

CITY COUNCIL AGENDA REPORT

Meeting Date: February 16, 2023

From: John Swiecki, Community Development Director

Subject: SP-CRO Sierra Point Commercial District; Zoning Text Amendment 2022-RZ-4; Zoning text amendment to Title 17, Chapter 17.18 of the Brisbane Municipal Code (BMC) to update existing research and development use provisions and performance standards; and finding that this project is exempt from environment review under CEQA Guidelines Section 15183(a).

COMMUNITY GOAL/RESULT

Safe Community - Residents and visitors will experience a sense of safety.

PURPOSE

To update the research and development (R&D) permitted and conditional use provisions contained in the SP-CRO Sierra Point Commercial District zoning, Brisbane Municipal Code Chapter 17.18.

RECOMMENDATION

Decide on the draft ordinance to amend the SP-CRO Sierra Point Commercial District R&D provisions (see Attachment 1).

BACKGROUND

BMC Section 17.02.675 defines research and development as "a use engaged in studying, testing, designing, analyzing and experimenting with potential or existing products, processes or services, including cannabis and cannabis products."

On June 16, 2008, City Council adopted zoning provisions, via Ordinance 528, allowing for R&D uses as either permitted by-right or as conditional uses in the Sierra Point Commercial District. With regards to using live animals, the ordinance provisions permitted by-right, R&D on live insects, rodents, rabbits, fish, and amphibians. R&D involving the use of live dogs, cats or nonhuman primates was prohibited. Use of other live animals that are not named as permitted or prohibited are subject to a conditional use permit. Additionally, a provision was included

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that City Council is named as the approving authority instead of the Planning Commission, as is the case with all other use permits.

In 2022, Bristol-Myers Squibb (BMS) applied for a use permit to conduct R&D using minipigs at 1400 Sierra Point Parkway. That has been the only R&D use permit application filed to date pursuant to the regulations described above. That application was heard by City Council on May 19, 2022, continued for further public hearing and then withdrawn by the applicant on August 26th, before a decision was made. Following the withdrawal of that application, the City Council directed staff to initiate a zoning code amendment to consider updates to the live animals testing provisions. An ad hoc City Council subcommittee (Councilmembers Cunningham and Mackin) met on October 31, 2022 and indicated a desire to consider prohibiting the use of all animals except those expressly permitted under the ordinance, thereby eliminating the category of conditionally permitted animal use. The subcommittee also expressed interest in considering the removal of rabbits from the R&D permitted uses list.

A public hearing was held at the Planning Commission on January 26, 2023 to consider the following draft amendments:

- Elimination of the use permit category of R&D using live animals. Thus, R&D using specifically named live animal groups would be permitted by right, and the use of all other animals would be prohibited.
- Rabbits would be removed from the permitted R&D uses category.
- Permitted R&D uses would be expanded beyond insects to the larger category of invertebrates (i.e. animals without a backbone such as insects, spiders, worms, etc.). Permitted uses would also be expanded from amphibians to also include reptiles.
- Aside from animal testing, use permits for R&D utilizing biological agents exceeding National Institute of Health (NIH) Risk Group 3 would still be required, but the approving authority would be the Planning Commission, instead of City Council, with Council still being the authority on appeal of a Planning Commission decision, as is the process for other use permits.
- An organizational cleanup of the performance standard provisions was also included in the draft ordinance.

The January 26, 2023 Planning Commission report and minutes are attached for reference. The Planning Commission, by a vote of 3-1, recommended that City Council deny the proposed ordinance. The Planning Commission resolution, draft minutes and agenda report are provided in Attachments 3, 4 and 5. Public correspondence to the Commission is provided in Attachment 6.

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DISCUSSION:

A summary of the Planning Commission's discussion of the draft ordinance is provided in the draft minutes, Attachment 4. In summary, the Commissioners voting against the amendment expressed their concern over limiting R&D using live animals as proposed and expressed a desire to allow the scientific community to take the lead regarding the need for animal studies, while the dissenting Commissioner spoke in favor of further limiting animal testing as proposed.

There was also some discussion of FDA Modernization Act 2.0, passed by Congress in December 2022, which removed the requirement to use animal testing in drug development. It allows drug companies the option of using "nonclinical test" instead of tests on animals when making new drug submissions to the U.S. Food and Drug Administration (FDA). This allows for a shift away from mandated animal studies for FDA approval, but does not go so far as to prohibit animal studies. Note that animal care at R&D facilities is the purview of the U.S. Dept of Agriculture (USDA).

The City Council has a few options with this application.

- 1. Vote to deny the zoning text amendment, thereby affirming the Planning Commission's recommendation. This would keep the existing provisions of BMC Chapter 17.18 unchanged. Note that under the current ordinance, there are no special findings provided for R&D use permits, but rather the standard findings contained in BMC Section 17.40.060 apply. That is, "In considering an application, the planning commission shall consider and give due regard to the nature and condition of all adjacent uses and structures, and to general and specific plans for the area in guestion. The planning commission shall determine whether or not the establishment, maintenance or operation of the use applied for will, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, or whether it will be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city. If the planning commission finds that the aforementioned conditions will not result from the particular use applied for, it may grant the use permit." These findings focus on potential impacts to neighbors, but do not specifically address issues of animal use related to R&D work. It does not appear the current findings are well suited to address concerns regarding animal testing.
- 2. Council may reject the Commission's recommendation and adopt the zoning text amendment as proposed. Clean and redlined versions of the draft ordinance are provided in Attachments 1 and 2.

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> 3. Council may adopt an amendment that is different from what has been provided. In this case, depending on Council's direction, staff may need to bring a revised draft ordinance back to Council for consideration. Council may provide direction and refer this matter back to the Planning Commission for further study.

FISCAL IMPACT

None.

MEASURE OF SUCCESS

To provide clear R&D provisions in the BMC.

ATTACHMENTS

- 1. Draft Ordinance Amending SP-CRO R&D Provisions
- 2. Redlined Draft Ordinance
- 3. Planning Commission Resolution 2022-RZ-4
- 4. Draft Planning Commission Meeting Minutes, January 26, 2023
- 5. Planning Commission Agenda Report, January 26, 2023
- 6. Correspondence

<u>John Swiecki</u> John Swiecki, Community Development Director

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Clay Holstine, City Manager

draft

ORDINANCE NO. ____ AN ORDINANCE OF THE CITY OF BRISBANE AMENDING SECTIONS 17.18.020, 17.18.030 AND 17.18.045 AND DELETING SECTION 17.18.035 OF THE BRISBANE MUNICIPAL CODE CONCERNING RESEARCH AND DEVELOPMENT USES IN THE SP-CRO SIERRA POINT COMMERCIAL DISTRICT

The City Council of the City of Brisbane hereby ordains as follows:

SECTION 1: Sections 17.18.020 and 17.18.030 are amended to read as follows:

17.18.020 - Permitted Uses

The following uses shall be allowed in the SP-CRO district:

- A. Offices;
- B. Hotels;
- C. Retail sales and rental;
- D. Restaurants;
- E. Bars;
- F. Financial institutions;
- G. Personal services;
- H. Commercial gyms and health facilities;
- I. Meeting halls;
- J. Marinas;
- K. Research and development, unless the use is classified as a conditional use pursuant to Section 17.18.030.F. Research and development may include the use of live invertebrate animals, such as insects, or any of the following live vertebrate animals: fish, amphibians, reptiles or rodents. Research and development involving the use of other live animals not listed here is prohibited. All research and development uses are subject to the performance standards set forth in <u>Section</u> <u>17.18.045</u>.

17.18.030 – Conditional uses.

The following conditional uses may be allowed in the SP-CRO district, upon the granting of a use permit pursuant to <u>Chapter 17.40</u> of this title:

A. Child care centers when:

- 1. Located more than five hundred (500) feet from the edge of the eastern-most lane of the Bayshore Freeway (U.S. 101);
- 2. Located within an area with a community noise equivalent level (CNEL) of not more than sixty (60) dB as determined by a professionally-prepared acoustical analysis report; or located within an area with a community noise equivalent level (CNEL) of sixty to eighty (60—80) dB and designed with the noise insulation features identified in a professionally-prepared acoustical analysis report so as to comply with Figure 2 in Appendix C of the state of California General Plan Guidelines 2003; and
- 3. Designed and operated so to comply with the noise levels specified in Brisbane Municipal Code <u>Section 8.28.040</u>, as per the recommendations of a professionally-prepared acoustical analysis report.
- B. Medical facilities.
- C. Commercial recreation.
- D. Transit/transportation facilities.
- E. Temporary uses.
- F. Research and development utilizing biological agents exceeding Risk Group 3 or Biosafety Level 3 as defined by the National Institute of Health or the Center for Disease Control.

SECTION 3: Section 17.18.035 is deleted in its entirety.

SECTION 4: Sections 17.18.045 is amended to read as follows:

17.18.045 - Performance standards.

A. All research and development uses shall submit to the planning department a risk analysis performed by a qualified hazardous or biologic materials professional specifying all hazardous or biologic materials to be utilized and methods of safe handling and disposal prior to building permit or business license issuance.

B. Research and development involving the use of live animals, specifically permitted in Section 17.18.020.K, shall be conducted in compliance with the Institute of Laboratory Animals Resources' Guide for the Care and Use of Laboratory Animals, and in compliance with all applicable federal, state and local laws and regulations as most recently amended.

C. Research and development uses involving the use of biological agents shall comply with all design standards set forth in the most current Center for Disease Control (CDC) Office of Health and Safety document "Biosafety in Microbiological and Biomedical Laboratories."

D. Research and Development involving cannabis is subject to the requirements set forth in <u>Chapter 17.33</u>.

E. Lighting shall be designed to avoid excessive glare as viewed from offsite locations, in compliance with the California Green Building Standards Code.

SECTION 11: If any section, subsection, sentence, clause or phrase of this Ordinance is for any reason held by a court of competent jurisdiction to be invalid or unconstitutional, such decision shall not affect the validity of the remaining portions of this Ordinance. The City Council of the City of Brisbane hereby declares that it would have passed this Ordinance and each section, subsection, sentence, clause and phrase thereof, irrespective of the fact that one or more sections, subsections, sentences, clauses or phrases may be held invalid or unconstitutional.

SECTION 12: This Ordinance shall be in full force and effect thirty days after its passage and adoption.

* * *

The above and foregoing Ordinance was regularly introduced and after the waiting time required by law, was thereafter passed and adopted at a regular meeting of the City Council of the City of Brisbane held on the _____ day of _____ 2023, by the following vote:

AYES:

NOES:

ABSENT:

ABSTAIN:

Mayor

ATTEST:

APPROVED AS TO FORM: Michael Ho Moul

City Clerk

Legal Counsel

ATTACHMENT 2 REDLINED DRAFT ORDINANCE

Chapter 17.18 - SP-CRO SIERRA POINT COMMERCIAL DISTRICT

Sections:

17.18.010 - Purposes of chapter.

In addition to the objectives set forth in <u>Section 17.01.030</u>, the SP-CRO Sierra Point Commercial District (hereinafter referred to as the "SP-CRO district") is included in the zoning ordinance to achieve the following purposes:

- A. To establish a zoning district for the Sierra Point subarea that provides for orderly development consistent with the adopted master use permit UP-11-78, the redevelopment plan for Brisbane Community Redevelopment Project Area Number One, and the combined site and architectural design guidelines for Sierra Point.
- B. To encourage a mix of office, commercial and recreational uses to best serve the residents and businesses of Brisbane and the businesses and employees in the Sierra Point subarea.
- C. To ensure that development in the Sierra Point subarea occurs in compliance with the highest development and design standards and meets the goals and objectives set forth in the general plan.

17.18.020 - Permitted uses.

The following uses shall be allowed in the SP-CRO district:

- A. Offices;
- B. Hotels;
- C. Retail sales and rental;
- D. Restaurants;
- E. Bars;
- F. Financial institutions;
- G. Personal services;
- H. Commercial gyms and health facilities;
- I. Meeting halls;
- J. Marinas;
- K. Research and development, including the use of live insects, rodents, rabbits, fish, and amphibians subject to the performance standards set forth in Section 17.18.045. Research and development

involving the use of live dogs (Canis genus) cats (Felis genus), or nonhuman primates is prohibited. Research and development involving the use of other live animals not otherwise permitted or prohibited herein may be permitted upon the granting of a conditional use pursuant to Section 17.18.030 Section 17.18.030. Research and development involving cannabis is additionally subject to the requirements in Chapter 17.33 Chapter 17.33 Research and development, unless the use is classified as a conditional use pursuant to Section 17.18.030.F. Research and development may include the use of live invertebrate animals, such as insects, or any of the following live vertebrate animals: fish, amphibians, reptiles or rodents. Research and development involving the use of other live animals not listed here is prohibited. All research and development uses are subject to the performance standards set forth in <u>Section 17.18.045</u>.

17.18.030 - Conditional uses.

The following conditional uses may be allowed in the SP-CRO district, upon the granting of a use permit pursuant to <u>Chapter 17.40</u> of this title:

- A. Child care centers when:
 - 1. Located more than five hundred (500) feet from the edge of the eastern-most lane of the Bayshore Freeway (U.S. 101);
 - 2. Located within an area with a community noise equivalent level (CNEL) of not more than sixty (60) dB as determined by a professionally-prepared acoustical analysis report; or located within an area with a community noise equivalent level (CNEL) of sixty to eighty (60—80) dB and designed with the noise insulation features identified in a professionally-prepared acoustical analysis report so as to comply with Figure 2 in Appendix C of the state of California General Plan Guidelines 2003; and
 - Designed and operated so to comply with the noise levels specified in Brisbane Municipal Code Section 8.28.040, as per the recommendations of a professionally-prepared acoustical analysis report.
- B. Medical facilities.
- C. Commercial recreation.
- D. Transit/transportation facilities.
- E. Temporary uses.
- F. Research and development utilizing biological agents exceeding Risk Group 3 or Biosafety Level 3 as defined by the National Institute of Health or the Center for Disease Control.

17.18.035 - Conditional uses-Research and development.

The following research and development-related uses may be allowed in the SP-CRO district, upon the granting of a use permit pursuant to Chapter 17.40 of this title, subject to the provision that the city council (instead of the planning commission) shall act as the reviewing and approving authority for all purposes under Chapter 17.40 for any such research and development-related conditional use permit(s):

- A. Any such use where the planning director determines, based solely upon the risk analysis required pursuant to Section 17.18.045 of this chapter and an evaluation by the fire marshal and the building official, that certain conditions of approval as recommended in the risk analysis or by the fire marshal or building official, are necessary to protect the public health, safety and welfare, and that such conditions are not otherwise included in any of the codes, standards or regulations applicable to such use. Notwithstanding the foregoing sentence, a use permit pursuant to Chapter 17.40 shall not be required if:
- The applicant seeking to conduct the research and development signs a written agreement to implement the additional conditions of approval that are recommended in the risk analysis or by the fire marshal or the building official;
- 2. A copy of such written agreement along with a description of the proposed research and development activity and a copy of the risk analysis and the recommendations of the fire marshal and the building official are delivered to the residence of each council member; and
- 3. No request has been communicated to the city clerk by any two (2) council members, within fifteen (15) days after delivery of the items described in subsection (A)(2) of this section, for the matter to be heard by the city council (in which event a use permit granted by the city council shall be required).
- B.—Any use proposing the use of live animals not otherwise approved or prohibited pursuant to Section 17.18.020(K) of this title in the conduct of research.
- C.— Any use utilizing biological agents exceeding Risk Group 3 or Biosafety Level 3 as defined by the National Institute of Health or the Center for Disease Control.

17.18.040 - Development regulations.

Development regulations for the SP-CRO district are as follows:

- A. Lot Area. The minimum area of any lot in the SP-CRO district shall be one acre.
- B. Lot Dimensions. The minimum dimensions of any lot in the SP-CRO district shall be as follows:

Width	Depth
100 feet	No requirement

- C. Setbacks. The minimum required setback for any lot in the SP-CRO district shall be as follows, except as otherwise established in the combined site and architectural guidelines for Sierra Point:
 - 1. Front setback: Twenty-five (25) feet;
 - 2. Side setbacks:
 - a. Interior side yards: Fifteen (15) feet.
 - b. Exterior side yards: Twenty (20) feet.
 - 3. Rear setbacks:
 - a. Interior lots: Twenty (20) feet.

- b. Corner lots: Fifteen (15) feet.
- D. Location of Structures. The location of structures relative to the mean high tide line shall comply with the requirements set forth in the combined site and architectural design guidelines for Sierra Point.
- E. Coverage. The maximum coverage by all structures on any lot shall be forty percent (40%).
- F. Height. The height of structures shall comply with the combined site and architectural design guidelines for Sierra Point.
- G. Landscaping Requirements.
 - 1. A minimum of twenty-five percent (25%) of the total lot area shall be landscaped. Additional landscaping requirements are set forth in the combined site and architectural design guidelines for Sierra Point.
 - 2. Irrigated Landscapes. New and rehabilitated, irrigated landscapes are subject to the provisions of the water conservation in landscaping ordinance (refer to <u>Chapter 15.70</u>) or the latest state provisions, whichever is more effective in conserving water.
- H. Recycling Area Requirements.
 - 1. Adequate, accessible and convenient areas for depositing, collecting and loading recyclable materials in receptacles shall be provided. The area shall be located and fully enclosed so as to adequately protect neighboring uses from adverse impacts such as noise, odor, vectors, wind-blown litter or glare. The area shall be designed to prevent storm water run-on to the area and runoff from the area, and roofs shall be designed to drain away from neighboring properties. A sign clearly identifying all recycling and solid waste collection and loading areas and the materials accepted therein shall be posted adjacent to all points of direct access to the area.
 - 2. This requirement shall apply to all new commercial or institutional buildings, and city facilities (including buildings, structures, marinas, and outdoor recreation areas owned by the city) where solid waste is collected and loaded. This requirement shall also apply to any existing development for which building permit applications are submitted within a twelve-month period collectively adding thirty percent (30%) or more to the existing floor area of the development project. The floor area of a marina shall be defined as the space dedicated to the docking or mooring of marine vessels. For existing developments occupied by multiple tenants, this requirement shall apply to building permit applications submitted by any tenant within a twelve-month period collectively adding thirty percent (30%) or more to the existing floor area of that portion of the development which said tenant leases, and such recycling areas shall be sufficient in capacity, number, and distribution to serve that portion of the development project which said tenant leases.

17.18.045 - Performance standards.

A. All research and development uses shall submit to the planning department a risk analysis performed by a qualified hazardous or biologic materials professional specifying all hazardous or biologic materials to be utilized and methods of safe handling and disposal prior to building permit or business license issuance.

B. Research and development involving the use of live animals, specifically permitted in Section 17.18.020.K, shall be conducted in compliance with the Institute of Laboratory Animals Resources' Guide

for the Care and Use of Laboratory Animals, and in compliance with all applicable federal, state and local laws and regulations as most recently amended and such other conditions as may be imposed by the city.

C. Research and development uses involving the use of biological agents shall comply with all design standards set forth in the most current Center for Disease Control (CDC) Office of Health and Safety document "Biosafety in Microbiological and Biomedical Laboratories."

D. Research and Development involving cannabis is subject to the requirements set forth in Chapter 17.33.

E. Lighting shall be designed to avoid excessive glare as viewed from offsite locations, in compliance with the California Green Building Standards Code.

17.18.050 - Parking.

All uses in the SP-CRO district shall comply with the parking regulations set forth in <u>Chapter 17.34</u> of this title.

17.18.060 - Signs.

All advertising signs in the SP-CRO district shall comply with the sign programs referenced in the combined site and architectural design guidelines for Sierra Point. If the proposed advertising sign is not covered by such sign programs, it shall comply with the sign regulations set forth in <u>Chapter 17.36</u> of this title.

17.18.070 - Design review.

The construction of any principal structure in the SP-CRO district shall be subject to the granting of a design permit in accordance with the provisions of <u>Chapter 17.42</u> of this title and shall comply with any applicable guidelines as set forth in the combined site and architectural design guidelines for Sierra Point.

RESOLUTION 2022-RZ-4

A RESOLUTION OF THE PLANNING COMMISSION OF BRISBANE RECOMMENDING CITY COUNCIL DENIAL OF ZONING TEXT AMENDMENT 2022-RZ-4 AMENDING REGULATIONS WITHIN TITLE 17 OF THE BRISBANE MUNICIPAL CODE CONCERNING RESEARCH AND DEVELOPMENT USES IN THE SP-CRO SIERRA POINT COMMERCIAL DISTRICT

WHEREAS, the City Council adopted Ordinance 528 on June 16, 2008, which provided for research and development (R&D) uses in the SP-CRO Sierra Point Commercial District; and

WHEREAS, City Council directed the Planning Commission to consider updates to the ordinance provisions regarding permitted uses, conditional uses and prohibited uses; and

WHEREAS, the draft ordinance attached as Exhibit A to this resolution proposes amendments to Title 17 (Zoning); and

WHEREAS, on January 26, 2023, the Planning Commission conducted a hearing of the application, publicly noticed in compliance with Brisbane Municipal Code Chapters 1.12 and 17.54, at which time any person interested in the matter was given an opportunity to be heard; and

WHEREAS, the Planning Commission reviewed and considered the staff memorandum relating to said application, and the written and oral evidence presented to the Planning Commission in support of and in opposition to the application; and

WHEREAS, the draft ordinance is statutorily exempt from the provisions of the California Environmental Quality Act (CEQA) per Section 15183(a) of the CEQA Guidelines; and

NOW, THEREFORE, based upon the evidence presented, both written and oral, the Planning Commission of the City of Brisbane hereby RECOMMENDS that the City Council **deny** the attached draft ordinance.

ADOPTED this twenty-sixth day of January, 2023, by the following vote:

AYES: Funke, Gooding, Lau NOES: Sayasane ABSENT: Patel

Roel Funke 1/30/2023

ROEL FUNKE Acting Chairperson

ATTEST:

JOHN SWIECKI, Community Development Director

D. PUBLIC HEARING: SP-CRO Sierra Point Commercial District; Zoning Text Amendment 2022-RZ-4; Zoning text amendment to Title 17, Chapter 17.18 of the Brisbane Municipal Code (BMC) to update existing research and development use provisions and performance standards; and finding that this project is exempt from environment review under CEQA Guidelines Section 15183(a); City of Brisbane, applicant.

Note: This item was continued from the Planning Commission meeting of January 12, 2023. No hearing was held on January 12th.

Senior Planner Johnson gave the staff presentation and answered question on how the animals were determined to be included or precluded from animal testing under the proposed amendment and clarified the history of the research and development use provisions and performance standards in the SP-CRO district.

Acting Chairperson Funke opened the public hearing.

Senior Planner Johnson read a written comment from Bill Van Raam, Brisbane resident, against the proposed ordinance amendment and in favor of allowing animal testing.

Brisbane residents Kim Follien and Michael Barnes also spoke against the proposed amendment and in favor of allowing animal testing.

With no one else wishing to address the Commission, a motion by Commissioner Gooding, seconded by Commissioner Sayasane to close the public hearing was approved 4-0.

The Commission deliberated on the proposed amendment. Commissioner's Gooding, Lau and Funke expressed concerns about limiting animal testing as proposed. The three Commissioners acknowledged recent federal legislation regarding animal testing, FDA Modernization Act 2.0, which removed the requirement to use animal testing in drug development. However, they expressed a desire to allow the scientific community to take the lead regarding the need for future animal studies and indicated that there was insufficient information regarding the viability of alternative models for the various kinds of medical research and that some amount of animal testing is still necessary to advance medicines and medical procedures that are beneficial to humans. Additionally, it was expressed that prohibitions on animal testing would simply push R&D companies to other cities, while Brisbane residents would still benefit from such R&D testing.

Commissioner Sayasane expressed her opinion that the City has the right to reflect its community values in its zoning regulations and supported the further limitation on animal testing in Brisbane.

After deliberation, a motion by Acting Chairperson Funke, seconded by Commissioner Lau, recommending City Council denial of Zoning Text Amendment 2022-RZ-4 via adoption of Resolution 2022-RZ-4 was approved 3-1. Commissioner Sayasane voted against the motion.

Acting Chairperson Funke read the appeals procedure.

ATTACHMENT 5



PLANNING COMMISSION AGENDA REPORT

Meeting Date: 1/26/2023

From: Ken Johnson, Senior Planner

Subject: SP-CRO Sierra Point Commercial District; Zoning Text Amendment 2022-RZ-4; Zoning text amendment to Title 17, Chapter 17.18 of the Brisbane Municipal Code (BMC) to update existing research and development use provisions and performance standards; and finding that this project is exempt from environment review under CEQA Guidelines Section 15183(a); City of Brisbane, applicant.

REQUEST: To update the research and development (R&D) permitted and conditional use provisions in the SP-CRO Sierra Point Commercial District.

RECOMMENDATION: Recommend City Council adoption of Zoning Text Amendment 2022-RZ-4 via adoption of Resolution 2022-RZ-4 (Attachment A).

ENVIRONMENTAL DETERMINATION: The project is exempt from the requirements of the California Environmental Quality Act (CEQA) pursuant to Section 15183(a) in that this proposal falls within a class of projects which are consistent with existing zoning or general plan policies for which an EIR was certified and shall therefore not require further review.

APPLICABLE CODE SECTIONS: Procedures for zoning amendments are provided in BMC Chapter 17.50. The proposed updates for this amendment pertain to R&D uses and are contained in BMC Chapter 17.18, Sections 17.18.020, 17.18.030, 17.18.035 and 17.18.045. Additionally, BMC Section 17.02.675 provides the City's definition of research and development.

BACKGROUND: BMC Section 17.02.675 defines research and development as "a use engaged in studying, testing, designing, analyzing and experimenting with potential or existing products, processes or services, including cannabis and cannabis products."

On June 16, 2008, City Council adopted zoning provisions via Ordinance 528 to allow for R&D uses as either permitted by-right or as conditional uses in the Sierra Point Commercial District. The provisions of that ordinance, with some exceptions, permitted R&D uses by right in the district. With regards to using live animals, the ordinance provisions permit by-right, R&D on live insects, rodents, rabbits, fish, and amphibians. R&D involving the use of live dogs, cats or nonhuman primates was prohibited. Use of other live animals that are not named as permitted or prohibited are subject to a conditional use permit, with a special provision that City Council is named as the approving authority instead of the Planning Commission.

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No special findings were provided for R&D use permits, but the standard findings contained in BMC Section 17.40.060 apply, "In considering an application, the planning commission shall consider and give due regard to the nature and condition of all adjacent uses and structures, and to general and specific plans for the area in question. The planning commission shall determine whether or not the establishment, maintenance or operation of the use applied for will, under the circumstances of the particular case, be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood of such proposed use, or whether it will be injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city. If the planning commission finds that the aforementioned conditions will not result from the particular use applied for, it may grant the use permit." These conditions focus on potential impacts to neighbors, but do not specifically address issues of animal care related to R&D work. Animal care at R&D facilities is the purview of the U.S. Dept of Agriculture (USDA).

In 2022, Bristol-Myers Squibb (BMS) applied for a use permit to conduct R&D using minipigs at 1400 Sierra Point Parkway, the only R&D use permit application filed to date pursuant to the regulations described above. That application was heard by City Council on May 19, 2022, continued for further public hearing and ultimately withdrawn by the applicant before a decision was made. Following that application, City Council directed staff to initiate an update to consider updates to the use provisions for live animals. Additionally, a City Council subcommittee met on October 31, 2022 and indicated a desire to consider removal of R&D conditional uses for animals, but also made a recommendation to consider removal of rabbits from the R&D permitted uses list. The subcommittee also requested that an email with linked articles, originally from Councilmember Cunningham to the City Manager and City Council, be provided to the Commission for reference. That is included as Attachment C.

DISCUSSION: The draft ordinance would amend certain provisions contained in BMC Chapter 17.18 - SP-CRO Sierra Point Commercial District, as outlined below. A redlined version of the proposed amendments is provided as Attachment B.

BMC Section 17.18.020 – Permitted Uses: The amendment would retain the provisions allowing for R&D by-right on insects, rodents, fish and amphibians. However, consistent with the Council subcommittee recommendation, use of rabbits would no longer be permitted. R&D on any other animals that are not specifically identified as permitted would now be prohibited, thus eliminating the conditional use category that presently exists. In addition to the change regarding use of rabbits, reptiles have been added as a permitted R&D use and the use of insects has been broadened to invertebrate animals. Invertebrates are those animals without a backbone and includes insects, spiders, worms, etc. The only vertebrate animals, those with a backbone, on the permitted for R&D list would be fish, amphibians, reptiles and rodents.

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Additionally, as an administrative clarification item, in reviewing this section staff noted that it also refers to cannabis R&D as permitted but is subject to BMC Chapter 17.33. Since that chapter is specific to cannabis performance standards, the cross reference was moved to BMC Section 17.18.045 – Performance Standards. It does not change the allowance of cannabis R&D as permitted in this district, since it's already named as an R&D use in the definition, as noted above.

An important distinction should also be noted, that manufacturing of products is not permitted in this district whether related to cannabis or other medical products. That remains unchanged.

BMC Sections 17.18.030 – Conditional Uses and 17.18.035 – Conditional Uses – Research and Development: BMC Section 17.18.035 - Conditional Uses-Research and Development is proposed to be deleted. There are three types of R&D uses identified in that section: 1) Risk analysis-based referral to the City Council by the Planning Director 2) live animals not otherwise named under permitted or prohibited uses and 3) uses exceeding Risk Group 3 or Biosafety level 3 as defined by the National Institute of Health (NIH) or the Center for Disease Control.

As indicated above, with the proposed amendment, R&D using live animals would no longer be permitted by use permit. They would either be permitted by-right or prohibited, depending on the animal species.

The provision pertaining to R&D utilizing biological agents exceeding Risk Group 3 or Biosafety Level 3 would be moved to Section 17.18.030 - Conditional Uses and such R&D uses would still require a conditional use permit, but as with all other conditional uses, the Planning Commission would be the approving authority instead of City Council. As is the case with all Planning Commission decisions, the Commission's decision on any use permit may be appealed to City Council, as provided in BMC Chapter 17.52 - Appeals.

The provisions for Planning Director referral of certain uses to the Council based on a risk analysis have been removed. The risk analysis would still be required, per BMC Section 17.18.045 - Performance Standards, to provide documentation prior to issuance of a building permit or business license. That documentation would then be used to identify whether the Risk Group 3 or Biosafety Level 3 threshold would be exceeded, at which point a proposed use would automatically be referred to the Planning Commission for a decision on a use permit application. The intent of this proposed change is to provide for greater clarity in the regulations as to what does and does not require a use permit, while still requiring a use permit for higher risk or biosafety level uses. Such uses would still be considered by the Planning Commission relative to the standard use permit findings related to potential impacts to neighbors, as indicated above.

In brief, elimination of Section 17.18.035 and moving certain R&D uses indicated above to Section 17.18.030 would provide for consistent processing requirements for all use permits in this district.

2022-RZ-4 January 26, 2023 Meeting Page 4 of 4

BMC Section 17.18.045 – Performance Standards: The performance standards for this district have been updated, as indicated above. The risk analysis for R&D would be required prior to building permit or business license issuance. The business license reference has been added, since certain incoming R&D businesses may occupy a space that has already been built out to suit their R&D needs. A building permit is not always required, but a business license is. The cross reference to BMC Chapter 17.33 for cannabis businesses has been added to the performance standards, as noted above.

ATTACHMENTS:

- A. Draft Resolution 2022-RZ-4 (including draft ordinance) See the City Council report Attachments 1, 2
- and 3 for the draft ordinance, redlined draft B. Redlined copy of proposed zoning text amendments
- C. Email from Council Subcommittee Member Cunningham, dated 6/2/22 the Planning Commission's resolution.

Ken Johnson

Ken Johnson, Senior Planner

John Swiscki John Swiecki, Community Development Director

6/2/22

Planning Commission Report - Attachment C

To: Holstine, Clay <<u>clayholstine@ci.brisbane.ca.us</u>> Subject: Bristol Myers ~ Minipig Testing Email from Council Subcommittee Member Cunningham

Hi Clay,

I would like all of this information to be distributed to the entire City Council please

Human *In Silico* Drug Trials Demonstrate Higher Accuracy than Animal Models in Predicting Clinical Pro-Arrhythmic Cardiotoxicity

It is understood that the use of Animal Testing has been the benchmark for many years, even as early as 2018

However, advanced computer and in vitro methods of testing as far back as the 1960's has proven more improved drug testing results than animal testing has given us

In Vitro Methods of Testing \sim

Advanced Computer Modeling (aka in silico models) ~

From the European Society of Cardiology

These alternatives to animal testing include sophisticated tests using human cells and tissues (also known as in vitro methods), advanced computermodeling techniques (often referred to as in silico models), and studies with human volunteers.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601077

Computer-based in silico clinical trials (European Society of Cardiology) There are >1900 article representing the advantages of non animal testing

As far back as 2018 (Smithsonian <u>https://www.smithsonianmag.com/innovation/why-we-should-test-heart-drugs-on-virtual-human-instead-animals-180968588/</u>)

Human Volunteers \sim

Virtual Human Testing (since 2018) ~

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5601077/

https://www.frontiersin.org/articles/10.3389/fphys.2017.00668/full

Computer-based in silico clinical trials (Oxford University)

https://www.frontiersin.org/articles/10.3389/fphys.2017.00668/full

Efficacy rates (Oxford University) ~ Department of Computer Science demonstrates that computational models representing human heart cells produce a higher accuracy than animal models in predicting an adverse drug effect. Therefore it is now possible to test a new heart drug in virtual humans

Pigs 75% - 85% efficacy

Virtual Human Computer simulations 89%-96% efficacy

https://mazuri.com/blogs/education-and-nutrition/mini-pigs-what-makes-minipig-mini

A mini pig refers to a class of domesticated pig ranging from 60 pounds to 200 pounds and 14 to 20 inches tall. "Mini" is used as a differentiator between traditional farm or production pigs and smaller pigs bred as companion animals. Mini pigs can be mixed or pure breeds, with common ancestry from Juliana, KuneKune, Pot-bellied and Göttingen mini pigs. Mini pigs reach maturity at five years old and have 20 years life expectancy. Like other pigs, mini pigs are incredibly smart and social animals. They are easy to train and can make great pets or therapy animals.

Karen Cunningham | She/Her City Council Member



City of Brisbane, CA USA City #: (415) 312-2662 | Cell: (415) 860-4698|

Email: <u>kcunningham@brisbaneca.org</u> City Hall hours (Covid Changes ~ please check City Website): M, T, Th: 8-5, W: 8-5, F: 8-1 Stay connected with us via the <u>Blast</u>, <u>GoRequest</u>, <u>Facebook</u>, <u>Twitter</u>, <u>YouTube</u> and <u>Instagram</u>!

ATTACHMENT 6

From: Michael Barnes (1) Conindentity, Com-> Sent: Tuesday, January 24, 2023 1:22 PM To: Padilla, Ingrid <<u>ipadilla@ci.brisbane.ca.us</u>> Subject: Planning Commission Meeting of 1/26/23

Dear Planning Commission,

Please deny the city councils Zoning Text Amendment 2022-RZ-4 provisions prohibiting animal testing and the elimination of conditional use permits.

Animal testing on Sierra Point has proven not to be detrimental to the health, safety, comfort and general welfare of the persons residing or working in the neighborhood, nor has it proven "...injurious or detrimental to property and improvements in the neighborhood or the general welfare of the city." In fact, the opposite is true.

The establishment of animal testing by right on Sierra Point allowed for the long-stalled build-out of that area with Biotech and Pharmaceutical buildings. These new buildings are providing a number of public benefits, including revenue to the city, improvements to the Bay Trail, jobs, elimination of landfill blight, and the development of life-saving medicines for our community and the world.

Sierra Point is now a safer, more comfortable and healthier place to visit. The Biotech and Pharmaceutical buildings themselves improve the properties, the neighborhood, and the general welfare of the city.

The city council application to prohibit animal testing is yet another anti-science Brisbane initiative, like our rejection of environmental remediation. I believe this application is the first step in running the drug companies out of Brisbane, since these companies only started moving to Sierra Point after animal testing was granted by right.

Having worked in the Biotech and Pharmaceutical industry for over 40 years, the last 25 in research, I can tell you that the drug industry has an economic, ethical and scientific interest in replacing animal testing. I have used many in vitro and in silico tools, but the sad fact is that we still cannot accurately predict or anticipate all the effects of novel drugs on an animal, or the effects an animal will have on a novel drug.

Without in vivo research, thousands of Americans would die. Did you know that pig heart valves are transplanted into humans? And that they have a clear advantage over artificial heart valves?

Please continue to allow Brisbane's already limited animal testing at Sierra Point, and reject the proposed in vivo testing prohibition and elimination of conditional uses. Keep the life-saving Biotech and

Pharmaceutical industries in Brisbane.

Michael Barnes Brisbane resident From: Kim Follien <u>fellienkin Conservation</u> Sent: Thursday, January 26, 2023 12:01 AM To: Padilla, Ingrid <<u>ipadilla@ci.brisbane.ca.us</u>> Subject: Regarding the 1/26/2023 Planning Commission Meeting/ Zoning Text Amendment 2022-RZ-4

Hi Ingrid,

Could you please forward this to the Planning Commission:

Dear Planning Commissioners,

I'm here to request that you reject Zoning Text Amendment 2022-RZ-4. The FDA typically requires drugs for human use to be tested on one rodent species and a non-rodent species prior to human clinical trials. One example is the mRNA COVID 19 vaccines made by Pfizer and Moderna, which the city recommended that we all get. They were tested on rodents and non-human primates. Additionally heart drugs typically need to be tested on Pigs, as rodents aren't a good human model. Limiting animal testing in Brisbane to only rodents, amphibians and insects is really limiting animal testing to just rodents, as I know of no human drug development that can use insects or amphibians.

While a recent U.S. law has eliminated the requirement that all drugs in development must undergo testing in animals prior to human clinical trials, the alternate testing methods, such as computer modeling are still quite limited, so won't work for all drugs, nor has any drug been approved yet using these alternate methods. I can tell you that the Pharmaceutical Industry will gladly use these alternative methods if they can because it reduces the time and cost of drug development, compared to animal testing.

Drug Development Scientists are the ones that should be determining what type of testing is best suited to ensure a safe drug for human use, not the Brisbane City Council. There are Brisbane residents that have benefitted and will benefit from drugs tested on animals, other than rodents. I highly doubt most Brisbane residents would refuse a vaccine or life saving drug for themselves or their children if it was tested on a non-rodent species, so this zoning text amendment makes no sense, is NIMBY, and is just providing an illusion that Brisbane rejects animal testing. The Biotechnology companies will just go somewhere else to do their drug development and Brisbane residents will continue to take those life saving drugs and vaccines.

Link to NPR article regarding the new US law no longer requiring animal testing: https://www.npr.org/2023/01/12/1148529799/fda-animal-testing-pharmaceuticals-drug-development

Best Regards, Kim Follien Brisbane Resident, and have been working in the Biotech Industry for the last 36 years

--Kim Follien (she/her)

Genentech, Inc. - A member of the Roche Group Senior Business Systems Analyst Product Analysis & Consultancy Chapter - ERP Business Analysis - Manufacturing&Supply Chain NA/LATAM Building 26 / N1-4 South San Francisco, CA 94080, USA Phone No.: +1 650-303-7285

FW: Correspondence: Animal Testing

Swiecki, John <johnswiecki@ci.brisbane.ca.us>

Thu 1/26/2023 8:39 PM

To: Johnson, Kenneth <kjohnson@ci.brisbane.ca.us>



John Swiecki, AICP | He/Him

Community Development Director Cell: 415.713.9266 |Office(message) 415.508.2120 | Email: jswiecki@brisbaneca.org Stay connected with us via the <u>Blast</u>, <u>GoRequest</u>, <u>Facebook</u>, <u>Twitter</u>, <u>YouTube</u> and <u>Instagram</u>!

From: Padilla, Ingrid <ipadilla@ci.brisbane.ca.us>
Sent: Thursday, January 26, 2023 8:39 PM
To: Ayres, Julia <jayres@ci.brisbane.ca.us>
Cc: Swiecki, John <johnswiecki@ci.brisbane.ca.us>
Subject: Correspondence: Animal Testing

For the Planning Commission- kindly forward correspondence from Bill Van Raam.

Ingrid Padilla City of Brisbane, City Clerk (415) 508-2113

From: Bill Van Raam < <u>http://www.constructuresconstructu</u>

Hi Ingrid I hope this gets to in time for tonight's Planning Commission meeting, and thank you for all you do.

I'm writing this letter to say please do not further restrict animal testing in Brisbane. I like so many others have benefited from testing, after thirty years of type one diabetes I had eye issues leading to the loss of sight in one eye but saving the sight in the other, kidney failure, subsequent kidney pancreas transplant, two strokes, heart attack with bypass surgery, there's been other things too but I'm trying to keep this short. The medicine and procedures would not have happened without animal testing. Computer models are a wonderful advancement in medicine but unfortunately they can't replace all animal testing, while I completely understand the emotional aspect of animal testing it is my opinion we shouldn't set back things because of our emotions. Thank you Brisbane resident Bill Van Raam