

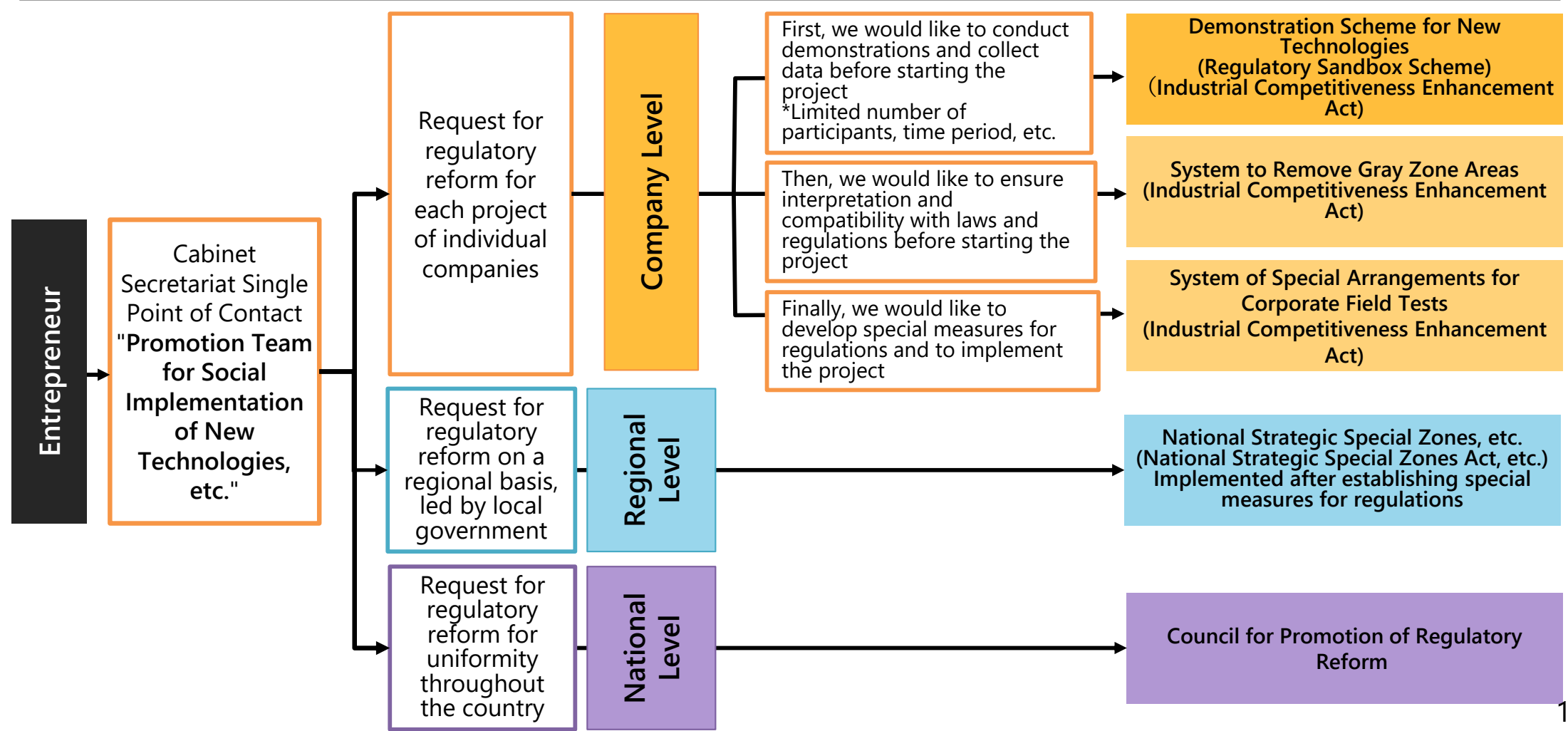
# Regulatory reform system for business units based on the Industrial Competitiveness Enhancement Act

Ministry of Economy, Trade and Industry (METI)

# Promotion of Regulatory Reform through "Three-Tier" Initiatives

- Regulatory reform is an important policy issue for achieving sustainable economic growth led by private-sector demand.
- In addition to "national level" reform through discussions at the Council for Promotion of Regulatory Reform, etc., and "regional level" reform through special zone systems, such as the National Strategic Special Zones, etc., we will promote regulatory reform by utilizing a three-tiered structure for "company level" reform that includes "Regulatory Sandbox Scheme," "System of Special Arrangements for Corporate Field Tests," and "System to Remove Gray Zone Areas".

## Relationship between all regulatory reform schemes



# Overview of the System to Remove Gray Zone Areas

- This is a system that allows entrepreneurs who intend to engage in new business activities to check in advance, in accordance with their specific business plans, whether the regulations are applicable or not so that they can conduct new business activities at ease, even in fields where the scope of application of current regulations is unclear.

## Application Flow

<Pre-Application>  
Clarification of gray zones  
(Prior consultation, if  
necessary)

The competent ministers (minister with jurisdiction over business and minister with jurisdiction over regulations) shall provide necessary information and advice in response to consultation with entrepreneurs amidst the confirmation of the content of new business activities.

Inquiry regarding the  
applicability of the regulation

1) Request for  
confirmation

Minister with  
jurisdiction over  
business

Minister with  
jurisdiction over  
regulations

2) Jointly signed  
by both ministers

Response regarding the  
applicability of the regulation

1) An entrepreneur who intends to engage in a new business activity shall request confirmation from the competent minister to check whether the regulations are applicable to the new business activity or not.

2) Upon receiving a request for confirmation, the competent minister determines whether or not the regulations are applicable in line with the specific business plan of the entrepreneur, and replies to the entrepreneur (generally, the minister replies within one month; if it's not possible then he has to notify the applicant of the reason within one month).

After responding to the inquirer, the competent minister publishes a summary of the response.

\*The inquiry form is published based on the consent of the inquirer.

## Example Case

### Comprehensive consulting service for sleeping environments

[Applicant] Nishikawa Corporation (Chuo, Tokyo)

[Project description]

For users who want to improve their sleep, we analyze and visualize their sleeping environment through interviews and simple measurements, and provide comprehensive consulting services related to the sleeping environment, including advice on improving the sleeping environment and recommended products based on the results of such analysis.

[Inquiry details]

Does this service fall under the category of "medical practice" permitted only for physicians under Article 17 of the Medical Practitioners Act?

Inquiry

Not  
applicable



(Quoted from the website of Nishikawa Co.)

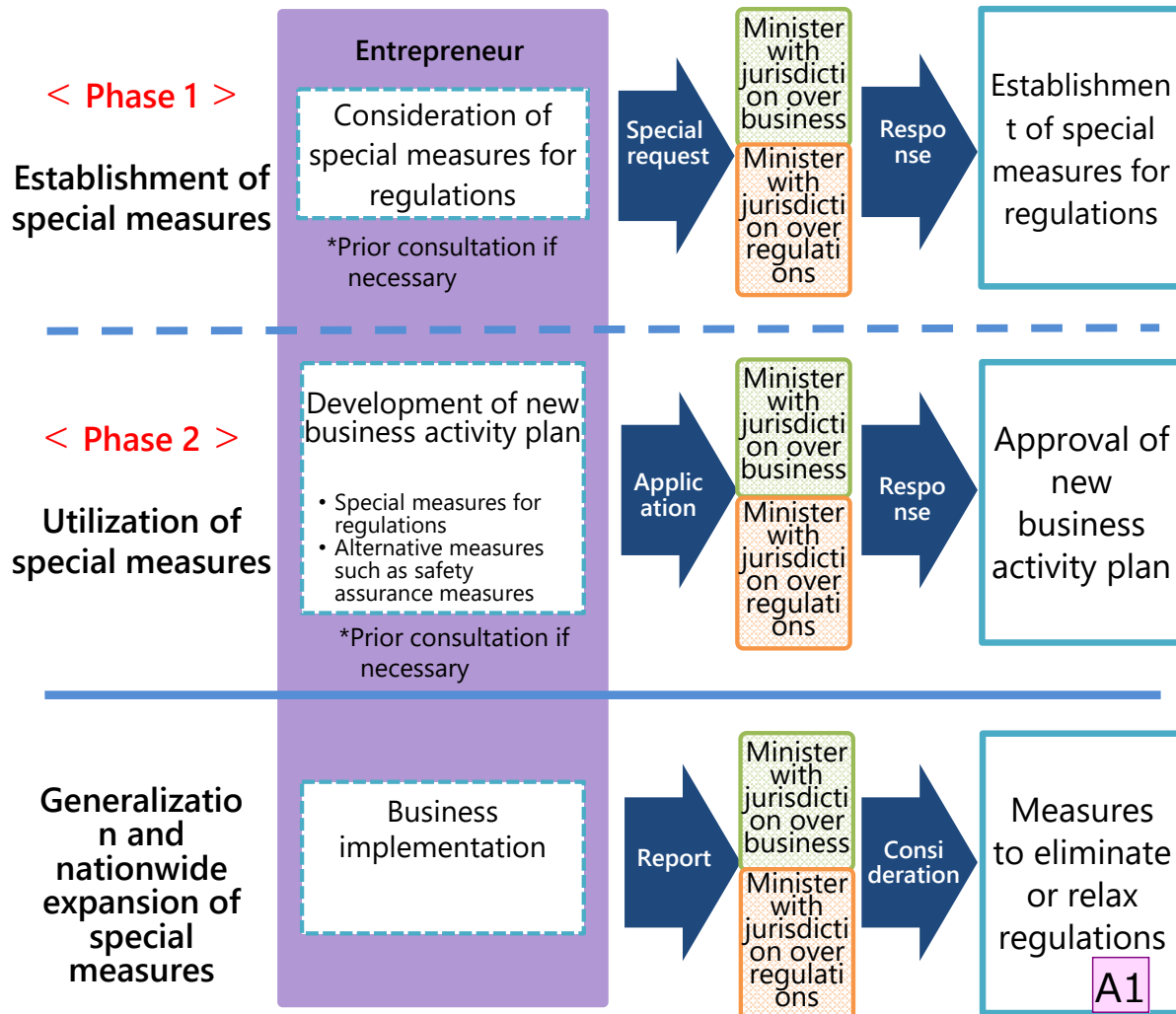
[Results]

**More than 30 stores** with a dedicated "Sleeping Counseling Center" have been **opened nationwide** to offer the services launched through the system.

# Overview of System of Special Arrangements for Corporate Field Tests

- This is a system that allows entrepreneurs who intend to engage in new business activities to propose special measures for regulations that would hinder such activities and allow the application on a "company level", in line with a specific business plan, provided that safety, etc., is ensured.

## Application Flow



\*In establishing special measures for regulations and approving new business activity plans, the opinions of the New Technology Effectiveness Evaluation Committee, etc., are heard as necessary.

## Example Case

### Riding high assist force electric-assist bicycles with trailers on public roads

[Applicant] Yamaha Motor Co. (Iwata, Shizuoka)  
Yamato Transport Co.(Chuo, Tokyo)

#### 【特例内容】

It is now possible to use electric-assist bicycles with the upper limit of assist force being three times the stepping force. (At that time, the Road Traffic Act's enforcement regulations had limited the assist force to two times)



\*Implement alternative measures such as road safety education for drivers involved and the establishment of a system to properly perform tasks required for safe driving, and conduct demonstrations.

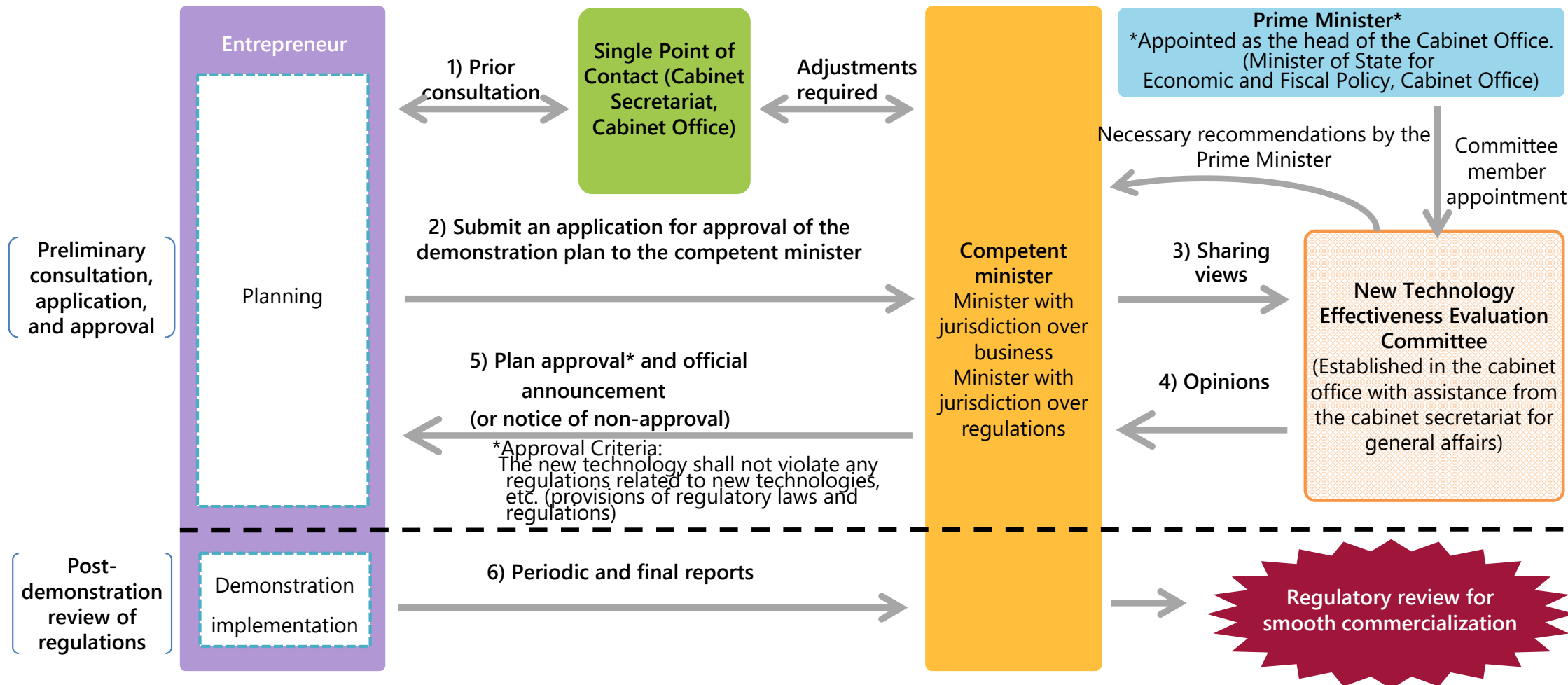
#### [Results]

Since the demonstration tests were conducted in Tokyo, Hokkaido, Kanagawa, Kyoto, Osaka, and Fukuoka, and satisfactory results were obtained on safety and other aspects while riding under various conditions, the regulations were relaxed (the Road Traffic Act's enforcement regulations were amended) and it is possible to use electric bicycles with the upper limit of assist force being three times the stepping force.

# Overview of the Regulatory Sandbox Scheme

- This is a system that allows for rapid demonstration of innovative technologies and business models such as AI, IoT, and blockchain by restricting the period of time and participants, etc. without being subject to regulations, and using the information and data obtained from the demonstration for the review purpose.

Basic policy (basic matters concerning the approval, etc.): Prime Minister (Cabinet Secretariat) prepares a draft and the Cabinet approves.

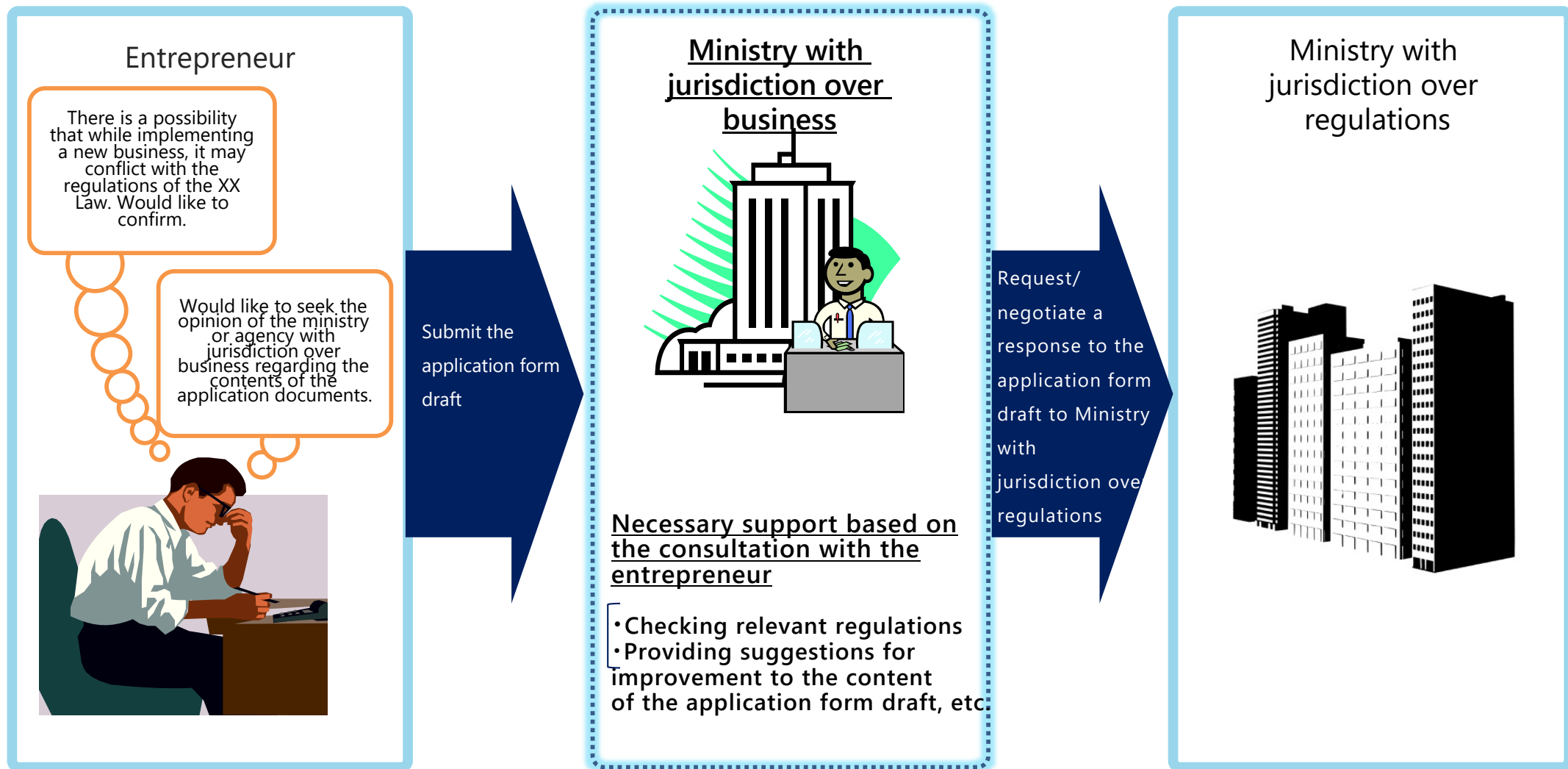


\*If new special measures for regulations are to be developed, a request is made to the competent minister prior to applying for planning (the process is the same as for plan approval)

# Role of the Ministry with Jurisdiction over Business

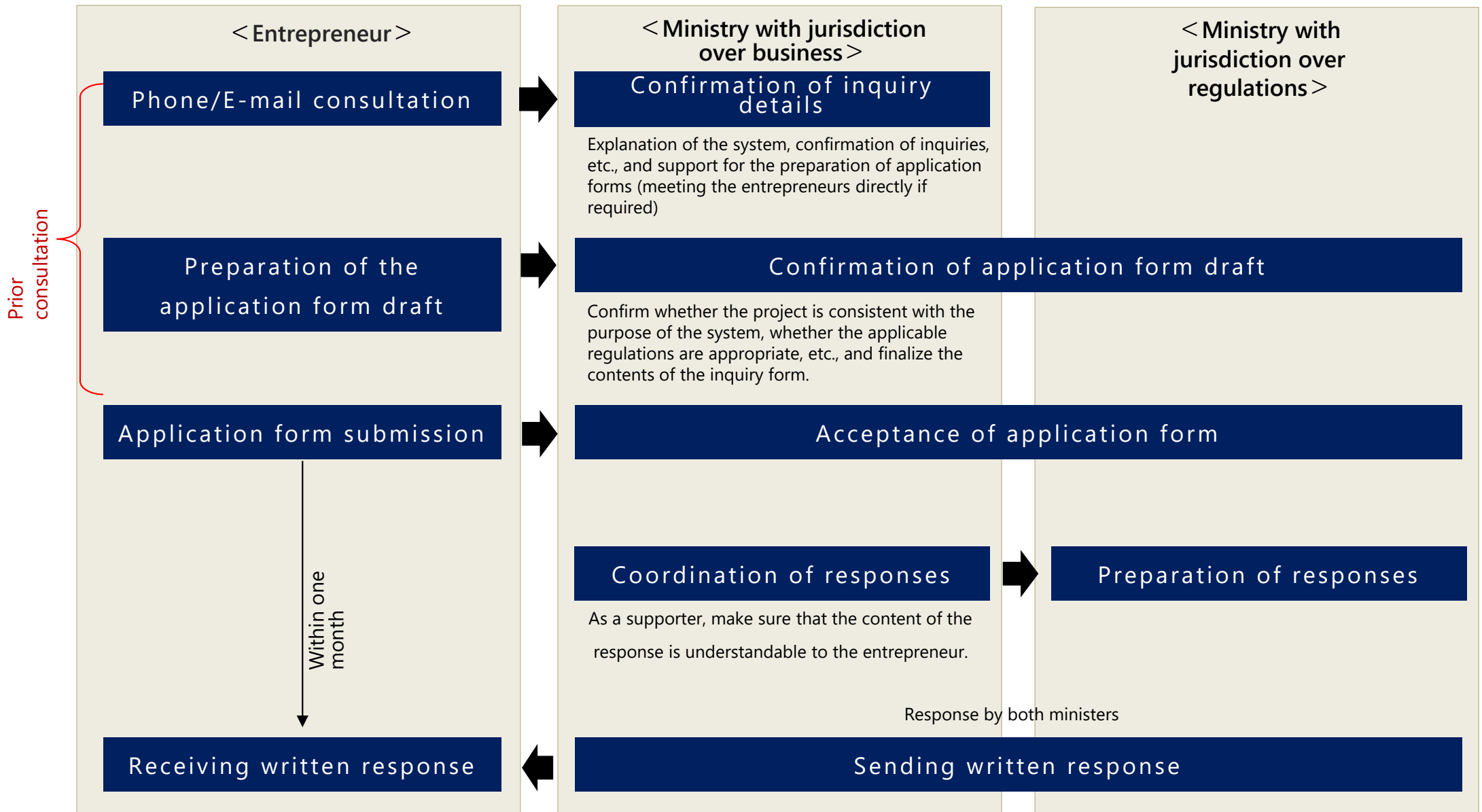
- When applying for the System to Remove Gray Zone Areas, etc., the ministry or agency responsible for the project supports proactively at each stage of the application process from the perspective of the entrepreneur who is considering applying for the system.

For example: Flow while utilizing the System to Remove Gray Zone Areas



# Flow of Procedures in the System

- While implementing the System to Remove Gray Zone Areas, etc., entrepreneurs can receive support from the section with jurisdiction over business.



# Using the System (Contact for Inquiries)

## List of METI contacts

- Industry Creation Policy Division, Economic and Industrial Policy Bureau, METI 03-3501-1560 (Direct line)

(Local Bureau of Economy, Trade and Industry)

- |  |   |              |
|--|---|--------------|
| • Hokkaido Bureau of Economy, Trade and Industry | Economic Policy Division                  | 011-709-1782 |
| • Tohoku Bureau of Economy, Trade and Industry   | Economic Policy Division                  | 022-221-487  |
| • Kanto Bureau of Economy, Trade and Industry    | Economic Policy Division                  | 048-600-0253 |
| • Chubu Bureau of Economy, Trade and Industry    | Economic Policy Division                  | 052-951-8457 |
| • Chubu Bureau of Economy, Trade and Industry    | General Affairs Division, Hokuriku Branch | 076-432-5588 |
| • Kansai Bureau of Economy, Trade and Industry   | Economic Policy Division                  | 06-6966-6011 |
| • Chugoku Bureau of Economy, Trade and Industry  | Economic Policy Division                  | 082-224-5684 |
| • Shikoku Bureau of Economy, Trade and Industry  | Economic Policy Division                  | 087-811-8513 |
| • Kyushu Bureau of Economy, Trade and Industry   | Economic Policy Division                  | 092-482-5430 |
| • Okinawa General Bureau                         | Economic Policy Division                  | 098-866-1730 |

## Point of contact for Regulatory Sandbox

- Committee on the Growth Strategy, Cabinet Secretariat 03-5253-2111 (Extension line 84834), 03-3581-0769 (Direct line)

Cabinet Secretariat's website on the regulatory sandbox scheme

<https://www.cas.go.jp/jp/seisaku/s-portal/regulatorysandbox.html>

## Point of contact at each government ministry and agency

- Community Safety Planning Division, Community Safety Bureau, National Police Agency 03-3581-0141 (Representative) (Extension line: 3023)
- \*Traffic Planning Division, Traffic Bureau for vehicle driving services and other transport authority-related matters 03-3581-0141 (Representative) (Extension line: 5064)
- Policy Planning Division, Policy Bureau, Financial Services Agency 03-3581-9547 (Direct line)
- Planning Division, Minister's Secretariat, Ministry of Internal Affairs and Communications 03-5253-5155 (Direct line)
- Ministry of Finance
  - \*Tobacco and Salt Industries Office, General Affairs Division, Financial Bureau for cigarette and salt-related business 03-3581-4111 (Representative) (Extension line: 5019)
  - \*Liquor Tax and Industry Division, National Tax Agency for the liquor industry 03-3581-4161 (Representative) (Extension line: 3424)
- General Affairs Division, Minister's Secretariat, Ministry of Health, Labour and Welfare 03-3595-3038 (Direct line)
- New Business and Food Industry Department, New Business and Food Industry Policy Division, Minister's Secretariat, Ministry of Agriculture, Forestry and Fisheries 03-6744-7181 (Direct line)
- Policy Division, Policy Bureau, Japanese Ministry of Land, Infrastructure, Transport and Tourism 03-5253-8320 (Direct line)
- Planning, Evaluation and Policy Promotion Office, Minister's Secretariat, Ministry of the Environment 03-3581-3351 (Representative) (Extension line: 6052)