as bottles or tubs are triple rinsed locally prior to disposal. Water is used for triple rinsing and the wash water is then disposed to the appropriate waste drain/drum/container. The container is then labelled, including initials and dates. Where there is potential for the generation of fumes/vapours from triple rinsing, the activity is carried out in a fume hood. Rinsed flammable containers stand in the fume hood for at

least four hours. Following the triple rinsing process, rinsed containers are classified as non-hazardous waste and where practicable can be recycled.

Empty containers > 2.5 litres are labelled as hazardous waste and left at the satellite waste collection area. Site Services then triple rinse the containers following the process outlined above and send them to be recycled where practicable.

No waste aerosol cans or other pressurised products, regardless of contents are discharged, punctured, shredded or crushed on-site, or disposed of as non-hazardous waste. They are segregated from other hazardous waste and disposed of at the nearest waste satellite location.

3.2 BIOHAZARDOUS WASTE STORAGE AND HANDLING

Biohazardous waste includes any waste material which is infectious or, because of its physical and/or biological characteristics, may pose a potential hazard to human health, animals, plants or the environment. Biohazardous waste at the site is segregated into the following waste streams:

- General medical waste;
- Class I and Class II biohazardous unautoclaved waste; and
- Class II (Virus and Mycoplasma) waste.

Details of all biohazardous waste transferred from waste satellite location is tracked using an electronic waste tracking system. Site Services place a barcode on the biohazardous waste label of all correctly segregated, packaged and labelled waste.

The barcode is scanned by Site Services and the waste is tracked from the point of generation at the satellite waste location until it is sent off site for disposal. Sealed and correctly labelled waste is collected by Site Services from the waste satellite locations and brought to central waste storage locations.

For Class II (Virus and Mycoplasma) waste a locking mechanism for bins has been implemented by Site Services and additional signage is added to the waste bins detailing restrictions associated with the handling of this type of waste e.g. staff handling this waste are restricted from entering the Drug Substance building for a minimum of 24 hours.

The SOP *Procedure for Waste Management* currently in place at the site details the appropriate segregation and collection methods for these biohazardous waste streams. Only the Site Services department are responsible for biohazardous waste streams.

3.2.1 Solid Biohazardous Waste

Genetically Modified Microorganisms (GMM) waste is segregated from other biohazardous waste streams and labelled as GMM Waste.

Solid biohazardous waste is disposed of within yellow bags and labelled as appropriate. The label also features a yellow dot indicating Biohazardous Waste.

Soild biohazardous waste of Class II (Virus and Mycoplasma) is double bagged and sealed using a cable tie.

Biohazardous sharps wastes are disposed of to yellow puncture resistant sharps boxes. Sharps boxes are only filled to 80% of the container volume. Biohazardous sharps bins are fully sealed and labelled.

3.2.2 Class I Waste and Class II (Cell Culture Cells) Waste

Biohazardous solid waste is autoclaved off-site by an approved biohazardous waste contractor. Biohazardous liquid waste streams are inactivated prior to disposal to drain.

GMM waste is segregated from all other waste types and inactivated by verified inactivation methods. All inactivation of GMM liquid waste is logged.

Disinfectants are used in accordance with vendor recommendations or otherwise directed by the Biological Safety Committee.

3.2.3 Class II (Virus and Mycoplasma) Waste

Biohazardous waste is autoclaved off-site by an approved biohazardous waste contractor.

Waste is double bagged, sealed with a cable tie and stored in labelled biohazardous waste bins.

When required, dedicated bins are brought to a collection area outside the labs by Site Services. The waste is removed from the labs by Site Services and placed in the dedicated bins for transport out of the area. Bins are lined with spill proof liners and have a locking mechanism which is engaged before transport of waste out of the area. The waste bins are brought to the east drum store where the waste is transferred to storage bins in a locked cage. Only Site Services can access this location.

Waste and spill proof liner is removed from dedicated bins and placed in the transport bins. Spill proof liner is replaced in the dedicated bins in preparation for further waste removals from the area.

Site Services personnel do not access the Drug Substance building for a minimum of 24 hours after handling this waste.

3.2.4 Animal By-Product Waste

Animal By-Product (ABP) waste, e.g. mammalian cell lines, foetal bovine serum, chicken bone marrow and spleen samples coming from the Biomedicine Design laboratory, is chemically inactivated and labelled as hazardous waste. This waste is segregated as agreed with Site Services and EHS post inactivation. This waste is then incinerated by an approved waste contractor.

ABP waste generated in QAQC laboratories may be disposed via process drains following inactivation.

3.2.5 Inactivation of Biohazardous Waste

The following inactivation methods may be used on site:

- Verified heat inactivation for large volume cell culture waste;
- Verified chemical inactivation for GMM waste;
- Verified pH inactivation for GMM waste; and
- Chemical inactivation of non-GMM biohazardous materials can use disinfectants other than those specified in verified chemical inactivation methods for GMM waste in accordance with disinfectant vendor recommendations.

3.3 NON- HAZARDOUS WASTE STORAGE AND HANDLING

Waste that does not comprise of, or has not come in contact with hazardous substances, including certain active pharmaceutical ingredients, is classified as non-hazardous. Non-hazardous solid waste generated across the site will be segregated according to its recyclable properties where possible. At a minimum the following non-hazardous waste streams will be segregated for recycling:

- Paper, cardboard, plastic, domestic;
- Canteen;
- Confidential paper;
- Cardboard;
- Timber e.g. pallets;
- Glass (laboratory);
- Metal;
- Construction/project waste e.g. soil, rubble (C&D waste);
- IPA wipes or tissue used with IPA;
- Toner cartridges; and
- General canteen oils.

Appropriate segregation of wastes at the source reduces the risk of cross-contamination and provides the greatest potential for recycling/recovery.

Non-recyclable non-hazardous is disposed of as general waste. Clear or white plastic refuse bags or other containers/receptacles approved by the EHS or site services department will be used for disposal of general waste.

Non-contaminated glassware is discarded to dedicated non-contaminated glass bins. These bins are left at the nearest waste satellite location for collection by site services.

The cafeteria supervisor manages segregation of all cafeteria waste. Cafeteria packaging waste including plastic, metal and cardboard will be segregated at source for recycling. Contaminated recyclables are disposed of as general non-hazardous waste, as described above. Segregation of food waste for composting is conducted when technically feasible and practicable.

The SOP *Procedure for Waste Management* currently in place at the site details who is responsible for each of these non-hazardous waste streams and the appropriate segregation and collection methods.

3.3.1 Sharps

A yellow puncture resistant, leak proof, autoclavable container is used to hold contaminated sharps waste, also known as a Cin-Bin. Separate UN approved containers can be used for sharp non-hazardous, and hazardous waste including broken glass. A general guideline to use is that a sharps waste is any device or object used to puncture or lacerate the skin.

In manufacturing areas where GMP requirements do not allow sharps bins or drums to be introduced to classified manufacturing areas, local procedures must be in place to ensure that sharps e.g. broken glass vials/syringes, are safely packaged and are labelled in accordance with the requirements of the SOP *Procedure for Waste Management* currently in place at the site.

3.3.2 On-Site Composter

The Grange Castle site has a small-scale, in-vessel composter (aerobic biodigester) which recycles and reuses organic food waste from the canteen facilities on site. The composter has a 15-30% output with the resulting compost used by Pfizer contract landscapers within the Grange Castle site perimeter in the planted areas such as trees, shrubbery and biodiversity lawn areas.

3.4 REMOVAL OF WASTE OFF SITE

Waste management companies, as authorised by the EPA and Pfizer Global EHS, are responsible for the transfer of waste off-site to authorised recovery/disposal facilities.

An Approved Waste Vendor List is in place at the installation for waste contractor selection and ensures all waste contractors conform to the relevant legislations and standards as well as Pfizer Ireland Pharmaceutical's environmental requirements.

Hazardous and biohazardous wastes to be sent offsite for recycling, treatment, storage, or disposal are only sent to locations that have been properly evaluated and are on the Approved Waste Vendor List.

3.5 RECORD KEEPING

The following documentation controls are in place for the site:

Table 1 *Record Keeping and Documentation Control*

Waste Stream	Item	Approach
All Streams	Waste Classification Form	The Waste Classification Form is used to compile all the required information to allow correct classification of the waste stream in accordance with all regulatory requirements. The form is stored electronically in the EHS shared drive and updated annually.

	European Waste Catalogue (EWC) Code	The data is stored electronically and retained for seven years
	Quantity	The data is stored electronically and retained for seven years
Hazardous (exported outside of Ireland)	Results of IEL Schedule 3(iii) Waste Analysis (if applicable)	The data is stored electronically and retained for seven years
	Waste Transfer Form (WTF) or Transfrontier Shipment (TFS) form	The data is stored electronically and retained for seven years
	Signed copy of WTF/TFS Annex Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) document	The data is stored electronically and retained for seven years
	Confirmation of receipt at Transfer station	The data is stored electronically and retained for seven years
	Confirmation of destruction/treatment	The data is stored electronically and retained for seven years
	Copy of TFS including date and signature of person performing and verifying destruction	The data is stored electronically and retained for seven years
Hazardous (within Ireland)	WTF form	The data is stored electronically and retained for seven years
	Confirmation of destruction/treatment	The data is stored electronically and retained for seven years
Non-hazardous	Non-hazardous waste management report maintained on the online portal	The data is stored electronically and retained for seven years

4.0 WASTE HIERARCHY

Pfizer Ireland Pharmaceuticals is committed to minimising the environmental impact of its operations and the waste management process for the installation is considered an essential and integral component in the efficient operation of the installation.

All wastes are managed in accordance with the site's waste management procedures, which are reviewed regularly to ensure there is continual improvement in the waste management practices.

In order to minimise the potential impact to the environment, the waste management procedures in place at the site seek to meet the intent of the waste management hierarchy (Refer to Figure 1 below).

In order of priority, the Waste Hierarchy sets out the most desirable approaches to waste management as involving:

a) Waste prevention;
b) The preparation of waste for re-use;

c) Recycling;
d) Other recovery, including energy recovery; and
e) Disposal.

It is Pfizer Ireland Pharmaceutical's policy that the installation must use the highest-prioritized waste-elimination/disposition method in the waste hierarchy that is practicable for the particular waste stream. The entire operations process has been designed with waste prevention/reduction in mind. Waste generation is tracked at a monthly sustainability meeting with senior management. Projects to optimise waste management on site are identified by a cross function team and a summary of their performance is also reviewed at the monthly sustainability meeting.

Figure 1 *Waste Hierarchy (Source: Indaver1)*

5.0 WASTE PREVENTION / MINIMISATION OF WASTE

EMS is in place for the installation as required under the IE Licence. The purpose of the EMS is to identify the environmental objectives and targets and action plans which have been created by Pfizer Ireland Pharmaceuticals.

Improvements in environmental performance are encouraged in the Environmental Management Plan associated with the IE Licence by setting a series of objectives and targets commonly associated with reducing resource material use (e.g., water, energy, paper) and waste production generally. The outcome of these objectives are reported on annually in the AER produced for the facility. Pfizer Ireland Pharmaceuticals will continue to establish meaningful targets for improvements in the areas of waste reduction throughout the lifetime of the operation of the installation where possible.

1 Waste Legislation Guide, Understanding Irish Waste Regulation. Indaver 2014.