CITY COUNCIL
STAFF REPORT

MEETING DATE: **March 27, 2023**

ITEM TITLE: **Consideration of Introducing an Ordinance Amending the City of San Carlos Municipal Code Title 18 to Regulate Laboratories with Biosafety Levels (BSL).**

RECOMMENDATION:

The Planning and Transportation Commission recommends (Resolution # PTC2023-05) that the City Council adopt an Ordinance amending San Carlos Municipal Code Title 18 to prohibit activities requiring Biosafety Level (BSL) 4 containment and to allow for activities requiring BSL-3 containment with a conditional use permit, as specified in the Ordinance as amended by the Commission.

City staff recommends that the City Council adopt an Ordinance amending San Carlos Municipal Code Title 18 to prohibit activities with Biosafety Levels (BSL) 3 and 4.

FISCAL IMPLICATIONS:

There are no direct fiscal implications to the City's general fund associated with the City Council adopting an Ordinance to regulate activities with an assigned Biosafety Level.

The Planning and Transportation Commission's recommended Ordinance, which would allow BSL-3 activities with a conditional sse permit (CUP) and prohibit BSL-4 activities, requires the applicant to submit an annual report as a part of monitoring compliance with the CUP. The City would issue a request for qualifications (RFQ) to solicit proposals from potential on-call consultants to conduct a peer review of the submitted annual report. The on-call consultant would also inspect the facility to ensure that the facility is accurately represented in the annual report and complies with the required regulations. The applicant would pay fees for processing the CUP and submit a deposit to pay for the City's on-call consultant / peer reviewer; therefore, there are no fiscal implications to the City's general fund for the review, processing, annual inspections, and reporting associated with the CUPs.

SUMMARY:

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) use BSLs to identify the special building design, safety equipment, and specific practices needed in a laboratory setting to protect workers, the environment, and the public. The four biosafety levels are BSL-1, BSL-2, BSL-3, and BSL-4, with BSL-4 requiring the highest (maximum) level of containment.

Currently, the City of San Carlos has no regulations specific to laboratories with biosafety levels. However, since 2015, the City of San Carlos has experienced an unprecedented amount of private sector investment and development, including business and employment growth in the life sciences and biotechnology sectors, especially in east San Carlos. Many life sciences and biotechnology companies require laboratories with biosafety levels for their research and work. Adopting regulations for laboratories with biosafety levels will provide protections and transparency for employees, nearby residents, and the overall San Carlos community.

Land use and zoning regulations are one way to regulate laboratories with biosafety levels. Biosafety is also addressed through:

- Numerous requirements from county, state, and federal agencies which regulate laboratories with biosafety levels
- Requirements around specific building design and safety equipment
- Requirements for security protocols and operational requirements
- California Building and Fire Codes regulations for flood proofing and elevation, and for seismic activities

Examples of county, state, and federal agencies which regulate laboratories with biosafety levels are listed in Table 2 below.

As of the writing of this staff report, no other cities within San Mateo County or the broader Bay Area have an outright ban on BSL-3 laboratories. Within San Mateo County, the cities of Brisbane, Burlingame, and Millbrae have adopted land use policies and/or regulations that regulate biosafety levels as summarized here and detailed in Table 3 below.

- City of Brisbane requires a conditional use permit from the City Council where research and development uses include BSL-4 activities.
- City of Burlingame prohibits BSL-3 and BSL-4 activities within the San Francisco International Airport (SFO) Safety Compatibility Zones.[1]
- City of Millbrae, within the San Francisco International Airport (SFO) Safety Compatibility Zones, requires a conditional use permit for BSL-1 and BSL-2, and prohibits BSL-3 and BSL-4 activities.

Before the Council are two ordinances for consideration:

- **Ordinance 1** allows BSL-3 activities with an approved conditional use permit and prohibits BSL-4 activities, as recommended by the Planning and Transportation Commission.

- **Ordinance 2** prohibits BSL-3 and BSL-4 activities.

Both ordinances allow for BSL-1 and BSL-2 activities with no additional regulations.

If Ordinance 1 is adopted, a conditional use permit would be required for both publicly and privately funded BSL-3 activities. Through the requirements of the CUP, both privately- and publicly-funded laboratories would be required to submit the same information to the City of San

[1] As noted below in this staff report, the *Comprehensive Airport Land Use Compatibility Plan for the Environs of San Carlos Airport* prohibits BSL-3 and BSL-4 activities within Zone 3.

Carlos as a part of the initial application, inspection, and subsequent annual reports. Through a RFQ process, the City would hire an on-call consultant with expertise in this area to review the initial CUP application, conduct inspections, and review the annual reports.

Adoption of either ordinance would result in the City of San Carlos being more restrictive in the regulation of biosafety levels (outside of airport safety zones) than any other city in San Mateo County and the broader Bay Area.

BACKGROUND:

On a policy level, in response to life science development interest, the City created the East Side Innovation District Vision Plan in 2021 to plan for changes in southeast San Carlos (the area defined by Holly Street, Brittan Avenue, Old County Road, and Highway 101). The City has also launched the Northeast Area Specific Plan process to plan for changes for the area north of Holly Street, to the San Carlos city limits at Belmont Creek, and between Highway 101 and Old County Road. The Northeast Area Specific Plan is anticipated for adoption in the fall of 2024.

During the October 25, 2021 City Council meeting, the City Council considered and adopted a Resolution to approve the *East Side Innovation District Vision Plan*. During public comments, a representative from the Greater East San Carlos (GESC) Neighborhood Association requested that the City Council consider regulating the biosafety levels (BSL) allowed within the city. Similar requests have been made by community members since that time.

During the recent *Focused General Plan Update* process, the City added the following new action to the Environmental Safety and Public Services Element:

> *Action ESPS-5.6*: *Prepare regulations that address biosafety levels (BSL) for new life science, biotechnology, or other scientific developments to ensure a healthy and safe San Carlos community.*

This item is in response to the new guidance in the General Plan and community requests.

Planning and Transportation Commission Recommendation

At the February 6, 2023, Planning and Transportation Commission meeting, City staff and consultants presented an item titled: *Consider a Resolution Recommending the City Council Adopt an Ordinance Amendment to the City of San Carlos Municipal Code Section 18 to Regulate Laboratories with Biosafety Levels (BSL)*. The staff report and attachments are available on the City's website at the following link – see Item 6a: https://cityofsancarlos.primegov.com/Portal/Meeting?meetingTemplateId=1407.(See Attachment 3 – Minutes from the February 6, 2023 Planning and Transportation Commission meeting.)

During the meeting, the Planning and Transportation Commission conducted the public hearing, voted to continue the item, and requested staff return to the Commission on March 6, 2023 with additional information about BSL-3 activities and information about precautions for security, exposure, and seismic and flooding events. (See Attachment 5 – Responses to Questions from the Planning and Transportation Commission and Public). The Commission also requested that staff prepare a Zoning Ordinance Amendment option that allows BSL-3 activities with a conditional use perrmit and prohibits BSL-4 activities.

At the March 6, 2023, Planning and Transportation Commission meeting, City staff and consultants presented an item titled: *Consideration of a Resolution Recommending the City Council Adopt an Ordinance Amending San Carlos Municipal Code Title 18 to Regulate Laboratories with Biosafety Levels (BSL)*. The staff report and attachments are available on the City's website at the following link – see Item 8b: https://cityofsancarlos.primegov.com/Portal/Meeting?meetingTemplateId=1581.(See Attachment 4 – Minutes from the March 6, 2023 Planning and Transportation Commission meeting.)

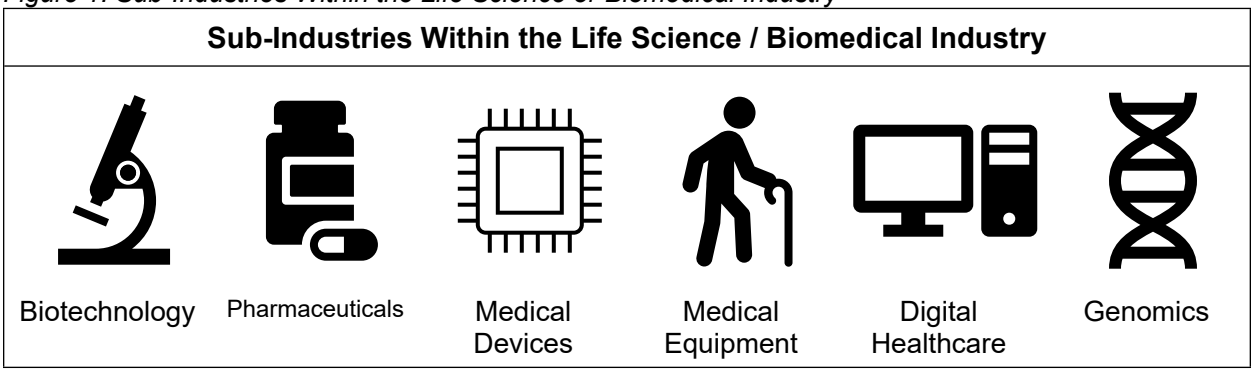
On March 6, 2023, the Planning and Transportation Commission approved Resolution # PTC2023-05, recommending that the City Council adopt an Ordinance amending San Carlos Municipal Code Title 18 to prohibit activities requiring Biosafety Level (BSL) 4 containment and to allow for activities requiring BSL-3 containment with a conditional use permit as specified in the Ordinance as amended by the Commission. (See Attachment 6 – Planning and Transportation Commission Recommendation). The Planning and Transportation Commission's amendment was to add a requirement for an inspection of the BSL-3 laboratory which would occur after the initial CUP approval (before occupancy of the laboratory), on an annual basis as a part of the annual report review, and upon decommissioning or closing of the laboratory. This change is reflected in Ordinance 1. (See Attachment 1 – Ordinance Allowing BSL-3 Activities with a Conditional Use Permit and Prohibiting BSL-4 Activities).

ANALYSIS:

Life Science and Biomedical Industry

The life science and biomedical industry focuses on the research and production of medical and healthcare products. This industry is comprised of many sub-industries. At a high-level, these sub-industries include: biotechnology, pharmaceuticals, medical devices, medical equipment, digital healthcare, and genomics, as illustrated in Figure 1. Each sub-industry has different characteristics, which can include regulations, space requirements, transportation needs, funding, and number of employees and associated formal educational levels, and others.

Figure 1. Sub-Industries Within the Life Science or Biomedical Industry



Many of the life science companies that are interested in locating in San Carlos are biotechnology companies. The characteristics that differentiate biotechnology companies from other biomedical companies are listed below:

- Smaller companies with fewer employees (than, for example, a pharmaceutical company).
- "Slower" or "more patient" funding and often funded by governmental grants.

- Focused on research and development, and therefore "early" in life cycle of a medical product or device.
- Often need laboratories to conduct their research.
- Need stable office space to conduct their research; biotechnology companies are not as nimble or easy to move as, for example, a digital healthcare company.
- Need reliable utility services because the research and experiments are ongoing and often run 24/7.

Based on the types of research that is being conducted, biotechnology laboratories have assigned biosafety levels, which is discussed below.

Biosafety Levels (BSL)

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) use Biosafety Levels (BSL) to classify microbiological and biomedical laboratories. The purpose of the BSL classification is to protect workers, the environment, and the public and regulate how hazardous materials are disposed and transported.

The four biosafety levels are BSL-1, BSL-2, BSL-3, and BSL-4, with BSL-4 requiring the highest (maximum) level of containment. The levels are defined in *Biosafety in Microbiological and Biomedical Laboratories*[2] (the BMBL) and are summarized in Table 1. Each level has specific requirements regarding building design, safety equipment, and specific practices required in each laboratory setting.

BSL-1 and BSL-2 labs are the most common types of labs in the Bay Area. BSL-3 labs are much less common in the Bay Area, and none are located in San Carlos.[3] BSL-4 laboratories are highly specialized facilities having the most stringent safety and security requirements; there are currently no operational BSL-4 labs in California.[4]

Table 1. Biosafety Level Descriptions[5]

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
BSL-1	These agents are not generally associated with disease in healthy people.	• Good micro-biological practice • Hand washing • No eating, drinking, or gum	• Pipetting devices: Mouth pipetting is prohibited	• No specific facility requirements

[2] Centers for Disease Control and Prevention, National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*. *6th Edition*. U.S. Department of Health and Human Services. Revised June 2020. https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf

[3] According to *USA Today* as of 2014, seven (7) BSL-3 laboratories are located in the Bay Area. https://www.usatoday.com/pages/interactives/biolabs/

[4] https://www.niaid.nih.gov/research/biosafety-labs-needed

[5] *Source: National Institute of Allergy and Infectious Diseases.* https://www.niaid.nih.gov/research/biosafety-labs-needed

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
		chewing in the laboratory		
BSL-2	These agents are associated with human disease.	BSL-1 practices, plus: • Limited lab access • Most work may be performed on a bench top • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	BSL-1 requirements, plus: • Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices • Lab coats, gloves, face protection, as needed	• Open bench-top • Sink for hand washing is required • Autoclave available
BSL-3*	These agents: • Are associated with human disease and cause illness by spreading through the air (aerosol) • Cause diseases that may have serious or lethal consequences	BSL-2 practices, plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering	• Class I or II Biological Safety Cabinets (BSCs) or other physical containment devices • Protective lab clothing, gloves, respiratory protection as needed	BSL-2 requirements, plus: • Physical separation from access corridors • Self-closing, double-door access • Exhaust air is not recirculated • Negative airflow into laboratory • Design includes back up/redundant systems
BSL-4	These agents: • Are associated with human disease and cause illness by spreading through the air (aerosol) or have an unknown	BSL-3 practices, plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	• Class II procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive-	BSL-3 requirements, plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and

Biosafety Level	Agents	Practices	Safety Equipment	Facilities
	cause of transmission • Cause diseases that are usually life threatening		pressure personnel suit	decontamination systems • Design includes back-up/redundant systems • Other requirements outlined in *Biosafety in Microbiological and Biomedical Laboratories*[1]

*Typically, BSL-3 labs are assembled for a specific research endeavor and are then decommissioned once the research is completed. It can be extremely difficult to retrofit existing physical spaces to build BSL-3 laboratories. Requirements such as negative airflow and other facility requirements make it difficult to retrofit a building if the mechanical systems were not initially designed to accommodate this use.

Current City of San Carlos Policies

Currently, the City of San Carlos does not have any adopted regulations specific to biosafety levels. The adopted *San Carlos 2030 General Plan*[6] does include the following policies which address biosafety levels and hazardous materials:

- Action ESPS-5.6 (Environmental Safety and Public Services Element): Prepare regulations that address biosafety levels (BSL) for new life science, biotechnology, or other scientific developments to ensure a healthy and safe San Carlos community.

- Policy CSS-4.1 (Community Safety and Services Element): Prohibit uses involving the manufacturing of hazardous materials throughout the city. Hazardous materials are defined in Chapter 6.95, Section 25501 0-1 of the [California] Health and Safety Code. This policy applies only to the direct manufacture of hazardous substances. It does not apply to the storage or use of such materials in conjunction with permitted industrial uses.

San Carlos Airport Safety Zone Policies

The City/County Association of Governments of San Mateo County (C/CAG) has adopted the *Comprehensive Airport Land Use Compatibility Plan for the Environs of San Carlos Airport*[7] (ALUCP) which establishes Airport Safety Zones, numbered 1-6 based on location. The San Carlos Airport Safety Zones are primarily located east of Highway 101 between Cormorant Drive on the north, and Bing Street on the south. Airport Safety Zone 3 and Zone 6 are the two zones that are located west of Highway 101. (See Attachment 7 – San Carlos Airport Safety Zones Map.)

[6] http://www.cityofsancarlos.org/Home/ShowDocument?id=1105
[7] https://ccag.ca.gov/wp-content/uploads/2015/11/SQL_FinalALUCP_Oct15_read.pdf

The ALUCP includes policies that govern the location of biosafety labs in the Airport Safety Zones. Policy 9.b limits where a biosafety lab can be located and states:

> *"Biosafety Level 1 does not involve hazardous materials and is not subject to the same restrictions as Biosafety Levels 2, 3, and 4. Biosafety Level 2 facilities are not permitted in Safety Zones 1, 2, and 5. Biosafety Level 3 and 4 facilities are not permitted in Safety Zones 1 through 5."*

Thus, in the Airport Safety Zone 3, facilities with Biosafety Levels 3 and 4 are not permitted; facilities with Biosafety Levels 1 and 2 are permitted. The ALUCP does not regulate Biosafety Levels in Zone 6.

Airport Safety Zone 3:

- Extends into a portion of the Palo Alto Medical Facility located at 301 Industrial Road. Zoned: Planned Development (PD-21).
- Partially covers the southwest corner of Highway 101 and Brittan Avenue. Zoned: General Community/Industrial (GCI); "Research and Development" is a permitted use in GCI. Currently developed with large format retail uses.

County, State, and Federal Regulatory Agencies

Many county, state, and federal agencies provide oversight over laboratories with biosafety levels. The specific agencies, and permits required, vary depending on the type of laboratory; however, Table 2 provides a sample of the agencies that regulate laboratories with biosafety levels. These agencies have requirements around practices within the labs, safety equipment, building design, waste disposal, transportation of waste, and other regulations.

Even in the absence of local regulations, laboratories with biosafety levels are highly regulated with stringent oversight.

Table 2. Regulatory Agencies

Entity	Regulatory Agency
Within San Mateo County	• San Mateo County Environmental Health Services Department which serves as the local "CUPA" (Certified Unified Program Agency) that oversees the Unified Hazardous Waste and Hazardous Materials Management Regulatory Program[8] • City/County Association of Governments of San Mateo County – San Carlos Airport Safety Zones • Local Fire Districts • Local Sanitary Districts
State of California	• Division of Occupational Safety and Health (OSHA) • Department of Industrial Relations • Environmental Protection Agency
Federal	• Centers for Disease Control and Prevention • National Institutes of Health • Department of Health and Human Services • Occupational Safety and Health Services • USDA Animal and Plant Health Inspection Service • Department of Commerce

[8] https://www.smchealth.org/hazardous-materials-cupa

Entity	Regulatory Agency
	• Department of Transportation

Biosafety Level Regulations in San Mateo County Jurisdictions

As of the writing of this staff report, no other cities within San Mateo County or the broader Bay Area prohibit BSL-3 laboratories. However, the cities of Brisbane, Burlingame, and Millbrae have adopted land use policies and/or regulations that regulate biosafety levels (see Table 3).[9] (See Attachment 8 – Code Language for Biosafety Regulations in San Mateo County Jurisdictions and Bay Area Jurisdictions.)

The cities of Menlo Park, Redwood City, San Mateo, and South San Francisco defer regulation to outside agencies, such as San Mateo County, local fire districts, local sanitary districts, and OSHA (see Table 4).

Table 3. San Mateo County Jurisdictions with Adopted Policies

Jurisdiction	Overview of Adopted Policies
Brisbane	• Conditional use permit required from the City Council where Research and Development uses include BSL-4. • Adopted performance standards require any Research and Development use incorporating biological agents to meet all the design standards, as defined by the respective Biosafety Levels, as required by the Center for Disease Control and Prevention (CDC) Office of Health and Safety document *Biosafety in Microbiological and Biomedical Laboratories*.
Burlingame	*Citywide* • Specific regulations applicable to various zoning districts and special designated areas, including Research and Development uses in commercial/industrial zones and mixed-use zones. *Within the San Francisco International Airport (SFO) Safety Compatibility Zones*[10] • Within SFO Safety Compatibility Zone 3, BSL-3 and BSL-4 facilities are not allowed. • Within SFO Safety Compatibility Zone 3, a Conditional Use Permit is required for Research and Development offices and laboratories if the use includes hazardous materials. • Within SFO Safety Compatibility Zone 2, no Research and Development laboratories are allowed if the use includes hazardous materials.

[9] In preparation of this staff report, staff also reviewed the policies for the cities of Belmont, Colma, Daly City, East Palo Alto, Emeryville, Foster City, Half Moon Bay, Pacifica, and San Bruno. Currently, these cities do not have any confirmed policies that regulate biosafety levels.

[10] The *Comprehensive Airport Land Use Compatibility Plan for the Environs of San Francisco International Airport* establishes Safety Compatibility Zones around the SFO Airport. The ALCUP determines which uses are incompatible and should be avoided in each zone. https://ccag.ca.gov/wp-content/uploads/2014/10/Consolidated_CCAG_ALUCP_November-20121.pdf

Jurisdiction	Overview of Adopted Policies
Millbrae	• Per adopted policies in the *Millbrae Station Area Plan*, facilities with BSL-1 and BSL-2 are allowed in SFO Safety Compatibility Zone 2, subject to a Conditional Use Permit.

Table 4. San Mateo County Jurisdictions with Reference to Review

Jurisdiction	Overview
Menlo Park	• Regulates the use of hazardous materials – Applications for uses with hazardous materials are routed to the Menlo Park Fire Protection District, San Mateo County Environmental Health Services Department, and West Bay Sanitary District for review and confirmation that the use would comply with relevant standards for each agency.
Redwood City	• Defers to hazardous materials regulations from the San Mateo County Environmental Health Services Department and the State of California.
San Mateo	• Defers to hazardous materials regulations from the San Mateo County Environmental Health Services Department and the State of California.
South San Francisco	• Defers to hazardous materials regulations from the San Mateo County Environmental Health Services Department and the State of California.

Analysis of Biosafety Level Regulations in Bay Area Jurisdictions

The cities of Fremont, Oakland, Palo Alto, and San Francisco have addressed biosafety levels in their zoning regulations, primarily through use definitions for laboratories, life science, research and development, and similar terms (see Table 5). (See Attachment 8 – Code Language for Biosafety Regulations in San Mateo County Jurisdictions and Bay Area Jurisdictions.)

The following are the key takeaways:

- In these cities, there is a great degree of variation regarding where BSL laboratories may be located (i.e., in which zoning districts) and the associated permitting process.
- In general, BSL-1 and BSL-2 do not require additional performance standards or regulations.
- The regulation of BSL-3 facilities depends on the nature of the zoning district.
- Example: In the City of San Francisco's mixed-use zones, there are no additional restrictions for BSL-3 than for BSL-1 or BSL-2.
- Example: The City of Fremont has incorporated definitions for BSL-1 through BSL-4 into its zoning regulations, and the use tables specifically reference the allowed biosafety levels in specific districts to avoid any ambiguity.

Table 5. Biosafety Level Regulations in Bay Area Jurisdictions[11]

BSL Level	Cities			
	Fremont	**Oakland**	**Palo Alto**	**San Francisco**

[11] Image sources: "Check" by Nasik Lababan from Noun Project. "No" by P.J. Onori from Noun Project.

BSL Level	Cities			
BSL-1	✓ Allowed in certain districts. Sometimes requires a Zoning Administrator Permit.	✓ Allowed in certain zoning districts.	✓ Allowed in areas zoned for Research and Development uses.	✓ Allowed in areas zoned for Laboratory uses and Life Science uses.
BSL-2	✓ Allowed in certain districts. Sometimes requires a Zoning Administrator Permit.	✓ Allowed in certain zoning districts.	✓ Allowed in areas zoned for Research and Development uses.	✓ Allowed in areas zoned for Laboratory uses and Life Science uses.
BSL-3	✓ Allowed in certain districts. Requires a Zoning Administrator Permit.	✓ Allowed in certain zoning districts.	✓ Allowed in areas zoned for Research and Development uses.	✓ Allowed in areas zoned for Laboratory uses and Life Science uses.
BSL-4	⊘ Not allowed.	✓ Allowed in areas zoned for Heavy/High Impact Industrial subject to a Conditional Use Permit.	⊘ Not allowed.	⊘ Not allowed.

Marketplace Feedback

City staff has received feedback from life science and biotechnology developers that allowing the construction of BSL-3 laboratories provides increased flexibility for research and project leaseability. They have shared that prohibiting BSL-3 laboratories may put San Carlos in a competitive disadvantage in the marketplace, especially since no other cities in San Mateo County or the overall Bay Area prohibit BSL-3 activities.

Conditional Use Permits

Conditional Use Permits (CUP) apply to uses that are generally consistent with the purposes of the underlying zoning district where they are proposed, but require special consideration to ensure that they can be designed, located, and operated in a manner that will not interfere with the use or enjoyment of surrounding properties. Conditional Use Permits are site-specific, and the CUP application review process allows for the evaluation of a proposed use at a specific site.

The Planning and Transportation Commission has the authority to approve, conditionally approve, or deny applications for conditional use permits. The proposed use must meet all the required findings for the Planning and Transportation Commission to approve the CUP. The required findings include a list of findings that apply to all CUPs (per Section 18.30.060. Required findings[12]). In some instances, use specific findings also apply, such as those included in Ordinance 1. Commission approval of CUPs are discretionary (i.e., approval is not "by-right"), and applications are reviewed on a case-by-case basis.

Prior to issuance of the permit, the CUP process allows for public input and consideration by the Planning and Transportation Commission. CUPs are revocable, if the applicant fails to comply with the conditions set forth in the permit (per Section 18.27.140: Revocation of permits of the San Carlos Municipal Code[13]).

Ordinances for Consideration

Two Ordinances are presented for the Council's consideration. These are titled "Ordinance 1" and "Ordinance 2."

Ordinance 1 allows BSL-3 activities with an approved conditional use permit and prohibits BSL-4 activities. Ordinance 1 was developed at the request of the Planning and Transportation Commission.

Ordinance 2 prohibits BSL-3 and BSL-4 activities.

These Ordinances are based on research regarding best practices around regulating laboratories, how other jurisdictions regulate laboratories with biosafety levels, and an understanding of how external agencies regulate and monitor laboratories with biosafety levels.

Both Ordinances contain the following:

- The addition of a zoning definition for "Biological Agent" and "Biosafety Level."

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[12] San Carlos Municipal Code, Section 18.30.060: Required findings.
https://www.codepublishing.com/CA/SanCarlos/#!/SanCarlos18/SanCarlos1830.html#18.30.060
[13] San Carlos Municipal Code, Section 18.27.140: Revocation of permits.
https://www.codepublishing.com/CA/SanCarlos/#!/SanCarlos18/SanCarlos1827.html#18.27.140

- Modifies the commercial and industrial land use regulation tables to expressly permit BSL-1 and BSL-2 activities and to expressly prohibit BSL-4 activities.

Ordinance 1 (Allows BSL-3 with a Conditional Use Permit):

- Adds new standards specific to BSL-3 activities, which requires a conditional use permit.
- Requires that research and development uses with BSL-3 activities be accessory to the primary use.
- Adds specific conditional use permit requirements, including the submittal of:
    - A Biosafety Plan, prepared in accordance with California Code of Regulations, Title 8, Division 1, Chapter 4, Subchapter 7, Group 16, Article 109, Section 5199(f)(4); and
    - A Medical Waste Management Plan, prepared in accordance with the requirements of the San Mateo County Medical Waste Program.
- Adds specific conditional use permit findings, which include:
    - 1) The applicant has made adequate provisions to address emergency procedures for uncontrolled releases within the laboratory facility and untreated releases outside the laboratory facility; and
    - 2) The applicant has provided a peer review of the proposed facility, safety equipment and practices by a qualified third-party demonstrating compliance with the guidelines set forth in Biosafety in Microbiological and Biomedical Laboratories (6th Edition or most recent) authored by the CDC and NIH.
- Adds specific conditional use permit operational and performance standards, which include:
    - 1) The activities involving the use of biological agents requiring BSL-3 containment measures shall be located no less than ten (10) feet above the base flood elevation as identified on the current FEMA Flood Insurance Rate Maps;
    - 2) The activities involving the use of biological agents requiring BSL-3 containment measures shall be limited to the on-site tenants of the subject development and shall not, under any circumstance, be used by entities located outside of the subject development;
    - 3) An inspection shall be conducted and a compliance report shall be submitted at the expense of the owner, operator, or tenant prior to initiating operations, and on each anniversary of the effective date of permit approval, and on the closure or discontinuance of the BSL-3 facility. Such reports shall be made by a qualified third party demonstrating continued compliance with the guidelines set forth in Biosafety in Microbiological and Biomedical Laboratories (6th Edition or most recent) authored by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH); and,
    - 4) Failure by the applicant to submit the reports required in 18.23.310.C.3 in a timely manner may result in revocation of the conditional use permit per San Carlos Municipal Code Section 18.27.140: Revocation of Permits.

Ordinance 2 (Prohibits BSL-3):

- Modifies the commercial and industrial land use regulation tables to prohibit BSL-3.

Table 6 provides a comparison of Ordinance 1 and 2.

Table 6. Comparison of Ordinance 1 and 2

BSL Level	Ordinance 1: *Allows BSL-3 with CUP*	Ordinance 2: *Prohibits BSL-3*
BSL-1	✓ Allowed; no permit required.	✓ Allowed; no permit required.
BSL-2	✓ Allowed; no permit required.	✓ Allowed; no permit required.
BSL-3	✓ Allowed upon approval of a Conditional Use Permit	⊘ Not allowed.
BSL-4	⊘ Not allowed.	⊘ Not allowed.

As stated in the Summary, adoption of either ordinance would result in the City of San Carlos being more restrictive in the regulation of biosafety levels (outside of airport safety zones) than any other city in San Mateo County and the broader Bay Area.

Monitoring Compliance with a Conditional Use Permit (under Ordinance 1)

If the City requires a conditional use permit for BSL-3 activities, monitoring compliance with the CUP will be an important aspect of this program. This Ordinance would include a requirement that an annual report be submitted to the City demonstrating continued compliance with the guidelines set forth in the *Biosafety in Microbiological and Biomedical Laboratories* authored by the Centers for Disease Control and Prevention and the National Institutes of Health:

1. **The applicant would be required to submit an Annual Report to the City for review and evaluation.**

   The Annual Report would document all regulatory processes with which the facility must comply and demonstrate compliance. The Annual Report must be prepared at the expense of the owner, operators, or tenant by an independent, third-party expert.

2. **A proposed on-call consultant (retained by the City) would peer review the Annual Report and conduct an inspection of the facility.**

The City would issue a Request for Qualifications (RFQ) to solicit proposals from potential on-call consultants to conduct a peer review of the submitted Annual Report. The applicant would submit a deposit to pay for the City's on-call consultant / peer reviewer.

The on-call consultant would also conduct an inspection of the facility to ensure that the facility is accurately represented in the Annual Report and complies with the required regulations.

3. **If the Annual Report and laboratory inspection is found to be in compliance**, no action would be needed. The next step would be the submission of another Annual Report and an inspection in one year's time.

4. **If the Annual Report and laboratory inspection is *not* found to be in compliance**, the applicant could risk revocation of the CUP based on lack of performance, per San Carlos Municipal Code, Section 18.27.140: Revocation of permits.[14]

5. **To monitor submission of the Annual Report,** the City's permitting system would provide a reminder prompt to staff that the Annual Report is due.

6. **A report and inspection would also be required to be submitted when the BSL-3 activity has ended, or the laboratory housing the BSL-3 activity is decommissioned.**

PUBLIC NOTICE AND COMMENTS:

Notice of this hearing and the two Ordinances presented for consideration was published in the *Examiner* newspaper on March 16, 2023. (See Attachment 10 – *Public Notice – Proof of Publication*.)

As of writing of the staff report, there were several comments received from the public. (See Attachment 9 – Correspondence from the Public.) These include the public comments received between January 25, 2023 to March 14, 2023.

ENVIRONMENTAL DETERMINATION:

The proposed amendments to the San Carlos Municipal Code are within the scope of the activities and impacts identified in the Focused General Plan Update Final Environmental Impact Report (EIR), and no new environmental effects have been found and no new mitigation is necessary. Therefore, no additional environmental review is required pursuant to Public Resources Code Section 21166 and California Environmental Quality Act (CEQA) Guidelines Section 15162 and 15168.

ALTERNATIVES:

The alternatives available to the City Council include:

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[14] San Carlos Municipal Code, Section 18.27.140: Revocation of permits.
https://www.codepublishing.com/CA/SanCarlos/#!/SanCarlos18/SanCarlos1827.html#18.27.140

1. Introduce an Ordinance to amend the San Carlos Municipal Code Sections 18.06.020 (Commercial Districts Land Use Regulations), 18.07.020 (Industrial Districts Land Use Regulations), and 18.41.020 (Definitions), and add Section 18.23.310 (Standards for Specific Uses and Activities) to allow for BSL-3 activities with a Conditional Use Permit as specified in the Ordinance and to prohibit Biosafety Level (BSL) 4 activities; or

2. Introduce an Ordinance to amend the San Carlos Municipal Code Sections 18.06.020 (Commercial Districts Land Use Regulations), 18.07.020 (Industrial Districts Land Use Regulations), and 18.41.020 (Definitions) to prohibit Biosafety Level (BSL) 3 and 4 activities; or

3. Do not enact an Ordinance to amend Title 18 to regulate Biosafety Level (BSL) activities; or

4. Provide staff with alternative direction.

Respectfully submitted by:

Al Savay, Community & Economic Development Director

Approved for submission by:

Jeff Maltbie, City Manager

ATTACHMENT(S):

1. Ordinance Allowing BSL-3 Activities with a Conditional Use Permit and Prohibiting BSL-4 Activities
2. Ordinance Prohibiting BSL-3 and BSL-4 Activities
3. Minutes from the February 6, 2023 Planning and Transportation Commission Meeting
4. Minutes from the March 6, 2023 Planning and Transportation Commission Meeting
5. Responses to Questions from the Planning and Transportation Commission and Public
6. Planning and Transportation Commission Recommendation
7. San Carlos Airport Safety Zones Map
8. Code Language for Biosafety Regulations in San Mateo dictions and Bay Area Jurisdictions
9. Correspondence from the Public, as of March 22, 2023
10. Public Notice – Proof of Publication