

## **Response to the submission of Hong Kong DNA Chips Ltd**

### ***I. Overall response***

- (a) We have decided not to invite participation of private laboratories in the prescribed genetic test procedure for good reasons. We consider it essential for the entire test to be placed under direct supervision of the Government to ensure control and prevent abuses. There will be official collaboration between the HKSARG and the Mainland authorities for the conducting of the genetic test.

The four objections raised by the Hong Kong DNA Chips Ltd against our proposed prescribed genetic test procedure are misconceived. In particular, the allegation that the Government has misinformed the public is totally unfounded. Our position is set out in the ensuing paragraphs.

### ***II. Response to specific issues***

#### **Objections on technical grounds**

##### ***Technological viability***

- (b) Our proposed prescribed genetic test that involves collaboration with the Mainland authorities' designated laboratory is technologically viable and sound. In conducting the test, the designated laboratory in the Mainland and the Government Laboratory will adopt the same technology and procedures which meet international accreditation standard.

This alignment is safeguarded by the implementation of a comprehensive set of quality assurance measures as outlined in the "codes of practice" attached in our letter of 21 November 2000. These measures include those that will ensure that variants such as changes in the composition of the reaction mixture; temperature changes; variation in time and space, equipment, personnel, etc will be minimized and will not affect the outcome of genetic analysis under the prescribed procedure.

The effectiveness of such a comprehensive set of quality assurance measures has been well tried out by international proficiency tests on genetic analysis. As a quality control exercise, interested laboratories worldwide including the Government Laboratory regularly participate in such proficiency tests recognized by various accreditation bodies all over the world. These tests are organized on a quarterly basis. A test organizer will each time distribute the same samples to over a hundred participants. The participating laboratories will return their analysis to the organizer who will then compile and publish the results obtained. Despite the many differences of the participants, those who adopt stringent quality assurance measures are always able to arrive at the same results and conclusions.

The Hong Kong DNA Chips Ltd claims in its submission to the effect that the only way to produce reliable genetic test result is to have the same operator performing all the tests for one particular family using the same test reagents and equipment. The company also claims that modern equipment cannot minimize variability between two separate experiments. These claims can be valid only when the laboratories concerned do not implement comprehensive assurance measures which is not the case in our prescribed procedure.

Contrary to the company's allegation, our prescribed genetic procedure will ensure reliability and accuracy of the result with our built-in monitoring mechanism where there will be independent testing of the two designated laboratories and cross checking of the test result.

### ***Accreditation***

- (c) The Government Laboratory is accredited for forensic serology and DNA analysis. Such accreditation status covers the full scope of forensic DNA analysis of which parentage testing is only a part.

### ***Efficient test procedure***

- (d) Our prescribed genetic test will enable efficient and reliable verification of a claimed parentage. The Mainland authorities and Immigration Department combined will take about three weeks to

produce a test result. The cross examination process is by no means inefficient as claimed in the submission. As explained in (b) above, it is indeed a built-in monitoring mechanism which will help to ensure the accuracy of the result and to prevent fraud throughout the procedure.

### **Mainland's interference**

- (e) In accordance with Article 22(4) of the Basic Law (BL), Mainland residents must apply for exit approval from the Mainland authorities for entry into the HKSAR for settlement. For the purpose of granting exit approval, the Mainland authorities wish to be assured of the claimed parent-child relationship pertaining to BL24(2)(3) and be directly involved in the process through which such relationship is established. We collaborate with the Mainland authorities in the genetic test procedure. We will use the cross-verified genetic test result for processing Certificate of Entitlement applications. The Mainland authorities will accept the test result for the purpose of processing exit permits.

### **Right to choose genetic services**

- (f) Hong Kong DNA Chips Ltd considers that applicants should be given the right to choose any DNA testing service. As explained in our previous submissions, there is a need for a prescribed genetic test procedure. Otherwise there will be no control over the integrity of the test procedure and the reliability of the test result. The reliability of the genetic test result depends not only on the technological standard of the laboratory concerned, but also on strict control over the specimen-taking and other processes to prevent fraud and abuses. While the test result produced by an accredited laboratory may achieve a stringent technical standard, the integrity of the process cannot be ensured short of Government's direct supervision and participation.

### **Right to privacy**

- (g) There will be full protection of the privacy of the applicant and his/her parents. The Government has to abide by the Personal Data (Privacy) Ordinance. Concrete measures that will be implemented to protect privacy include – (i) the tissue samples taken will only be

used for its collection purpose, i.e. for verification of a claimed parentage for the purpose of processing an application for a Certificate of Entitlement; (ii) the tissue samples will be disposed of once a decision is made on the application; and (iii) the applicants and their parents who are required to undergo the prescribed genetic test will be informed of these arrangements in (i) and (ii) in writing.

Our proposed arrangements whereby the Government Laboratory will conduct tests and provide the test result to the Immigration Department for verification of a claimed parentage in connection with an application for a Certificate of Entitlement will not give rise to any conflict of interest as alleged in Hong Kong DNA Chips Ltd's submission. This arrangement is necessary and appropriate. The Government Laboratory has the technical capability to conduct the prescribed test. But the Laboratory cannot take over the job of processing applications for a Certificate of Entitlement which is a statutory duty of the Director of Immigration.

### **Right to appeal**

- (h) In case a person is aggrieved by the Director's decision not to issue a Certificate of Entitlement due to insufficient evidence to prove the claimed parentage, he may lodge an appeal to the Immigration Tribunal under section s.2AD of the Immigration Ordinance.

### **Proposed alternative testing strategy**

- (i) It is proposed in Hong Kong DNA Chips Ltd's submission that a Government centre be set up to collect DNA samples before sending them to private laboratories for testing. The prescribed test procedures will be conducted in collaboration with the Mainland authorities. The Mainland authorities have indicated that they would only wish to engage the Government in such collaboration. Indeed there are practical difficulties for the Mainland authorities to collaborate with private laboratories in Hong Kong as they will then need to achieve technical alignment and cross verification with all designated laboratories in Hong Kong. The Government Laboratory will also need to decide how best to indirectly monitor the work of private laboratories on their collaboration with the Mainland side. Such monitoring will be complicated and costly.

## **Fee issues**

- (j) We will charge a fee on a full cost recovery basis. The present fee level is arrived at based on an estimated caseload of 3 000 per year. We explained at the meetings of the Panel on Security of the Council held on 18 January 2000 and 1 June 2000 that the earlier estimated fee was an initial estimate. The fee is revised to the present level of about \$4 600 per family following adjustment which is found necessary after the recent completion of the simulated tests. We will regularly review the fee level in the light of the actual caseload. We will ensure that the test is conducted in the most cost-effective manner so that the fee is kept at a reasonable level. In any event, fee waiver/reduction will be considered where justified on a case by case basis.

## **Caseload**

- (k) The yearly caseload of 3 000 was an estimate arrived at for planning purposes. It is not feasible to come up with the exact number of persons who will be required to undergo a genetic test, for whether an applicant is required to take the test will be considered on a case by case basis.

The 170 000 persons mentioned in the submission refer to the estimated number of persons who were born out of registered marriage and are eligible for right of abode. This figure is arrived at by the Census and Statistics Department through its survey conducted in March – May 1999. These persons include but are not restricted to persons born out of wedlock.

The classification of “children born within registered marriage” and “children born out of registered marriage” is adopted in the survey because they are clear and unambiguous classification required for obtaining accurate data for the purpose of the survey.

Persons are classified as being “born out of registered marriage” if their parent(s) has/have no proof of marriage that is recognized by the relevant authorities. Such persons could be born of unregistered marriage [de facto marriage], cohabitation or under circumstances where the relationships do not involve any form of marriage or

cohabitation.

As the data were collected by the Randomized Response Technique, only the total number of “children born out of registered marriage” could be estimated. There is thus no specific information on the number of persons who were born of “unregistered marriage” or “born out of wedlock”.

In other words, we do not know how many of the 170 000 persons are born out of wedlock. It is also difficult to predict whether and when those who were born out of wedlock are prepared to submit applications. Whether these persons will need to undergo the prescribed genetic test will be considered individually in the light of factual circumstances. We will review the caseload after the genetic test procedure is in operation and make necessary adjustments as and when required.

Security Bureau  
November 2000