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TSCA Contained R&D Checklist for Intergeneric Microorganisms

Regulation (40 C.F.R.)	Description
§ 725.234(a)	Microorganism must be used solely for R&D purposes.
§ 725.234(b)	Microorganism must be used by, or directly under the supervision of a TQI. *Document that the TQI is someone who:* • *because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the microorganism that is used under his or her supervision;* • *is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize such risks; and* • *is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting a research and development activity.*
§ 725.234(c)	There can be no intentional testing outside the structure. *Describe the design and operation of the structures. Describe how the buildings and vessels that surround the genetically modified organisms control the organism and prevent releases to the environment. If applicable, document compliance with NIH Guidelines at IV-B-4-d. Describe restricted and controlled access to structure.*
§ 725.234(d)(1)	Containment and inactivation controls in place must take into account factors relevant to the organism's ability to survive in the environment and potential routes of release **via air.** *Describe the physical containment, end-of-pipe controls, chemical additions, or heat treatment used to prevent releases of viable cells in aerosols and off-gas.*
§ 725.234(d)(1)	Containment and inactivation controls in place must take into account

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	factors relevant to the organism's ability to survive in the environment and potential routes of release **via solids.** *Describe the procedures used to achieve, for example, any log reduction in solid wastes, such as heat sterilization or chemical treatment. Include test results demonstrating the reduction. All solid release points should be described.*
§ 725.234(d)(1)	Containment and inactivation controls in place must take into account factors relevant to the organism's ability to survive in the environment and potential routes of release **via water**. *Describe the procedures used to achieve, for example, a log reduction in liquid wastes, such as heat sterilization or chemical treatment. Include test results demonstrating the reduction. All wastewater release points should be described. If process fluids will be recycled, describe the method or system used to return wastewater to the initial vessel. Describe the procedure that will be used to reduce microbial populations in the culture remaining from samples and inocula. For example, describe any procedures prior to disposal.*
§ 725.234(d)(1)	Containment and inactivation controls in place must take into account factors relevant to the organism's ability to survive in the environment and potential routes of release **via equipment**. *Consider all equipment within the structure and whether there are any release points to the environment. Describe how equipment and work surfaces are cleaned and decontaminated.*
§ 725.234(d)(1)	Document the secondary/contingent containment and inactivation controls in place that take into account factors relevant to the organism's ability to survive in the environment and potential routes of release via air, water, waste and equipment. *Describe the procedures that will be used to clean up spills and other releases, and any treatment before disposal. Develop an emergency response plan.*
§ 725.234(d)(1)	Describe the containment procedure for any transfer between facilities. *Describe the procedures and systems that will be used to prevent dissemination of the new microorganism through other routes. Identify, as*

Regulation (40 C.F.R.)	Description
	appropriate, contractors for these procedures, and how the transport equipment is treated.
§ 725.234(d)(1)	Describe hygiene procedures designed to minimize the potential for release of the modified microorganism in or on people, including maintenance and custodial personnel, and in or on insects and rodents.
§ 725.235(b)	Notification to employees and others, *e.g.*, conspicuous labeling system, conspicuous placement of notices in areas where exposure may occur, and written notification to each person potentially exposed. *Describe the training and written guidance provided to employees on safety and industrial hygiene. Written training materials may include safety manuals, standard operating procedures (SOPs), and safety data sheets (SDSs).*
§§ 725.234(d)(2) and (3) and 725.235(c)(2)	Document for company records the selection, and the certification approving the selection, of containment and/or inactivation controls.
§ 725.234(d)(2)	Document the approval and certification of the TQI's selection of containment and/or inactivation controls by another authorized company official.
§ 725.234(d)(3)	Maintain copies or citations to information reviewed for purposes of the risk determination.
§ 725.235(b)	For employee notification, maintain copies of the notifications provided to employees and documentation of the method of notification.
§ 725.235(b)	For others to whom the organism is distributed outside of the facility, maintain records of the names and addresses of persons to whom the organism is distributed, the organism's identity, and the amount (for example, colony-forming units) distributed.
§ 725.235(c)	If applicable, document that compliance with the NIH guidelines has been achieved.

TEMPLATE: Appointment of Technically Qualified Individual for purposes of TSCA Compliance with 40 C.F.R. Part 725

Pursuant to 40 C.F.R. § 725.234, [**Company Name**] will be undertaking research and development (R&D) activities conducted at [**Insert Address**]. As such, a technically qualified individual (TQI) must oversee the use of the microorganism at that facility.

> Pursuant to 40 C.F.R. § 725.3, the term TQI means a person or persons:
> (1) Who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the microorganism which is used under his or her supervision;
> (2) Who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize such risks; and
> (3) Who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting a research and development activity.

[**Name and Title of Individual**] is hereby appointed as TQI.

Responsibilities associated with this appointment include but are not limited to: (1) selection of appropriate equipment and procedures; (2) appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize health and environmental risks, and (2) safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting R&D activity.

All information provided in this certification is complete and truthful as of the date of signature.

Name and Title of Authorized Official: [**Insert Name and Title]**

Signature of Authorized Official:

Date:

TEMPLATE: Research and Development Exemption Containment Certification

This certification applies to the Research and Development Activities occurring at **[insert name and address of facility]** which are required to comply with the U.S. Toxic Substances Control Act (TSCA) and the Environmental Protection Agency's (EPA's) implementing regulations at 40 C.F.R. §§ 725.234 and 725.235.

Containment and inactivation procedures have been selected by the following individual appointed as the Technically Qualified Individual ("TQI") for the facility named herein, **[insert name and title of individual selected as the TQI]**. Protocols and documentation concerning the containment and inactivation controls are on file. Inquiries should be made to:

[Insert name and contact information of TQI]

Pursuant to 40 C.F.R. § 725.234(d)(2), the undersigned authorized official certifies to the best of his/her knowledge and belief:

[insert name of facility] intends to manufacture, import, or process microorganisms subject to TSCA in small quantities for research and development. Prior to the commencement of this activity, the containment and inactivation procedures selected by the TQI for meeting the conditions of the TSCA Research and Development Activities Exemption for activities within a contained structure are hereby approved.

All information provided in this certification is complete and truthful as of the date of signature.

Name and Title of Authorized Official:

Signature of Authorized Official:

Date:

TEMPLATE: Customer Notification - TSCA Research and Development Exemption

[Company Letterhead]

Dear Customer:

[Trade Name] is being produced by **[Company Name]** and provided to you under the "contained research and development" (contained R&D) exemption to the microbial commercial activity notification (MCAN) requirements of section 5 of the Toxic Substances Control Act (TSCA). Accordingly, **this product may be used only for research and development purposes at your facility under the conditions stated at 40 C.F.R. §§ 725.234 and 725.235.**

We have reviewed and evaluated available information to determine whether there is reason to believe that there is any risk which may be associated with its use. Based on our review, the potential hazards are included on the product information sheet **[or safety data sheet]** for this material as provided to you.

We understand that this substance will be used only under the supervision of a technically qualified individual. By technically qualified, we mean a person who –

- because of education, training, or experience, or a combination of these factors, can understand the health and environmental risks associated with the microorganism that is used under his or her supervision;
- is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or microbiological research to minimize such risks; and
- is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the microorganism as may be appropriate or required within the scope of conducting a research and development activity.

Please let us know if you have any questions.

Sincerely,